crossing over

GENOMICS IN THE PUBLIC ARENA

edited by Edna Einsiedel and Frank Timmermans

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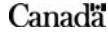

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Introduction

Edna Einsiedel

THE TITLE OF THIS BOOK is drawn from a biological process involving the exchange of genetic material between chromosomes as part of the process of reproduction and inheritance. During meiosis, DNA segments are exchanged as two chromosomes – one from each parent – intertwine in their dance for heredity. The resulting chromosome is different from its two starter 'parents,' contributing to diversity, to occasional mutations, and, in the end, to a more robust gene pool.

This notion of crossing over is the metaphor we chose as the theme for the conference we held in Kananaskis, Alberta, on 25–27 April 2003. We invited a number of participants from diverse fields and backgrounds: economics, law, communications, the sciences, and bioethics. We had people representing different sectors or interests as well – policy-makers, civil society, industry, and academia. By examining the social world of biotechnology through diverse lenses, we anticipated that our understandings of the challenges to society posed by this relatively new technology and its applications would be enriched.

While researchers in the field of the social, ethical, legal, or environmental aspects of genomics have typically focused on *either* biomedical issues *or* on agricultural applications (particularly GM food), many of the issues that underlie each set of applications are also cross-over issues. This is true of governance questions, intellectual property challenges, commercialization of innovation conundrums, and questions around policy decision-making. In presenting the issues, we have selected section theme key questions that represent these commonalities.

It was fitting that our conference happened to take place on the fiftieth anniversary of the publication of the double helix in the journal Nature by two intrepid young scientists, James Watson and Francis Crick (1953). Much has happened since that period, from the arenas of intellectual property to the funding and financial architectures of research on strategic technologies such as biotechnology; and from the outcomes in the laboratory to the outcomes in the policy world. The markers that became singularly important included the discovery that we could actually transfer genes from one species to another, and the first legal judgment that genetically engineered organisms could be claimed as intellectual property. During this time, the human genome was also MAPPed, as were other whole organisms, from the model plant Arabidopsis to the fruit fly. The tools with which we stored and analyzed information – including genetic information – similarly grew in capacity and sophistication, making possible the establishment of genetic storehouses like gene banks. Society has had difficulty keeping up with these milestones.

The questions for us seem to have grown more profound: Should we own higher life forms, or, for that matter, any living matter? What structural arrangements for genomics research will ensure that technologies adopted are not just economically beneficial but also socially and environmentally sustainable? *How* we talk about these questions also becomes more urgent. What linguistic tropes do we employ and how do these influence how we act? What roles do the media play and what kinds of impacts do they have on which technological directions are taken? What ethical questions are implicated in considerations of these technological applications? What governance arrangements are appropriate for addressing these challenges? At the highest level, technology in the public sphere involves choices about what it means to be human, about the kind of society we want. It is toward a better understanding of technology and society that we hope these contributions will lead us.

The themes we explore to address these questions fall in six areas: the economic and organizational underpinnings of biotechnology (Part 1); the interactions between policy communities and various publics (Part 2); the different representations of the technology among publics (Part 3) and in the media (Part 4); the societal considerations that play important roles alongside the science (Part 5); and some of the future prospects of this technological landscape (Part 6).

In Part 1 of the book, a political economist and two anthropologists offer different perspectives on organizational arrangements and practices around biotechnology knowledge production. The first investigates the evolution of new organizational forms of knowledge production – in this case, through networks of research partnerships as these networks work through the challenges of developing intellectual property rights. The second takes an anthropological approach and describes the discourses of finance, as biotechnological knowledge moves through the development pipeline.

Part 2 deals with policy development, which occurs through interactions between different policy communities and various publics. The different nature and pace of biotechnology development in North America and Europe have come to symbolize how technologies are deeply embedded in social contexts that help shape different outcomes. Biotechnology policy in Europe is described through the interplay between the balancing of the demands (felt by many governments) of European competitiveness through this strategic technology development and the competing demands of various European publics for caution if not outright rejection. On the North American front, a different form of pressure is explored through stakeholders who are pushing technological development through legislative fiats. Two chapters highlight how different publics can push, shape, and force technology into intended and unintended forms.

Publics wear different hats, employing different metrics when they examine what is on offer, a topic that will be addressed in Part 3. As consumers, their purchase intentions may be governed by one set of criteria; as citizens, they examine technological products with other criteria. When confronted with the various messages about genetics, they do not evaluate these messages uncritically and are discerning in their assessments of genetic information.

In Part 4, the different interpretations of technology are further explored through the representations and judgments made by the media and by publics. These interpretations are examined by asking what happens to messages as they move through the dissemination channels. There are two common assumptions made about such a process: the first is that the messages that come out of the scientific transmission channel are 'distorted' once processed by the media. The second is that publics who receive these messages respond uncritically to media offerings. Both are clearly simplistic and are examined in several chapters. One empirical investigation of media coverage of gene discoveries demonstrates that the media do not necessarily always oversell or hype these scientific discoveries; the surprising finding is that such hyping can occur in the academic journals themselves. Another examination of what the media do with these sorts of stories describes the different roles media can play as they highlight technology development: they can provide venues for promotion and finance, they tell stories through favoured narrative devices, and they can dictate the menu of subjects on offer for their audiences.

As will be demonstrated in Part 5, the metrics of societal judgments show the increasing prominence of other considerations. Ethical considerations underlie how some publics have framed their hopes and concerns. Animal welfare and rights have taken on greater importance and they complement the self-interest that has been assumed to govern entirely the expression of public preferences. Interests in further discovery of medical cures are also modulated by competing concerns about how genetic information is protected, utilized, and commodified. The experience of Iceland with the establishment of a national gene bank

provides a cautionary tale for other jurisdictions considering the creation of similar institutions.

Finally, in Part 6, the future of genomics is explored in two ways: by examining what nanotechnology – an emerging technology with links to biotechnology – might look like, and by looking back through the lens of literature to see what past technological visions can tell us about technological futures.

This book project would not have come to fruition without the support of Genome Canada, which funds large-scale genomics research in Canada. Among the projects it supports are studies on genomics, economic, environmental, ethical, legal and social issues (GE3LS). Our Genome Prairie GE3LS research program – which sponsored the conference from which this book sprouted – has been a fortunate beneficiary. We have added two additional chapters to this book that were not part of the original conference, in order to provide a more rounded coverage of the theme of the book. The efforts of our colleagues who participated in this book project are warmly acknowledged.

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Part 1

The Financial Pipeline

1 The Challenge of Creating, Protecting & Exploiting Networked Knowledge

Peter W. B. Phillips

1 INTRODUCTION

1.1 *The Advent of Biotechnology*

IN THE CLASSICAL MODEL OF innovation, relatively small groups of researchers (either in public laboratories or in private research groups) engage in a mostly self-contained, linear process of research and development, which ultimately leads to commercialization through direct or contracted production and marketing. This type of research structure was exemplified by the research departments at Consolidated Edison, 3M and Xerox, where fully-dedicated research staff was given freedom to investigate and invent new products for commercialization by the host company (Pool 1997).

Much of the early life-science research also conformed to this model, except that it was often carried out in public laboratories, *e.g.,* the discovery of the structure of DNA by Watson and Crick at Cambridge University (Watson 2001). While these individual efforts drew upon knowledge generated by others, most of them operated in relative isolation, with little formal or informal exchange of information during the discovery phase. This model – 'standing on the shoulders of giants' – has generally been the basis for the global research effort since the scientific and industrial revolutions of the seventeenth century. While it may have been appropriate in earlier times, when many innovations were simply the product of inventors' ingenuity, in more recent years, many institutions, companies and industries have deployed a different strategy to develop and exploit life-science inventions.

In recent years, the global life-science research effort has undergone a significant transformation. A few key scientific discoveries since 1970 – particularly

genomics, genetic MAPPing, gene splicing, and proteomic[1] and metabolic profiling – have opened up vast new avenues for research of new plants, animals, microbes and molecules that could have applications in medicine, agriculture, extraction, processing and the environment. While the impressive innovations in science and technology have been preconditions for technical progress, a number of other important factors have contributed to this transformation. Specifically, during the 1980s and 1990s, property rights were extended to a wide range of new inventions, and capital and labour markets were liberalized, precipitating a veritable flood of new capital into research and development in the 1990s. Even as the first wave of biotechnology research was waning in the late 1990s, gene-sequencing methods accelerated, opening new areas for research.

1.2 *The Need for Increased Cooperation and Networking*

The increasing specialization and complexity of science makes it difficult to realize isolated or independent breakthroughs or comprehensive research programs. Both this specialization and the fragmentation of IPRs have required greater collaboration and networking to achieve research results. Networks of institutions and researchers have evolved to handle the transfer, acquisition, and use of various forms of knowledge. Typically, these networks operate above the level of the firm or the organization, but below the global level; they are inherently regional and supra-organizational. Hence, there are often legal, managerial, social and economic variables that may affect how these networks operate.

While the apparent rise in collegiality is justified by the potential gains in research productivity, it can often compound the already difficult and costly processes of managing intellectual property rights. Meanwhile, the increased role of profit-seeking and the extensive use of formal intellectual property rights mechanisms (*e.g.,* patents) have created barriers to free exchange of knowledge as well as greater scrutiny of those exchanges that do occur.

However, in more recent years, many institutions, companies, and industries have deployed a different strategy to develop and exploit life-science inventions. Increasingly, research programs are not simply standing on others' shoulders, but rather are working side-by-side in formal or informal collaborations or research networks. Sometimes these structures have grown organically, and sometimes they have been actively supported and encouraged by government. In Canada, much of the current wave of research has been precipitated – and partially supported – by Industry Canada, through Genome Canada. One general operating principle for Genome Canada, and for most of its approved research projects, is that they should involve the best collaborators or researchers from wherever they may be around the world. In some cases that has led to teams with many members from different institutions, from different provinces, and in some cases from different countries.

In a recent paper (Phillips 2002), I have argued that life-science innovation closely mirrors a non-linear, chain-link 'networked' structure. Phillips

and Khachatourians (2001) present a detailed study of one such networked structure – involved in the transformation of the canola industry by biotechnology – but there are many other examples, especially in the world of genomics.

1.3 *A Case Study: The Abiotic Stress Project*

One prime example of this new operating challenge is the Genome Canada/Genome Prairie project examining the functional genomics of abiotic stress in crops. This project is designed to examine the complex phenomenon of tolerance of plants to abiotic stresses, which results from a complicated cascade of events in the plant cell. Until recently, various components of such tolerances had been studied in isolation, but comprehensive examination of this cascade of genetic and biochemical processes was not possible. The availability of high throughput genomics and proteomics[2] technologies, on the one hand, and bioinformatics tools for gene and protein analysis, on the other, created the opportunity to conduct a comprehensive study of the genome, the transcriptome[3] and the proteome of selected plants under different physiological conditions, which may then be used to decipher the genetic features that enable a plant to withstand abiotic stress. The researchers chose to work on wheat (Triticum aestivum) and canola (Brassica napus) for the following reasons: (1) the fact that they are major food crops, grown worldwide, and are of great economic importance as sources of revenue for Canada; (2) the fact that there is an extensive volume of genetic data available for these species and their close relatives, providing a good resource base for the proposed research; and, finally, (3) the expectation that an understanding of the abiotic stress machinery in these two species – representing a monocot and dicot,[4] respectively – could provide insights into other plant species with industrial and agricultural uses.

The Abiotic Stress Project epitomizes the complex nature of many of these new-style research efforts. Initially, the project brings together a widely dispersed multi-disciplinary research team, involving twenty-one principal scientists in eight universities and two federal research agencies in four provinces and seventy research associates, post-doctoral fellows, graduate students and summer students. Many of the principal scientists involved in these projects have collaborators in other parts of Canada and elsewhere in the world. The Cereals Project will interact closely with a number of global wheat and other small-grain cereal projects, including the Wheat Project funded by the National Science Foundation in the U.S., international groups such as the International Triticeae MAPPing Initiative (ITMI) and the International Triticeae EST Cooperative (ITEC), a Genome Quebec abiotic stress team, and an array of other international research programs working in the area of low temperature tolerance in cereals. The scientists involved in the Brassica/Arabidopsis component of the project actively collaborate with a number of academic institutes and private companies, including the University of Wisconsin, Horticulture Research International (HRI) in the U.K., Advanta, Aventis and Pioneer Hi-Bred.

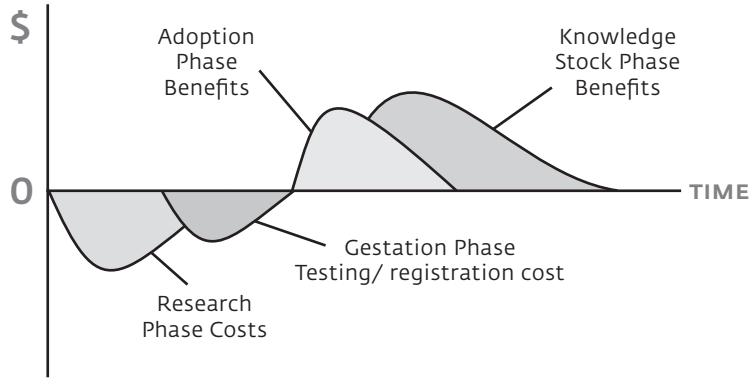

Figure 1.1 The Chain-Link Model of Innovation.
Source: adapted from Kline and Rosenberg (1986).

This wide-ranging team will draw on the global agricultural research base and will have access to the latest proprietary processes and equipment for genomics, proteomics, and bioinformatics work. The main outputs from the project will include academic publications, DNA markers, software for genetic MAPPing and genomic analysis, databases and genetic MAPPing populations, genetically improved crop plants, and spin-off biotechnology companies.

It took the research and management team more than two years to set up the project and to receive funding approval from Genome Canada (which finally occurred in 2001). Part of the delay was due to the fact that Genome Canada was being developed simultaneously. Then, another year went by before the project got underway, due to the challenges involved in the negotiation of the operating agreement between Genome Prairie and the home institutions of the twenty-one principal investigators. By 2002, the project was operational, but there remains significant doubt about how the intellectual property resulting from the project will be handled; at least in part, this is the result of incomplete contract specifications about the valuation of incoming in-kind intellectual property.

This 'brave new world' of scientific advancement has created many new and complex relationships and networks that have yet to be fully examined. In this chapter, I will offer a theoretical and methodological framework for examining those relationships and apply it to the research discovery process, as well as to the identification of market and non-market failures and alternate strategies.

2 THEORETICAL FRAMEWORK

Managing networked knowledge involves three discrete aspects. First, a model of innovation has to be developed that captures the full spectrum of the different kinds of knowledge being developed and used. This section will draw on the

innovation literature to delineate a chain-linked, networked model of innovation. Second, the exchanges or transactions need to be elucidated. While neoclassical economics handles this challenge by assuming that all parties to a transaction have full information, the New Institutional Economics (NIE) framework relaxes that assumption and investigates different outcomes. Third, the non-economic dimensions of networked knowledge need to be examined. This section draws on cluster theory to illuminate the roles of non-market actors. Finally, I combine the three perspectives into a framework for investigating networked knowledge in the life-science world.

2.1 *The Nature of Knowledge*

The first dimension that has to be addressed is the innovation system. If new developments were merely the result of inspiration, the traditional linear view of research and development discussed above would be appropriate. Yet, if one examines systemic innovation processes (such as those epitomized by the Abiotic Stress Project), and particularly the many inputs and outputs they usually involve, it becomes clear that no single firm or region can be viewed as truly self-sufficient or self-sustaining.

Kline and Rosenberg (1986) provide a non-linear approach that explicitly identifies the role of both market and research knowledge and the potential for open research systems. Their chain-link model of innovation is depicted in fig. 1.1. In essence, it represents a linear process, moving from potential market to invention, design, adaptation, and adoption. Added to it are feedback loops from each stage to previous stages, on the one hand, and the potential for the innovator to seek out existing knowledge, or to undertake or commission research to solve problems in the innovation process, on the other. This dynamic model raises a number of questions about the types and roles of knowledge involved in the process. Some of the knowledge will be available or could be developed within the firm or outside of it.

There are multiple types of knowledge involved in such a system. Malecki (1997) provides a way of categorizing types of knowledge that helps to identify which route a firm, institution, or network might follow to acquire or develop the knowledge required to innovate. He identifies four distinct types of knowledge: 'know-why,' 'know-what,' 'know-how' and 'know-who' (see table 1.1). Each type of knowledge has specific features (Organisation for Economic Co-operation and Development 1996).

Know-why refers to scientific knowledge of the principles and laws of nature; for the most part it is derived from research efforts undertaken globally in publicly-funded universities and non-profit research institutes; it is subsequently codified and published in academic or professional journals, making it fully accessible to everyone who would be interested in it. In the chain-link model, this knowledge would be in the 'knowledge' block, having been created almost exclusively in the 'research' block.

Table 1.1
A Classification of Types of Knowledge*

	Degree of Codification	*Produced by*	*Extent of Disclosure*
Know-Why	Completely codified.	Universities and public laboratories.	Fully disclosed and published in scientific journals.
Know-What	Completely codified.	Universities, public laboratories and private companies.	Fully disclosed in patents.
Know-How	Not codified.	Hands-on experiments in laboratories.	Tacit; limited dispersion.
Know-Who	Not codified.	Exists within firms or research communities.	Tacit; limited to community.

* *Source:* after text in Malecki (1997, 58).

Know-what refers to knowledge about facts and techniques; usually it can be codified and transferred through the commercial marketplace. In the chain-link model, the stock of know-what is also in the 'knowledge' block, having been created in the research, invention, design and adoption stages, respectively.

Know-how refers to the combination of intellectual, educational and physical dexterity, skills and analytical capacity to design a hypothesis-driven protocol with a set of expected outcomes; it involves the ability of scientists to effectively combine the know-why and know-what to innovate. This capacity is often learned through education and technical training and perfected by *doing*, which in part generates a degree of difficulty for the uninitiated and makes it more difficult to codify and, hence, more difficult to transfer it to others. Know-how would be represented in the research block and also in the invention, design, and adaptation stages.

Finally, *know-who*, which "involves information about who knows what and who knows how to do what" (Organisation for Economic Co-operation and Development 1996), is becoming increasingly important in the biotechnology-based agri-food industry. The breadth of knowledge that is required to innovate has expanded to such extent that collaboration has become indispensable. In today's context, know-who also requires knowledge of – and access to – private sector knowledge generators who, at times, may hold back the flow of crucial enabling information, expertise, and knowledge. Know-who knowledge is seldom codified; instead, it often accumulates within an organization or, at times, in communities where there is a cluster of public and private entities that (1) are all engaged in the same type of research and development, (2) often exchange

Table 1.2
Predicting the Organizational Form of Vertical Control*

	Low task-programmability		*High task-programmability*	
	Low asset-specificity	*High asset-specificity*	*Low asset-specificity*	*High asset-specificity*
Low non-separability	Spot market	Long-term contract	Spot market	Joint venture
High non-separability	Relational contract	Clan (hierarchy)	Inside contract	Hierarchy

* *Source:* Mahoney (1992, 576).

technologies, biological materials and resources, and (3) pursue common staff training or cross-training opportunities. The arrows in the chain-link model would represent this type of knowledge, since the establishment of relationships that lead to trusting networks of know-who is the basis for those flows.

2.2 *Transactional Forms*

Each of the above-mentioned types of knowledge is likely to be subject to some form of exchange. In the transaction-cost economics, the control variable of analysis is the transaction. According to Williamson (1981), a transaction is said to occur when a good or service is transferred across a technologically separable interface, *e.g.,* when one stage of processing or assembly activity ends and another begins. This usually happens between institutions, but, in the new world of increasing specialization and networked research, this can happen within single institutions, or between individuals operating outside of formal institutional control. For example, many scientists are involved in formal scientific exchanges through publication, patenting and/or contract-based collaborations; yet, at the same time they will often engage in informal exchanges of contextual information about how or where to undertake research, with others who may not be collaborators and are, in fact, potential competitors.

Whether the transactions are formal or informal, they are never without costs. Transactions can be characterized by their structure and dimensions. Dahlman (1979) posits that transactions involve three cost components, relating to search, negotiation, and enforcement, respectively. Williamson (1979) has defined three principal dimensions in which transactions may differ from one another, with respect to their relative costs. First, transaction uncertainty may vary, depending on the extent of communication or strategic behaviour. Second, the frequency of a transaction – *i.e.,* occasional or recurring – can influence costs. Third, asset-specificity arises when the opportunity cost of a particular transaction is much lower in its best alternative use; thus, when the original transaction is terminated, the asset has reduced value.

Agency theory offers a complementary explanation for transaction costs. The approach assumes that firms ('principals') contract with 'agents' to avoid market risk inherent in arms-length market transactions. Once again, there is a concern that 'opportunistic' agents will take advantage of any imbalance of power, in this case resulting from the inability to measure either their contribution of inputs to the task (called programmability) or their contribution to the total output (called non-separability). In short, the more measurement problems there are, the higher the cost of buying the service from others relative to undertaking the activity in-house; as a result, non-market co-ordination is more likely to be pursued. Mahoney (1992) offered a synthesis of the two approaches – agency theory and asset-specificity – to explain the various economic institutions that might emerge to manage different types of transactions (see table 1.2). These ranged from simple, arms-length spot markets to fully vertically integrated operations, with a number of non-market relationships (*e.g.,* hierarchy, clan or cluster communities with established norms) options to deal with network knowledge aspects.

2.3 *Institutional Structure*

Each of these knowledge types, subject to different transactional dimensions, will likely be delivered by the market, by the state, or by collective institutions (*cf.* Picciotto 1995; Gray *et al.* 1999). Three types of 'pure' goods are possible.

Private, market goods are consumed voluntarily by individuals and have high excludability (*i.e.,* the ability to control access to their use) and high rivalry (*i.e.,* the degree to which different consumers' consumption and use affect those of others). Traditionally, goods that occupy space or have formal legal boundaries have been well served by markets. In the knowledge world, patented recipes or technologies would fall in this category.

Public goods are characterized by low excludability, low rivalry and low voice (*i.e.,* the ability of members in a sector to have their opinion heard by those who make the decisions) and are generally consumed involuntarily. In the biotechnology industry, this would include know-why, *i.e.,* basic scientific research.

Finally, *common pool goods* (*e.g.,* market development and pre-commercial, non-competitive research) are usually consumed by only a subset of society (*e.g.,* multiple actors in industry); they have low excludability, but high voice. In the biotechnology world, this would include the highly asset-specific know-how and know-who knowledge.

Fig. 1.2 represents the institutional options. The public or state sector (A) represents the citizens of a country and pursues policies to maximize the interests of society altogether, producing public goods. The market sector (C) owns property and attempts to maximize profits on those investments by producing private, market goods. Finally, the voluntary sector (E) consists of those that join a project to reap the benefits of collective action and to pursue goals that cannot otherwise be accomplished through individual action (*e.g.,* common

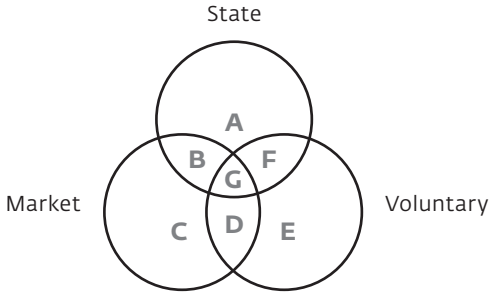

Figure 1.2 Picciotto Model
Source: Picciotto 1995. Reproduced by permission of the World Bank.

pool goods). The intersecting areas labelled B, D, F and G represent institutions that operate between and within the overlapping dominant parameters of the public, market and voluntary sectors (public organizations, NGOs, and hybrid corporations respectively). This is the realm of networked knowledge (Ryan and Phillips 2003). None of the pure market, state or collective institutions are able to successfully deliver networked knowledge and goods without some adjustments, because their valuation perspectives, operational objectives and structural form are designed to optimally deliver the pure goods (market, public and collective).

This aspect of the framework highlights the important role of strategy and management rules. The public sector is optimally suited to creating public-good, know-why scientific knowledge and uses a social welfare evaluation framework for decision-making, using cost-benefit analysis to maximize producer and consumer surplus. While private or industry returns are incorporated in their analysis, they are often not formally delineated. Private firms, in contrast, use valuation models derived from accountancy to optimize the net present value of investments in technology development. Hence, their decision-tool ignores consumer surplus and any producer surpluses or investment costs that do not enter their balance sheets. Finally, collective organizations are ideally suited to deliver high-voice goods, such as know-how and know-who knowledge. In contrast to the other two institutions, collective institutions seek to create value for their members through generating new knowledge that has potential use in multiple systems. While it is unclear how actors in this domain value knowledge, the collective benefit of membership – operating within the context of an open platform – transcends individual objectives of valuing and levering knowledge, yet has a smaller focus than public valuation.

Each cluster activity inevitably favours different formal or informal intellectual property (IP) mechanisms, according to organizational objectives and organizational ability to leverage different kinds of knowledge. Academics developing pure science emphasize publication and the use of copyright, while

actors developing technology look to patents and trade secrets to protect interests. Collective institutions value less formal, open, pooled or networked knowledge management, with access being controlled through a shared language, a common culture and extensive collective experience. What is less clear is how the hybrid organizations (areas B, D, F, and G) value or manage their knowledge assets.

In sum, in the realm of networks and networked knowledge, we must consider the nature of the knowledge being developed and used, the transactional forms mediating the exchanges, and the institutional structure of the relationships that manage the development and use of intellectual property.

3 STRATEGIC IMPLICATIONS

Ultimately, each major life-science project can be consolidated into a single organizing framework, where the different roles and perspective can be considered. For simplicity, we have adapted the 'life-cycle of knowledge' model from Alston *et al.* (1995; see fig. 1.3). These authors distil the process into four discrete (but at times overlapping) stages of development. They start with a research phase (which involves setting up and undertaking research), followed closely by a gestation phase (which involves proof of concept, patent and other IPR applications, and other pre-market commercialization investments), an adoption phase (which could involve incremental investment for IP management and product maintenance) and, ultimately, a knowledge-stock phase (where the various kinds of knowledge generated are used as inputs to further research).

Different actors would see these stages differently, with private or collective actors tending to ignore some or all of the costs (*e.g.,* public goods provided as inputs to the research phase) or benefits (*e.g.,* the knowledge-stock phase). Regardless of the scope of the valuation exercise, each of the actors is assumed to be attempting to optimize their risk-adjusted net present value of their benefits, net of their costs. In theory, at least, the state would be the only actor interested in the entire valuation of costs and benefits.

Below, I examine the four stages of the life cycle of various Genome Prairie projects (such as the Abiotic Stress Project) to identify where the mismatch of incentives and institutions either increases the costs of the project or reduces the benefits from the optimum. I then examine in each case how different institutional structures might yield a 'Pareto improvement.' (The Pareto principle posits that an improvement is possible where some people can be made better off while no others are made worse off, or at least losers can be fully compensated by the winners.)

3.1 *The Research Phase*

The challenge in the research phase of any project is to assemble the necessary array of knowledge – why, what, how and who – to add to the stock of knowledge and to develop and deliver a new process or product that has commercial potential. To that end, in addition to assembling the necessary input, it is vital that

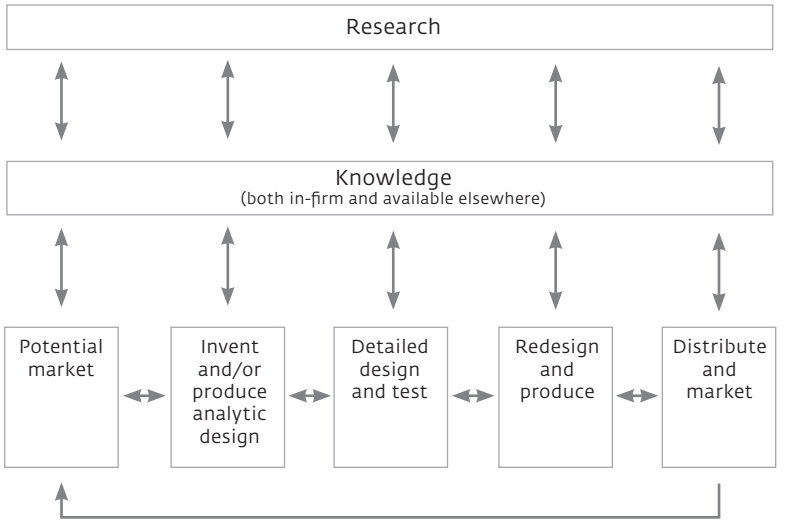

Figure 1.3 The Life Cycle of Knowledge Valuation.
Source: after text in Alston *et al.* (1998).

appropriate agreements be provided that will enable the investors to capture the appropriate scale and types of benefits to justify their investments. Depending on whether an investor is private or public, the returns can come from the resulting market power, from royalties and profits, from consumer surpluses, or from the knowledge-stock benefits. Using the theoretical framework delineated in section 2, we can identify the key types of knowledge being created or used and the institutions needed to handle the relevant array of exchanges and relationships. Table 1.3 lists the implications of strategic goals and technical factors, while table 1.4 summarizes the theoretically optimal, the actual and the potential institutions for handling the research phase.

Back in the days when research was organized in a more linear way – and especially in the case of publicly funded and led projects – there were often few formal barriers to the exchange of know-why or know-what knowledge, and it was relatively easy to assemble teams of researchers with the know-how and know-who to make these projects successful. One factor responsible for this was that few private – and even fewer public – entities had formal IP management plans (in part because, before 1980, patent use was restricted). Another, equally important factor was that the number of researchers was smaller. (In 1960, there were fewer than twenty people anywhere in the world that worked for any extended period on rape-seed, and most of them worked in Canada in a university or a federal laboratory.) Nowadays, the research phase has become much more complex, as private property rights have proliferated, and as science has become increasingly specialized. The number of active patents varies widely by crop, with more than 13,000 patents on rice, 10,500 on corn, 5,500

Table 1.3
The Research Phase: Implications of Goals and Technical Factors

Factor	*Implications*
Strategic goal	• Search for, and negotiation of, a research project. • Assembling codified, know-why and know-what knowledge. • Combining this with tacit know-how and know-who. • Creation of a new product or process.
Technical factors	• One-time transactions, involving low task-programmability, low non-separability and high asset-specificity.

on cotton and 2,100 on wheat (U.S. Patent and Trademark Office 2000). Even for a small crop like canola, more than 650 patents have been issued and many more have been filed (Canadian Intellectual Property Office 1999). An even greater challenge is the task of finding the right people to work with. A review of the academic citation databanks of the Institute for Scientific Investigations (Phillips 2002) showed that more than 6,900 authors in approximately 1,500 organizations in seventy-nine countries undertook and published research on rape-seed or canola.

While there is always uncertainty about the ability of any given researcher or research team to think up some new product or process, the universal problem facing researchers is the challenge of developing and initiating a research project in the first place. This involves finding the appropriate teams to do the work (embodying the know-how and know-who) and acquiring the appropriate rights to prior art (either through searches in the public domain, or by negotiating research and commercialization licenses to patented technologies).

Most analyses of research policy have focused on the role of patents. Researchers have examined the incentive effects of patents, the impact of the scope and duration of patents on successive invention, as well as the impact of patents on freedom to operate, and on the creation and distribution of economic surpluses. While all these issues are important, the biggest single practical problem that patents and other property rights cause is a rise in the cost of effecting the exchange of intellectual property. No single enterprise has full freedom to operate without negotiating access to someone else's technology. Even apart from the potential for rapacious monopolistic practices to block competitors' research (discussed in depth by Dierker and Phillips 2003), there are out-of-pocket costs of negotiating licenses. Some analysts estimate that a full license to use another's patented technology, and to commercialize any resulting research projects, costs anywhere between U.S. $10,000 and U.S. $50,000 (R. Hinther, National Research Council/Plant Biotechnology Institute, pers. comm., April 2001). In some cases, owners of a technology require an up-front, non-refundable payment of up to

Table 1.4
The Research Phase: Optimal, Actual and Potential Institutions

Institution	*Characteristics*
Optimal institution	• Long-term contract or hierarchy.
Actual institutions	• Short-term, one-time contracts involving multiple partners operating with incompatible and/or competitive operating mandates creates pressures to negotiate all benefits in a single process.
Institutional options	• Long-term renewable contracts with more chances for rebalancing benefits and costs over the longer term.

U.S. $50,000 just to enter negotiations. Each research program is likely to need more than one single technology. For example, 'Roundup-Ready' corn required nine core technologies owned by five entities, while 'Golden Rice' required more than seventy technologies, owned by forty-two organizations.

The second challenge is to assemble and access the most appropriate know-why, codified knowledge (*i.e.,* the state of the art knowledge). For example, even though Canada is the largest producer of pure agricultural research into canola, it only produces about 30% of the global output of research and it still has to import about 87% of the basic research from other scientific disciplines in other countries (Phillips and Khachatourians 2001). The task of staying abreast of – and 'absorbing' – the best of this global research is a major challenge. Elsewhere I have shown that, at least for canola, international collaborations probably yield a higher scientific return than domestic collaborations, which helps to justify the added costs of those more complex relationships (Phillips 2002).

Using the framework offered by Mahoney (1992), we can determine the optimal institutional structure(s) to handle the exchange of these knowledge factors. The structuring and management of research projects can be very time-consuming, given the need both for an extensive search for the right partners and inputs, and for the negotiation of the terms of exchange and common action. In a perfect world with full information and no transaction costs, full and complete contracts would be optimal. However, we know that transaction costs are non-trivial, and that the probability of having a commercial success in any given project is relatively low (usually, less than 10% of projects return the costs of the investment). Hence, as transaction costs rise, it becomes less likely that a full contract will be developed. Furthermore, we can posit that research programs tend to exhibit low task-programmability (*i.e.,* we can not tell partners how to engage in discovery activities), low non-separability (*i.e.,* it is hard to determine relative shares of an idea) and the results have very high asset-specificity (*i.e.,* the technology or product often has a very specific use). The difficulty is that this leads to a classic case of 'hold up': investors are not

willing to invest, because their bargaining power after a research breakthrough would be very low (Milgrom and Roberts 1992). Mahoney's typology suggests that a long-term contract would be one way to resolve this conundrum, but the difficulty is that most of these projects will end up being one-offs; hence, it is often impossible to develop long-term contracts. His alternate solution is to use social capital (*e.g.,* norms and relationships) in a hierarchy or clan structure, or, in modern parlance, a cluster. In essence, by using the cluster as the basis for a research relationship, the difficulties of negotiating one-off deals can be overcome, as the research community operates as if it is engaged in a repeated game. Hence, participants in a cluster would not negotiate each deal as if it was a one-time event. Rather, they would be willing to leave some terms and conditions unspecified, on the (usually justified) assumption that the strength of the overall community relationships would reduce the probability that any firm or actor would act opportunistically and with guile.

So, how do the Genome Canada projects compare to the theoretically-derived optimum model? Each of its projects involves collaborations. Genome Canada bears a maximum of 50% of the total costs of any project; in the first instance, this is a limited-term, one-time arrangement, which, on average, lasts for about 3 years. Furthermore, because the projects are supposed to be world-scale and world-class, they tend to establish new relationships among collaborators from disparate areas. For example, while many of the collaborators in the Abiotic Stress Project knew of each other, this was the first time many of them worked on a common project. In the case of Genome Prairie (unlike in Genome Ontario, Genome Quebec and Genome BC), most projects also involve institutions in more than one province, which makes the negotiations more complicated, as regional equity also has to be strived for. Finally, Genome Canada and Industry Canada established early on that their relationship to the projects and management within the projects would be governed by one-time contracts. This combination of factors – one-off, new collaborations governed by one-time contracts – is arguably the least optimal structure for efficient development of the projects. Indeed, the evidence supports the theory. The first round of Genome Prairie projects, announced in June 2001, were subject to intense negotiations in the following months. The interim letters of agreement were only initialled in April 2002, while the final contracts governing the projects were finally signed in 2003. Funds did not flow until ten months after the June 2001 announcement. Many other projects in the Genome Canada world suffered a similar fate. The few cases in which developments were much faster involved projects with collaborators with well-established relationships, based either in narrow subject areas or in regional innovation systems. The GE3LS Project in Western Canada will be assembling more conclusive evidence from these and other collaborative ventures in order to identify the costs more explicitly and to examine the role of prior relationships (*i.e.,* social capital) in influencing the costs and timing of negotiations.

To get a sense of how hierarchies or clans lower transactional costs, one can examine how regional systems of innovation or industrial clusters operate as hybrid actors (*e.g.,* in areas B, D, F and G in fig. 1.2). The Saskatoon-based agri-food research cluster serves as an example (Phillips 2002). This community is credited with a series of world-market firsts (*e.g.,* agrobacterium technologies) and product firsts (*e.g.,* herbicide tolerant canola and flax). It took the lead in the development of the concept for a National Agricultural Genome Centre (which, although unsuccessful in reaching that particular goal, ended up providing a model for Genome Canada); besides, the community is leading three major genomics agri-food projects. Most of these initiatives were developed without formal ex ante contracts; instead, leaders in the community engaged in developing the projects under the assumption that any gains and losses would be apportioned equitably, or at that any short-term losses would be compensated by future joint projects. This apparent altruism is nothing more than an extension of the community's business model. Phillips and Khachatourians (2001) and Phillips (2002) have examined how over the years Saskatoon has become a national centre for the generation, transmission and consolidation of non-codified knowledge in the agricultural biotechnology industry. At the core of this community are Agriculture and Agri-food Canada and the National Research Council. Both have extensive arrangements with each other, with public universities and with private companies. This allows them to learn from their collaborations, thereby adding further to the know-how knowledge and providing a visible, efficient point of entry for know-how and know-who. The public institutes also provide a home-base for the research 'stars,' which, according to Zucker *et al.* (1998), reduces the search costs for other researchers and subsequent commercialization; the largest single geographic concentration of stars and near-stars in the canola research world is located in Saskatoon, where eleven out of sixty-nine or 16% of the top scientists live and work (Phillips 2002). Although the public and private institutions have become more proprietary in recent years, the social capital built up over the years largely remains.

A second model of development is represented by the Vaccine and Infectious Disease Organization (VIDO) Mucosal Immunity Project in Saskatoon. When VIDO, as the lead institution on this Genome Prairie project, went to negotiate this project, they discovered that their twelve-year-old network of relationships in a related National Centre of Excellence provided them with a ready-built clan in which to negotiate the start-up. As a result, they report almost none of the difficulties experienced by other projects, such as the Abiotic Stress Project, where investigators did not have any long-term relationships among themselves before they started the project.

In conclusion, the Genome Canada model of development, although well intentioned, would, at first sight, appear to be flawed, both, on theoretical and on practical grounds. Although there is some evidence to suggest that there are some 'better' – if not 'best' – practices, clearly, more research is required to

Table 1.5
The Gestation Phase: Implications of Goals and Technical Factors

Factor	*Implications*
Strategic goal	• Protection of intellectual property resulting from the research phase. • Achieving regulatory approval and market introduction.
Technical factors	• Low-frequency transactions, involving high task-programmability, low non-separability and high asset-specificity.

examine the hybrid models of project management. In future rounds of research investment, the Government of Canada and the Genome Centres would do well to consider the economic implications of their activities and to contemplate using established communities as the operational bases for collaborative projects, thereby levering the latent social capital, reducing the costs of structuring the projects, and advancing the research agenda more rapidly.

3.2 *The Gestation Phase*

The gestation phase entails taking the results of the research activities and determining how to optimize their commercial and social benefits. This involves, not in any particular order, developing the proof of concept, gaining regulatory approval (if required), choosing and implementing the appropriate intellectual property mechanism (*e.g.,* patent, copyright, trademark, trade secret, plant breeders' right) and deciding on how much and in what forums to publish. In essence, this involves significant investment in searching for the appropriate know-how, negotiating arrangements and enforcing their successful delivery. This phase could be relatively short, if the research invention is demonstrably useful, does not require regulatory approval, and relates to a fast-breaking area. In contrast, where the research result relates to a product (such as a pharmaceutical or a genetically modified food), the proof of concept and regulatory stages could take more than a decade, thereby significantly delaying the moment at which the product could enter the market. Using the theoretical framework delineated in section 2, we can identify the main types of knowledge being created or used and the kinds of institutions required to handle the relevant array of exchanges and relationships. Table 1.5 lists the implications of strategic goals and technical factors, while table 1.6 summarizes the theoretically optimal, the actual and the potential institutions for handling the gestation phase.

There is a wide array of skills and knowledge required to successfully navigate through the gestation phase. In the first instance, proof of concept likely involves the know-how of the research team to develop the methodologies and to undertake the experiments that would be needed to demonstrate the efficacy

Table 1.6
The Gestation Phase: Optimal, Actual and Potential Institutions

Institution	*Characteristics*
Optimal institution	• Joint ventures.
Actual institutions	• Each partner institution owns intellectual property discovered by their researchers and is responsible for commercializing this property. • Intellectual property is highly fragmented, and often inaccessible, due to a lack of access to tacit knowledge.
Institutional options	• New joint venture, either between projects and Genome Prairie, or with a commercial agent (*e.g.,* VIDO-Pyxis Genomics).

and scientific merit of the invention. Thus, this could simply be viewed as an extension of the research phase. The dividing line between the two stages is based on the presence of a technical 'invention' as defined under patent rules. It is not necessary for an inventor to have fully proved his/her concept, before applying for proprietary rights. In fact, given the 'first to *file*' rule for deciding ownership priority in the U.S. system (in contrast to the system in other countries, where priority is granted to the first to *invent*), in fast moving areas it is vital for inventors to file at the first sign of an inventive step, in order to lock in their rights. Thus, while research continues, the process is broadened at this point to engage business development offices, patent attorneys and patent agents. Meanwhile, at this stage, project leaders will begin the process of testing the waters for commercialization and assembling the requisite materials to satisfy regulators. Although the steps for acquiring a patent, meeting regulatory provisions and valuing an innovation are often codified, the skill and artifice in satisfying the systems are almost as individualized as the practitioners themselves.

The challenge of assembling the know-how and know-who to navigate this stage varies, depending on the circumstances of the inventor. It is in this step where many inventions founder. While many research projects achieve some technical success, the costs of successfully navigating the gestation phase often far outweigh the value of the invention. Costs involved in proof of concept can vary from nothing at all to millions of dollars; the cost of acquiring a patent can range from Can $12,000 to Can $416,000, depending on the intended breadth, complexity and market reach; the cost of regulatory compliance ranges from Can $1.5 million for simple plant transformations, to Can $75 million for a new therapeutic pharmaceutical (where only one in ten succeeds); and initial public offerings generally cost a minimum of 10% of any market offering. Success or failure will depend critically on whether the scientific and commercial leaders have the requisite know-how.

Using the framework offered by Mahoney (1992), we can examine the theoretically optimal institutional structure(s) for handling the exchange of this knowledge. These are relatively low-frequency transactions with:

- high task-programmability (the successful completion of the various gestation steps – patent filing, regulatory acceptance – can be delineated);
- low non-separability (the ability to succeed in any single step in the gestation period is fundamentally affected by the contributions of the entire team); and
- high asset-specificity (approval at any stage is specific to the product or technology).

Based on these features, the optimal structure would be a joint venture, with shared investments and shared equity in the results.

Genome Canada's structure is not fully clear yet, but it would appear from early relationships that joint venture is one of the models it has adopted (operating in area D in fig. 1.2). Many of the projects have not clearly delineated how they might commercialize any results, beyond identifying who would own the rights to any inventions. Many of the Genome Prairie projects involve universities and public laboratories, and they have been directed to handle any resulting IP through their own existing business models. A problem facing many of the projects – such as the Abiotic Stress Project – is that, while the Genome Centre agreements provide freedom to operate with any research results for those in the collaborations, they have effectively fragmented all IP portfolios into an unorganized array of institutions. There are a few exceptions. VIDO's Mucosal Immunity Project has created a joint venture with Pyxis Genomics to commercialize any results, which, at least on the face of it, meets the theoretical minimum for optimality.

In conclusion, the Genome Centres should consider a strategy of more formally consolidating any resulting IP in a joint venture, in order to overcome the transactional problems of other less formal structures. The VIDO-Pyxis model offers one possible distributed model, while another, more formal model might be that of the University of California IP office, which consolidates research results from all of the state campuses.

3.3 *The Adoption Phase*

Once we arrive at the adoption phase, we have gone beyond the practical experience of the Canadian genome projects. Nevertheless, now is the time to consider the options facing the Genome Centres and their projects. This stage entails marketing the results of the research. If the research teams would choose to develop and produce their technology or product on their own behalf, that would involve search, negotiation and enforcement costs; if, on the other hand, the technology would be sold or licensed to others, then the main cost would

Table 1.7
The Adoption Phase: Implications of Goals and Technical Factors

Factor	*Implications*
Strategic goal	• Achieving optimal adoption of the technology or product and realizing a return on that activity.
Technical factors	• IP for sale has high asset-specificity. • Licenses impose significant problems of non-separability. • Direct production frequently relates to repeated transactions involving products or technologies with wide-ranging task-programmability, non-separability and asset-specificity.

Table 1.8
The Adoption Phase: Optimal, Actual and Potential Institutions

Institution	*Characteristics*
Optimal institution	• IP for sale and licenses would be best handled in the context of longer-term relationships. • Almost any organizational option could work for direct production.
Actual institutions	• Each partner institution owns intellectual property discovered by their researchers and is responsible for commercializing this property. • Most have little or no experience with anything except outright sale.
Institutional options	• Spin-offs, joint ventures and/or various relational contracts.

be related to enforcement. Regardless, the stakes are high, as this is where any realizable commercial returns will be achieved. Using the framework delineated in section 3, we can identify some of the choices that the Genome Centres and the project leaders will be faced with in coming years, as results of their research are being realized (see tables 1.7 and 1.8).

Success or failure in the marketplace is often a direct result of how a product or technology is handled in the gestation phase. The key to success is access to the tacit and codified knowledge of the marketplace, which is generally not possessed by the research world. It is vitally important to have optimal access to, and input of, these key knowledge actors, as only a few projects ever have the potential to yield significant commercial returns. The industry rule-of-thumb is that fewer than one in ten projects yields results with enough commercial

merit to bother patenting, and only 10% of those – *i.e.,* 1% of the initial number of projects – will return the capital invested. Ultimately, only one in every 4,000–10,000 inventions earns massive profits. If a portfolio misses that one winner, it will inevitably be a long-term loser.

The theory suggests that sales and licenses pose clear institutional challenges. If the inventor chooses to sell an IP position, it would face high asset-specificity; as such, negotiating the sale in the context of some longer-term relationship (*e.g.,* joint venture, long-term contract or hierarchy) would be optimal. By making the sale part of a repeated game, both parties have an incentive to negotiate less rapaciously and to jointly enforce the agreements. Joint ventures involving a sharing of a portfolio of IP often achieve this end. One-off licensing, in contrast, poses almost insurmountable problems of enforcement, which can be overcome by engaging in licensing within communities or joint ventures. Hence, slightly better contract terms with unknown buyers or licensees may not compensate for the risk of them acting opportunistically.

If, on the other hand, the inventor decides to commercialize the product or technology directly, then there is nothing definitive that can be said about the optimal institutions, except that the inventors and their partners need to keep aware of the multitude of organizational options that could be relevant to the production and marketing of their inventions. The key is to consider the individual product attributes and the capital and labour necessary to satisfy the market. In many cases, this will involve some investments with high asset-specificity (*e.g.,* market development) and a range of measurement problems, which would suggest that an array of institutional options (ranging from spot markets to joint ventures and relational contracts) could be useful in successfully commercializing a product.

Genome Canada may have compounded the normal challenges of commercializing new products by relying so much upon the pre-existing business development strategies in the partner institutions. In the first instance, most of the universities have very explicit rules that prohibit the protection of intellectual property through trade secrets, which, in many cases, is a formidable tool in negotiating and extracting optimal returns from the market. In addition, while most of those institutions are quite effective at protecting and selling or licensing the IP, few have any particular preference for – or demonstrated success in – working with partners in their local community. Furthermore, few have had any experience or success in spin-offs, joint ventures or relational contracts. As a result, much of the commercial gain that might be realized could either be lost completely (in case the products would not be adopted) or could be dissipated through institutions that are unable to control opportunistic activities or manage transactions costs.

Table 1.9
The Knowledge-Stock Phase: Implications of Goals and Technical Factors

Factor	*Implications*
Strategic goal	• Facilitating the access and use of codified knowledge. • For leading jurisdictions using any strategic position to continue to lead with research.
Technical factors	• Repeated transactions, involving low task-programmability, high non-separability and high asset-specificity.

Table 1.10
The Knowledge-Stock Phase: Optimal, Actual and Potential Institutions

Institution	*Characteristics*
Optimal institution	• Hierarchy or clan structure.
Actual institutions	• Segmented IP positions, managed by individual business offices
Institutional options	• Pooled IP positions–especially for pathways–licensed or cross-licensed with ongoing research communities.

3.4 *The Knowledge-Stock Phase*

In many instances, the largest social benefit of research is not derived from commercialization and sale of products to consumers, but from the continued benefits of the knowledge that provides a basis for future research. This knowledge-stock phenomenon is implicitly acknowledged in the 'public good' agenda at most universities, but it has not been incorporated into their IP management plans in any strategic way. Tables 1.9 and 1.10 identify some of the key considerations that IP managers must consider to optimize the commercial and public benefits of the knowledge-stock phase.

The difficulty comes from the fact that few patent-holding institutions recognize that many of the patents being filed have little or no appropriable value in the market, and perhaps should simply be released freely into the public domain through publication. Currently, most public institutions act very proprietarily about their innovations. In Canada, each of the more than sixty universities and colleges has its own commercialization office and each of the major federal laboratories or research agencies individually manages its own intellectual property. As a result, public commercialization efforts are fragmented, forgoing any economies of scale, reducing their bargaining power relative to large private biotechnology companies and dissipating any lock-in or network effects that could come from patent pooling (Shapiro and Varian 1999). This is further

compounded by the current practice of most public institutions in Canada to explicitly and formally distribute a significant share (10% to 50%) of any royalties or licensing fees to the inventors (Phillips and Gustafson *n.d.*). While that might seem an appropriate strategy on the part of the public sector, it poses real problems for commercialization of innovations and any subsequent decisions to abandon any patents. The public sector may have made cross-licensing or cluster development more difficult by linking incentives to specific patents (Phillips and Dierker 2002). Furthermore, many of the public institutions have a stated preference and policy to license their innovations widely, rather than to a single entity, in order to get the greatest public good. The problem is that many new technologies require some further investment in development in order to commercialize them. The public sector preference for wide commercialization creates a hold-up problem, as private investors realize that competition would reduce their ability to recoup their expenses for further development.

Mahoney's framework suggests that the presence of repeated transactions involving low task-programmability (the knowledge-stock values will vary widely by user), high non-separability (optimal usage will often involve multiple researchers) and high asset-specificity (any value generated would be subject to hold-ups) could be optimally managed in the context of clans or clusters.

As is the case with the adoption phase, Genome Canada may have compounded the ongoing challenge of managing the knowledge-stock phase by relying on the pre-existing business development strategies in the partner institutions. Given the networked nature of much of the research being supported, there is potential that pooled IP positions could generate some 'network' value. Fragmenting the IP portfolio makes that much harder to realize.

There is no unambiguously right way to manage the knowledge-stock effect, but many researchers who suggest that pooled IP positions – especially for critical metabolic pathways (such as the breeding of a specific set of traits into a species) – could help to build network or lock-in effects (Shapiro and Varian 1999; Graff and Zilberman 2001). This IP pool could be licensed or cross-licensed with the ongoing research communities, or used to lever new investments from others in the development and expansion of the IP. Clearly, these institutions would be located in the hybrid worlds of B, D, F and G in fig. 1.2.

4 CONCLUSIONS

Research is increasingly generating 'networked' knowledge, a new asset with potential new economic and commercial value but also one that faces a new set of complex relationships and transactional costs. In this chapter, I have offered a theoretical and methodological framework for examining those relationships and applied it to the research discovery process, in order to identify market and non-market failures as well as alternate strategies. This framework was used, first, to delineate the types of knowledge being generated and used in networks,

and, then, to examine the transactional forms mediating the exchanges, and the institutional structure of the relationships that manage the development and use of networked intellectual property.

The approach has provided a number of insights. Although Genome Canada's involvement has undoubtedly accelerated the rate of research, it is far from clear whether that will result in innovation, that is, in the transformation of inventions into socially valued products or services that persist in society. The Genome Canada model of development, although well intentioned, would appear to be flawed, both on theoretical and on practical grounds. In current and future rounds of research investment, the Government of Canada and the Genome Centres would do well to consider the economic implications of their activities and to contemplate using a wider range of institutional options to manage the creation and use of genomics-based products and technologies. These new models – primarily based on established communities of researchers and companies (clusters) – present great potential to lever the latent social capital in the Canadian research and commercial system, hence reducing the costs of managing projects, and advancing the research agenda more rapidly.

I would like to conclude this chapter by drawing attention to two areas of further study that follow from the approach taken in this chapter. First, the actual costs incurred by the existing IP management structures would go a long way in quantifying the scope of the problem. Currently, we are simply making educated guesses about the magnitude of the problem. The GE3LS Project has plans to survey all of the Genome Canada projects – and an array of other projects of comparable scale and scope – to do just that. Second, much more research needs to be undertaken in order to further delineate the structure and function of, driving forces behind, and management systems for these hybrid systems (types B, D, F and G in fig. 1.2). There is an extensive literature as well as ample evidence about how the pure types – public, private and collective organizations – operate, but little about how organizations operating in the overlapping areas bridge the differences in orientation and approach.

Notes

1 Proteome: proteins expressed by a cell or organ at a particular time and under specific conditions. Proteomics: the study of the full set of proteins encoded by a genome.
2 See note 1.
3 Transcriptome: the full complement of activated genes, mRNAs, or transcripts in a particular tissue at a particular time.
4 Dicot: a flowering plant with two embryonic seed leaves or cotyledons that usually appear at germination. Monocot: any of various flowering plants, such as grasses, orchids, and lilies, having a single cotyledon in the seed.

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2 From Bank to Bench to Pharmacy Shelf: Biotechnology & the Culture of Finance

Usher Fleising & Charles Mather

1 INTRODUCTION

IN THIS CHAPTER, WE EXPLORE how business people experience the new genetics and the cultural scene where finance and genetics touch. To understand the union of finance and genetics – *i.e.,* the commercialization of genetics – we adopt a symbolic and interpretive perspective and cast the union as an ideological coming together. The basic tenet of our theoretical framework is that genetics is a multi-vocal symbol, a concept with multiple meanings and properties. Our goal is to interpret the meaning of genetics as it emerges out of the culture of biotechnology.

Each of the cultures or sub-cultures involved in the discovery and development of genetically derived medicines and medical technologies emphasizes different values and properties of genetics. In the realm of industry, a successful medicine is first and foremost a commodity that creates share value. The finance model inverts the scientific and clinical models – to make medicines, one does not start at the bench (the domain of laboratory science) but, rather, one starts at the bank (the domain of finance) – economic capital is the primary requirement for making medicine. The industry of genomics is driven by the need for capital, it is organized around raising money, maintaining 'deal-flow,' merging and acquiring companies, and buying and selling.

The orientation of industry toward increasing shareholder value and developing marketable goods predisposes it to favour therapeutics over diagnostics. Actors in the financial world take comfort in the security of a product and can be suspicious toward the science of genomics. Suspicion arises as a result of the uncertainty of the science and its ability to produce medicines and medical

technology. The uncertainty of science translates into business uncertainty and risk. The culture of biotechnology has developed in response to this uncertainty and risk, and this is evident in both the meaning of genetics and in the way that industry is organized to produce medicines and medical technology from genetic science.

2 STUDY BACKGROUND AND METHODS

The information upon which this chapter is based comes from ethnographic research by a team of academics in the Department of Anthropology at the University of Calgary. As cultural anthropologists, we have a general interest in the metaphors and concepts that shape and guide peoples' activities (*e.g.,* Fleising 1989, 1991, 2000, 2001, 2003; Mather, Bickford, and Fleising 2004). The research team has sought, among other things, to make sense of medicines and medical technology (including biotechnology) in terms of the culture(s) involved in their creation and use (*e.g.,* Bickford, Mather, and Fleising, in press). The bulk of our research has occurred under the rubric of a three-year multi-site project devoted to elucidating the metaphor of the drug pipeline (see Mather, Fleising, and Taylor 2004; Mather 2005). Team members have conducted research among scientists (at the bench), in clinics (at the bedside) and in the financial markets (at the bank). This chapter draws from our research in the culture of finance.

Data collection began in 1998 at the Biotechnology Industry Organization (BIO) trade show in New York City. Fleising attended the conference as a participant-observer – taking field notes to create descriptive accounts. This was followed by attendance at the 1999 BIO trade show in Seattle, the 2000 trade show in Boston, and the 2001 trade show in San Diego. The BIO conferences were preparatory exercises for more concentrated fieldwork in Manhattan. The trade shows run for 4 days and combine a business fair with symposia. Fleising focused his activities by attending all finance sessions and networking with individuals involved in financing. The concentrated fieldwork in the financial markets of Manhattan occurred over five months, from September 2001 to February 2002. Methods consisted of unstructured interviews and observations. Interviews were conducted with investment bankers, scientist entrepreneurs, portfolio managers, investment relations VPs, and investment analysts. Alongside interviews, observations were made at four private (*i.e.,* by invitation only) Healthcare/Biotech conferences reserved for major investors and analysts. Post-fieldwork study has involved identifying recurrent themes and metaphors in the interview and observational data and connecting this information with results from our research in other parts of the drug pipeline.

3 IDEOLOGY & THE INTEGRATION OF GENETICS & FINANCE

The notion that the integration of finance and genetics is an ideological phenomenon became apparent during the earliest stages of our research program. During

a finance session at the 1999 BIO conference, a founder of the biotechnology industry asserted to a panel audience that biotechnology was about "genesis, genetics, genitals and money." The speaker united the categories 'science,' 'myth,' 'body,' and 'business,' in a selective, emotive, oversimplified and legitimate language (Sutton *et al.* 1962, 3), and this corresponds perfectly with an interpretive and social-psychological definition of ideology, including the idea that ideology is a call to action.

One way to interpret this symbolic string is to assign 'genitals' and 'money' to the personal and mundane, and to assign 'genetics' and 'genesis' to the mysterious and esoteric (see table 2.1).

Table 2.1
Alternative Classifications of Symbolic Associations with Respect to Biotechnology

Symbolic Associations	*Personal & Mundane*	*Mysterious & Esoteric*
Organic	Genitals	Genetics
Socio-Moral	Money	Genesis

Knowledge about the former is immediate and obvious, while knowledge about the latter is locked up in the distant and secretive worlds of professionalized science and religion. 'Genesis' and 'genetics' belong with the theoretical and the sacred, whereas 'genitals' and 'money' belong with the practical and the profane. However, we can have yet another pairing, where 'genetics' and 'genitals' represent the organic and 'genesis' and 'money' represents the socio-moral. The concern then becomes how to ensure that the organic is balanced with or subverted to the socio-moral, *i.e.,* how to make it so that science serves society rather then having society serve science.

Cross-culturally, anthropologists have identified a myriad of institutions and rituals that serve to repair and protect the boundaries between the socio-moral and the organic, thereby securing the well-being of the community. In our interpretation, the whole Genetics, Ethics, Environment, Economy, Law and Society (GE3LS) program in Genome Canada – to whose efforts we may include this chapter and the other contributions to this volume – may be analyzed as a liturgy for dealing, in a ritualized way, with the societal tensions created by breaches of, and perturbations at, the boundary between the organic and the socio-moral. After all, the regulatory framework is there to monitor the state of the body. In a democratic system where public input counts but economics is ideologically the prime mover, the historical development of a process such as GE3LS reflects the continuing human drama of reconciling the organic and the socio-moral (Turner 1990).

The symbolic agents for creating a GE3LS process are an institutionalized methodology for reconciling inventions for tinkering with the organic, on the one hand, with what constitutes proper, valued, and just behaviour, on the other. An incongruence between these two domains can signal moral deviance, as nature and culture become unbalanced, because an organic substance for the control of nature (genetically-based therapeutics and diagnostics), produced by human technology, is set against the proper socio-moral functioning of society. It is this tension between the organic and the socio-moral that places a texture of moral ambivalence on all healing systems. The particular tension of interest here is the tension between money and finance, on the one hand, and the new genetics, on the other.

4 THE DRUG PIPELINE

The drug pipeline is a corporate metaphor for the discovery and development of medicines. In terms of its social life, a potential medical commodity (a wannabe drug) begins rather modestly and ambiguously at the bench, having rather low status until it is deemed worthy of an initial drug application. After four years, thousands of candidates, and hundreds of millions of dollars, a privileged few candidate medicines are deemed worthy of the sacrifices required for the next stage of the pipeline – the clinical trials. Of every ten candidates that enter the clinical trial phase, only *one* will be blessed, usually by the (U.S.) Food and Drug Administration (FDA), as worthy of ingestion by patients. The world of drug candidates beats a path to the FDA and the United States, as America consumes 40% of the U.S. $360 billion world drug market.

This ten- to fifteen-year ritual process has developed over the last one hundred years; the first drug and labelling laws came into effect in 1903, following deaths attributed to bad batches of diphtheria antitoxin (Liebeneau 1987). The pipeline represents a succession of laws and policies, established to regulate health. The political scientist Taylor Caldwell (1987) has referred to this integration of life-science knowledge into the regulatory process as a "biocracy."

The most recent study from the Tufts Center for the Study of Drug Development (DiMasi 2001) puts the cost of getting a drug through the pipeline at about eight hundred million dollars. In 1987 the cost was estimated at U.S. $231 million. Yet, as one investment banker told us, "no one really knows what it costs," a sentiment echoed by a common remark in the world of finance that "it depends what you count." Some claim that discovery is more expensive than testing, while figures from *The Economist* (1998) show the opposite, *i.e.,* that testing costs more. Our interpretation is that all these experiences are true; *i.e.,* that there is a scale of variation in drug discovery and development that encompasses many permutations and combinations of cost and time. Currently, there are about four hundred products in clinical trials of which about 11% will complete phase III and receive approval; this is a very uncertain and risky business indeed!

Our research team has focused on the way products pass through the various stages and domains that make up the pipeline. 'Domains' are cultural settings characterized by specific forms of knowledge and practice and in the case of the drug pipeline these include the medical, the financial, the scientific, the regulatory, and the public domain. We are interested in the social life of drugs, and the 'rites of passage' – for example, bench and clinical research, regulatory process, financial deals, and marketing campaigns – that transform products from one stage of the pipeline to the next. The discovery and development of medicines hinges upon ritual knowledge and practice; making medicines requires making sacrifices of intellectual capital (time and effort) as well as financial capital (money and wealth).

Our interest in the financial domain concerns not only how the pipeline produces therapeutics, but also how it produces diagnostics. Our research suggests, however, that despite the fact that diagnostics are highly valued in the scientific and clinical domains of the pipeline, the primary value of genetics to actors in the financial domain is as a source of therapeutics. This has marked implications for the direction that application of genetic knowledge will take. One could argue, for example, that diagnostic technology is a decidedly 'upstream' intervention, while therapeutics are 'downstream' solutions, *i.e.,* are further down the value-chain. Whether the focus of clinical intervention is upstream or downstream will have substantive effects on healthcare costs and the incidence and prevalence of different types of morbidity in the larger population.

5 THE FINANCE MODEL, CAPITAL MARKETS, & DEAL MAKERS

Making the pipeline work requires the input of intellectual capital and economic capital. In the finance model the assumption is that you cannot make medicine without finance – *i.e.,* that the bank comes before the bench – contrary to the popular notion among university administrators that you go from bench to bank.

To emphasize and distinguish the *science* of biotechnology from the *business* of biotechnology, it is instructive to begin with a definition for genomics. The standard nominal definition that might be found in a dictionary of biology is this one from the website of the Biotechnology Industry Organization (BIO 2004):

> Genomics is the scientific study of the genome and the role genes play, individually and collectively, in determining structure, directing growth and development, and controlling biological functions. It consists of two branches: structural genomics and functional genomics.

A second definition is an operational one frequently found at biotechnology industry meetings: "Genomics is systematic industrialized molecular biology in order to increase shots on goal in biotechnology." These definitions mark a clear distinction in separating the science of biotechnology from the business of biotechnology. Another clear indication of the connection between finance and medical science is the statement that "disease is a market opportunity." The definition of disease as a market opportunity was articulated by a person at a finance session for biotechnology executives who understood its meaning in a medical context. Like the statement that "biotechnology is about genesis, genetics, genitals and money," the assertion that "disease is a market opportunity" is a *model* for action, and, therefore, an expression of an ideology. Following Sutton et al (1962, 2), ideology is "…any system of beliefs, publicly expressed with the manifest purpose of influencing the sentiments and actions of others" (Sutton *et al.* 1962, 2). Ideology is a symbolic outlet for emotional energy, and is often made evident by figurative speech, as seen in the quotes from above which are packed with rhetorical elements (*e.g.,* metaphor, personification, and irony). According to an industry savant, one can, in fact, hypothesize a historical moment, when disease became a market opportunity. This was when private sector research and development (R&D) surpassed public R&D finance. In 1980, eighty per cent of the one billion dollars spent on biotechnology research worldwide came from academic sources; and, by 1986, industry accounted for two-thirds of the six billion dollars spent on biotechnology research (Hacking 1986, 251). In 2001, the budget of the National Institutes of Health (NIH) was U.S. $16 billion. Just the R&D investment of the top tier pharmaceutical companies alone matched this U.S. $16 billion figure (Cook-Deegan *et al.* 2001).

While the making of medicine requires money up-front, the requirement for capital is actually continuous, especially in biotechnology, which has been described as having an insatiable appetite for capital. In a session on finance in biotechnology, a Venture Capitalist told an audience of prospective biotechnology companies, "You will be raising money forever," to which a fellow panellist, a medical doctor and biotechnology CEO, added, "You will be rejected constantly." The financial domain includes a group of actors called senior managers – often referred to as 'scientist entrepreneurs' – who are on a non-stop treadmill in pursuit of cash; they are often on the road and engaged in maintaining 'deal flow.' Senior managers in the life-science industries go to two places to 'raise money forever' and maintain 'deal flow': Wall Street (*i.e.,* the capital markets) and the big pharmaceutical internationals.

In order to understand deal flow and the culture of finance in the world of biotechnology, one needs to know about the culture and organization of the capital markets. Table 2.2 is a simplified representation of how the capital markets are organized for deal flow.

The critical elements here are the dealmakers captured in the distinction between the buy side and the sell side. The venture capitalists participate on

Table 2.2
The Capital Markets

Wall Street Issues	*Professional Investment Community*	
	Sell Side	*Buy Side*
Information: Food and Drug Administration *Development industries:* High risk *Securities and Exchange Commission* (SEC)	*Corporate finance:* Investment bankers Mergers and acquisitions Road shows *Analysts:* Reports are public Chinese Wall	*Portfolio managers:* Varied funds Pick, manage, sell *Analysts:* Reports are restricted *Investment philosophies*

the buy side, although at some point they also sell. In fact, because the sell side also buys and the buy side at some point must sell, even veterans in the business comment that they first had difficulty sorting out the buy side/sell side taxonomy. The social context for deal-making is captured in the Wall Street Issues taxonomy, an issue elaborated upon below.

It is prudent to establish that for the professional investing community, there is a distinction between public and private businesses, *i.e.,* those that trade on the public exchange markets – the NASDAQ and New York Stock Exchanges being the most important examples – and businesses that are owned by a group of investors. Of the biotechnology companies, not a single one is family-owned, while only 20% are public companies. An additional note of importance is that venture capitalists operate in the private domain, but both buy as well as sell.

The sell side represents the people who put the deal together; they work primarily as intermediaries, raising capital and taking commissions. This is the place of rest of the investment banker. A significant amount of finance activity revolves around mergers and acquisitions (M&A). M&A activity is lucrative for the banking business, and such activity intensifies when capital is scarce and companies are searching for ways to maintain deal flow. Bankers encourage M&A in biotechnology as a way of reducing the number of companies, as they claim that the two to three thousand ones that are currently active are simply too many (Van Brunt 2000). One way in which deal flow is activated is in a cycle of activity known as a 'road show.' Road shows are intensive periods of activity, involving travel and endless meetings and presentations. Their purpose is to convince the buy side to provide money. It is a form of courtship; in fact, metaphorically, it is like a period of estrus, when the females come into heat and there is a frenzy of activity. In addition to 'road show,' the terms 'bridal shower' and 'bake-off' are used to describe this ritual.

Analysts are technical experts who evaluate company performance and probability for success. Sell side analysts have been in the news recently, because of

activities at Enron and Merrill Lynch. A conflict of interest exists for analysts residing in an organization that also does banking; if an investment banker is courting a deal with a client, it is counter-productive for an analyst with the same bank to write a negative report on the same company. 'The Chinese wall' is the metaphorical name given to the supposed enforcement of a strict separation between the analysis side and the banking side of the investment banking business. Some informants claim that this wall has never actually existed. Recent reforms of the capital markets are resulting in a separation of the banking and research functions of the business, a situation that is a throwback to how the industry was organized before commissions on Wall Street were deregulated in 1975 (Geisst 1997).

The buy side people are syndicates of money looking for a home. Informants emphasized constantly that there is always a lot of money available – there is never a shortage – it is constantly looking for a place to rest. Mutual and pension funds are one element here, as are hedge funds, insurance, endowments and bank trusts.

'Pick, manage, sell,' is the job of the buy side, and the expectation is to make money at sale. The critical cultural feature here – true also of the venture capitalists – is the understanding that investors have an exit strategy. This is where the emotional attachment of scientists to their companies suddenly confronts the reality of the capital markets. The investors are suddenly discovered to not have the same long-term commitments as the founders. An emotional awakening occurs as founding scientists lose control of their image for 'their dream,' when the buy side picks the opportunity to cash out. The opportunity for liquidity is the primary motive for the buy side to invest in the first place. The buy side also has their analysts, principally because they do not trust the analyst reports from the sell side. These reports, unlike those from the banks, are not public; instead, they are closely guarded.

6 WALL STREET ISSUES & WALL STREET CULTURE

Wall Street issues confront the biotechnology industry as much as they do other sectors. Biotechnology is part of a grouping known as development industries, which also includes computer and telecommunications industries, industries that are unique in that they rely extensively on intellectual capital. The Securities and Exchange Commission (SEC) is the moral bureaucracy that governs the capital markets in the U.S. It has a minor impact on the finance of biotechnology firms, when compared with another moral bureaucracy, the Food and Drug Administration (FDA). An FDA ruling or rumour has significant impact on the value of a biotechnology firm, which emphasizes the intensity of the relationship between finance and information, or 'news,' as it is called on the street. Information is everything; the market moves on information, and people go to jail and pay huge fines for using information inappropriately (*i.e.,* when

they engage in insider trading). In Baskin and Miranti's (1997) extensive and detailed history of corporate finance, one third of an index page is required for the entry 'information.' There is a well-known saying that even amateur investors have heard: "buy on rumour; sell on news."

At this point we can formulate some generalizations about Wall Street culture.

1 *The dominant ideology is shareholder value*. The ideology of maximizing shareholder value comes with a caveat that recognizes that, often, emotion gets in the way of making decisions that are in the best interest of shareholders. This is especially true in biotechnology because it is about the emotional issue of health.

2 *Performance is everything*. This means that, in order to sustain deal flow, there need to be tangible markers of success. This could be an ability to structure deals and/or an ability to demonstrate the management skills required to meet milestones.

3 *A need for information*. The need for news – especially for public biotechnology companies – is a huge strain on the scientists. This is true for any development industry where there is a heavy reliance on the development of new technologies, or where crucial tests of performance and efficacy are required. Again, the ability to sustain deal flow demands a steady diet of news, preferably, of course, good news.

4 *Time is present- and future-oriented*. Another characteristic of Wall Street culture is an orientation to time that is strongly grounded in the present, but that anticipates a certain future. Reference to the past is rare, because it is present circumstances that affect business decisions. This kind of orientation results in a requirement for the professional investing community to work in real time. In an interview on the subject, an industry consultant pointed out that buy and sell side people usually did not indicate "Ph.D." on their business cards, when, in fact, many did indeed hold doctorates. The image of the Ph.D. is of a person who is reflective (a negative attribute in deal-making) and who suffers from what a second industry consultant called "the 'what if' syndrome." There is no time for 'what if' in the heat of making a deal or an offer to buy or sell. There is a premium placed on certainty.

5 *Deal flow is transactional and opportunistic*. In the context of a culture of deal flow, it is interesting to note the character of relationships and partnerships in the financial domain of pipeline. Wall Street has evolved to where institutional relationships are fleeting, rather than enduring. This structural shift is the result of a series of SEC reforms, especially the deregulation of commissions in 1975.

6 *Wall Street culture is counter-intuitive*. Actors in Wall Street place a premium on the ability to 'think on your feet' and make multi-million dollar decisions in the heat of the moment (see, *e.g.,* the book, *Liars Poker*, by Michael Lewis [1990]).

The next few sections touch on a number of themes that give color and context to the culture of finance in biotechnology and broaden the cultural scene of the capital markets.

Table 2.3
Biotech Alliances of Top 20 Pharmas (Alliance Type by Year of Signing)*

Years	*Diagnostic*	*Drug delivery*	*Therapeutic*	*Out-licence*	*Total number of alliances*
1988–90	11	30	126	19	186
1991–93	17	42	215	65	339
1994–96	25	73	425	78	601
1997–99	17	84	544	95	740
2000–02	17	77	582	81	757
Totals	87	306	1892	338	2623

* *Source:* after McCully and Van Brunt (2003). Reproduced by permission of *Signals Magazine*.

7 THE SYMBOLIC CAPITAL OF PHARMACOGENOMICS & GENE DATA BANKING: WHERE IS THE MONEY?

A good example of the dynamics of the relationship between finance and the new genetics comes from the second major source for the financing of biotechnology, the big pharmaceutical multinationals. There is a huge gap between the economic capital associated with predictive medicine, and the symbolic capital represented in the voluminous academic and public policy literature on genetic testing and gene data banking. Table 2.3 demonstrates, first, that the amount of ink that flows in the academic and policy literature on pharmacogenomics and genotyping is hugely out of proportion with the dollar value of this sector of the industry, and, second, it demonstrates to the business side why they should not be in the bioinformatics business, and why indeed many companies have abandoned bioinformatics as a commercial strategy.

A review of formal alliances signed between 'Big Pharma' and biotechnology companies between 1988 and 2002 reveals that deals for diagnostics – the place of rest for pharmacogenomics and genotyping – represents only 3% of

2,623 cases. Twelve per cent centred on drug delivery, while 13% concerned out-licensed products. However, the vast majority – 72% over the entire fifteen-year period – had a therapeutics focus. In the latest three-year period (2000–02), the number for therapeutic deals jumped to 77%.

It is the *symbolic* significance of genotyping and personalized medicine that is important. Business does not place genetic differences on a value scale; for them, the only relevant question is, where is the money in it? In other words, it is a challenge to develop a solid business plan, based on haplotyping or pharmacogenomics. There is a poor translation from cultural capital to economic capital. In the period between 2000 and 2002, the average equity investment for therapeutics was U.S. $180 million, compared to a U.S. $5.4 million average deal for diagnostics (McCully and Van Brunt 2003). Post-2000, one would be hard-pressed to find a company that identifies itself as a pharmacogenomics company. Many industry analysts consider the commodification of the Human Genome Project to be a bad project. The moral of the story is "Get yee downstream." Downstream means further down the value-chain, beyond target discovery and bioinformatics, to actually making medicines. This message became very strong in 2000, and is nicely captured in the following statement (cited in McCully and Van Brunt 2003):

> I'm an old-fashioned guy. There's only one way to make money in the pharmaceuticals business, and that's to make pharmaceuticals. At the end of the day, it's, "Do you have a product, yes or no? Is it making money, yes or no?" Everything else is, "It's cool, it's sexy, *but*: do you have a product, yes, or no?" If your answer is "no", your stock is $2. If your answer is "yes," your stock is $50.

Now, despite what this old-fashioned guy says, it is possible for your two-dollar stock to behave like a fifty-dollar stock, although probably not as much anymore, as Wall Street has come to appreciate the uncertainty of science.

Myriad Genetics – (in)famous for its marketing of genetic testing for breast cancer – gets good analyst reports, because of its ability to actively move its pipeline of drug discoveries downstream, *i.e.,* to commercialize its discoveries. Its reputation comes from having candidate products (*e.g.,* Flurizan for colon cancer) in various stages of clinical trials. Predictive medicine is only 50% of business revenue for Myriad and this will decline – a nice niche, but not pivotal in the final assessment of the company.

8 SECTOR ATTRIBUTES

Select quotations from significant business leaders in the pharmaceutical, biotechnology and venture capital communities provide another way of expanding on the cultural scene of the biotechnology business.

- And the trouble with all our new ideas in biotech, each time we have a new idea, there is no data. In fact, there still isn't any data from the old idea when we get the new idea.
- We've been through the genomics companies and the combinatorial chemistry companies and the target validation companies and now we're doing the functional genomics and the proteomics companies.
- You can spend ten years and wind up with a goose egg. It's a black hole for capital.

These quotations reflect the general cultural features of uncertainty and risk that dominate both the business and the science of biotechnology. The sentiment being expressed is that the business side has finally understood the extent to which the science is uncertain. Ironically, however, there is a sense in which the science has more permanence and extended life than does the business. An informant who worked as a business consultant characterizes the industry as "a product masquerading as a company" and in the next breath asks, "The science will survive, but will the company survive?" This picture of the business of biotechnology is commonly understood, and it reflects the tensions that surround interactions between scientists and business managers. Biotechnology is more about selling ideas and dreams than it is about shipping goods: "There is nothing to warehouse and nothing to ship," according to an exasperated materials handling consultant at a trade show.

However, the dreams and ideas biotechnology offers are about health and illness, and this brings passion to the industry. The passion is often personal, but also broadly sociocentric, and partly emerges from a sense of being in a business that has social value and benefit. For actors in the financial domain the business is "more than a job, because you are dealing with illness." Yet, individuals feel uneasy, because the values and demands of doing business can interfere with the intention of producing social good. The following remarks clearly illustrate this point.

- Wall Street is not in the health business. Wall Street invests in Philip-Morris…. They're in the moneymaking business. And that doesn't say anything ethically, morally or whatever; that's detached. And if we don't make money, very simply, we get discounted. And today we have been discounted.
- The first thing the CEO sees when he opens his eyes in the morning is the cash on his balance sheet. How much longer will it last? What is the burn rate?… [Going public] obscures the altruistic parts of the business.

By way of summary, the biotechnology industry can be characterized as being fuelled by ego, greed, and wholesome intent. The words 'ego' and 'greed' are often used by insiders and the concept of wholesome intent summarizes the

passion for social responsibility that is also a part of the business. The term comes from Mitchel Abolafia (1996) who studied commodity and treasury bill traders in Chicago and New York. This wholesome intent in the medical arena is a playing out of an American social conflict (grounded in interpretations of the U.S. Constitution) over who bears responsibility for the health of the nation: the government or the private sector.

9 CONCLUSIONS

The question, why do we have the pipeline? raises emotional issues because the pipeline is about hope, the use of knowledge, and social justice. It is about the value we place on using the culturally-acquired knowledge of medical research. It is about the hope that this is the right thing to do. It is also about the hope that profits can be made, and about the moral basis for making these profits – even greed is a form of hope. Finally, it is about the equitable and fair distribution of medicines to all who may need them. "The political economy of hope" – as Mary Jo DelVecchio Good (1995) refers to the global trade in medicine – is about the traffic between technology (DNA-based medicine), the economic structures of production (the capital markets) and ideology (the culture for therapeutic intervention). This traffic includes a socio-moral engagement that is acted out in all societies. The theoretical framework that has been adopted in this chapter privileges the symbology of power and a meaning-centred representation of therapeutic intervention. The symbology of power is operationalized by adopting a social-psychological definition for ideology; the site for therapeutic intervention is the culture for the finance of biotechnology in the capital markets of the United States.

Every society must contend with disease, illness, and the emotional fires of suffering and hope that accompany the unwell. While all societies have strategies for maintaining health, there is variation in what is considered a disease, and in what are believed to be the causes of disease, how diseases are classified, and how the society is organized to deal with disease and its consequences. Medical biotechnology is part of a continuing drama that began when some creature found solace in licking its wounds and those of its near kin.

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Part 2

Policies & Publics

3 Agricultural Biotechnology in Europe at the Crossroads

Helge Torgersen

1 INTRODUCTION

CURRENTLY, EUROPE IS AT A CROSSROADS in the debate about agricultural biotechnology. The European Union (E.U.) member countries are implementing the new *Directive 2001/18/EC* on releases and marketing (European Union 2001), and the European Commission has ended its de facto moratorium that had been in place for half a decade. This has been interpreted as a step towards normalization, and as an opportunity for the technology to be implemented in Europe. Public opinion in many countries has stabilized into a moderate, but definite, dislike of the technology and its products. However, the era of heavy battles seems to have ended. In the long run, biotechnology advocates appear to have been able to subdue public anxieties.

Throughout, the United States and other key crop-exporting countries had consistently challenged through the World Trade Organization (WTO) the European Union's reluctance to end the moratorium and to lift import restrictions on transgenic crops. The approval of a transgenic corn product, while signalling an opening up of the European market, was nevertheless highly contentious, occurring as a decision of the Commission only after E.U. governments failed to reach agreement on whether to lift the ban. This may indicate the potential for re-animation of past conflicts, which pro-biotechnology interests in Europe had hoped to overcome. So, the question remains whether normalization has taken place, or, instead, whether a new round of conflicts remains on the horizon. In order to address this issue, I will go back in time and re-examine those past debates.

In this chapter, I will briefly discuss the different phases in the public perception of biotechnology and the events that gave rise to the current situation in

Europe. Then I will highlight some contextual factors, in order to put recent regulatory changes into perspective. Subsequently I will discuss new tools that have been devised to overcome the status quo, and, finally, I will outline some possible future developments.

2 THE CHANGING CLIMATE: PHASES OF PUBLIC PERCEPTION & REGULATION OF BIOTECHNOLOGY

Media analysis is a powerful tool for identifying the different issues that were prominent during various phases in the development of European biotechnology, and the public debate it gave rise to, over the last thirty years (Torgersen *et al.* 2002). Coverage in the early 1970s was dominated by a view of biotechnology as a scientific endeavour. When public opposition emerged, scientists initially succeeded in reassuring the public. During the next phase, in the early 1980s, biotechnology's economic prospects became a main issue, and the industry started to defend itself against the resistance that resulted from concerns about the safety of the technology. Already then, both promoters and opponents of biotechnology asserted links with other contested issues, thereby extending the range of arguments beyond the issue of risk. In an attempt to confine the conflicts that had emerged over the balance of risk and benefits, governments began to regulate the field. In the next phase, during the late 1980s, the anticipated nationals regulation prompted the E.U.'s institutions to promote harmonization for the future common market of biotechnology products. Yet, not only the regulatory styles, but also the history of the debate in different member countries varied, which made harmonization a difficult task. Eventually, by the early 1990s, biotechnology had, by and large, become accepted, and conflicts had declined.

However, when consumer food products materialized after the mid-1990s, old conflicts re-emerged over new issues, marking the beginning of a fourth phase, which lasted well beyond the millennium shift. Existing modes of regulation turned out to be inadequate, and opposition rose, even in countries where people had previously been relatively positive towards biotechnology. Towards the end of the decade, regulators pulled the emergency brake and issued a de facto moratorium for genetically modified crops at the E.U. level. Since that time, new regulations were devised in order to facilitate the introduction of products that, elsewhere in the world, had already been on the market for a long time, but that were still negatively perceived by a reluctant European public.

At this point, having experienced several changes in the European landscape with regard to regulation and public perception of biotechnology, more developments may be anticipated. We have seen countries within the European Union becoming forerunners in technological development, in regulation and in public debate. We have experienced swings and turnarounds, and new tools have been applied to old conflicts that resurfaced. In particular, we have observed the separation of the developmental paths of medical and agricultural biotechnology,

in terms of public acceptance, of industrial investment and of research funding. Medical biotechnology is welcomed by a large majority of Europeans (Gaskell *et al.* 2001). So far, negative personal consequences (*e.g.,* impacts of genetic tests on insurance rates) have not materialized, mostly due to the fact that the health system is still overwhelmingly financed by the public sector.

In contrast to medical applications of biotechnology, agricultural ones remained strongly detested by many publics. One trigger event was the pending import of U.S.-grown transgenic crops in 1997. For a long time, this issue caused the public to link food issues to biotechnology; ultimately, this dealt a severe blow to agricultural biotechnology applications in many European countries. Yet, the reasons for these developments and the ways they unfolded were very different in the various European countries. There was no coordinated response to U.S. attempts to force open the European market for transgenic crops. Neither was there a unified and consistent E.U. policy with respect to agricultural biotechnology in the late 1990s, or a united European public opinion opposing American imports. In fact, what we saw was a pandemonium of different interests and views that had one thing in common: the public did not want genetically modified crops on the European market, for a wide range of reasons.

Interestingly, and perhaps for the first time, European environmental non-governmental organizations (NGOs) succeeded in achieving a certain degree of synchronization between different countries' national publics. Mobilization always happens at a local or – in the case of the E.U. – at a national level, if only for the lack of widely consumed transnational news media. In Europe, the existence of such transnational media would simply be impossible, due to the large number of languages spoken. Nevertheless, the pending import provided NGOs with a trigger that sensitized national publics in many countries. Another strategy employed through large parts of Europe was to seek links with retail chains in order to make sure that GM products were detected and stigmatized early on. This strategy proved to be the Achilles heel for companies that had planned to market such products, and it provided the tool for converting an initial activists' campaign into a mass mobilization. The concerted actions of some large NGOs, together with those of groups acting at the national level, gave rise to the illusory perception of a united European public.

In this climate, it became very difficult for national governments to pursue a policy supportive of biotechnology. Again, the national responses were quite varied, as they were adapted to the respective national contexts. Some governments sacrificed agricultural biotechnology in order to be able to further support medical research and development, especially if the country's seed industry had already been weak before the introduction of GM crops. Other countries tried to steer a middle ground and to improve risk assessment procedures. And, at least temporarily, a few countries actively opposed agricultural biotechnology. For example, before the late 1990s, France had been one of the most outspoken

promoters of agricultural biotechnology in Europe. Suddenly it turned into one of the most outspoken opponents. The French government made the decision on how to deal with GM crops subject to a consensus conference-like 'public debate,' which was very unusual for a country with an expert-led and rather top-down regulatory style. 'Stop' and 'go' signals followed each other in relatively quick succession.

In Italy, the pending import became an issue of public debate only after reports about Dolly, the cloned sheep, had been stirring up the public agenda. In other words, there was a spillover effect that linked two issues that were only related to each other in that both had something to do with biotechnology. Italy did not hesitate and issued a ban on several crops. Later, some counties started declaring themselves 'genetic-engineering-free areas.'

In Austria, where, in the meantime, such areas had become popular, too, resentment had started with the ill-conceived first national release of a transgenic plant for research purposes. It had prepared the ground against agricultural biotechnology as a whole and boosted the demand for organic produce. Austria went through a successful public petition against biotechnology, initiated by a rainbow coalition including environmental NGOs. With respect to approvals, Austria applied the 'precautionary principle' as an argument to prohibit GM crops, much to the dislike of the European Commission and certain other E.U. member states.

In Denmark, food safety and environmental concerns together renewed an old and still on-going debate that had temporarily calmed down.

In striking contrast, Germany remained rather quiet for a while. It took on a 'duck-and-cover' strategy and tried to keep the issue at a low level. This was in stark contrast to the situation in the late 1980s, when the German example had prompted the European Commission to develop regulations, in order to contain a debate that was thought to jeopardize the future of biotechnology.

In Britain, public sensitivity to food issues and regulatory misconduct after the 'mad cow' or BSE crisis were ingredients for a press coverage highlighting hidden food risks. When a scientist investigating possible food risks from GMOs disclosed some preliminary findings in an interview and subsequently was laid off, this elicited a newspaper campaign with considerable impact. Britain then started quite extensive farm-scale trials in order to test the claims made by opponents about possible negative impacts.

The European Commission tried to maintain a policy that aimed to "make biotechnology happen" (Jasanoff 1995). However, the regulatory tools it had available to achieve that goal turned out to be dysfunctional. As member countries could not agree whether there were risks attached to any particular transgenic product or not, decision-making ended up in a limbo between the European institutions and the member states. Some of them applied a temporary ban as a last resort, a regulatory lever originally devised as an emergency exit only; the situation became untenable. Against the intentions of the Commission, the

member states voted for a moratorium, specifying that no new products would be accepted for review according to the E.U. regulatory framework, until this very framework would have been modified.

At first sight, the rationale behind the history of the decision-making process at the level of the E.U. is not obvious. Yet, if we expand the analysis to include the events in the individual member countries, it becomes clear that the decision-making process in the E.U. is an outcome of very diverse national developments. Elements such as the BSE crisis played a role in several countries, but the overall situation and the admixture of ingredients varied profoundly from one member state to the other. Yet, the varied national responses had one common denominator: they were all aimed at gaining time. When the de facto moratorium was declared, the attempt to gain time, had, in a sense, been officially approved at the E.U. level. However, the strategy to delay the decision did not emerge within the European Commission; on the contrary, the Commission expressed its dismay with the state of affairs on more than one occasion. Nevertheless, the moratorium did provide a sufficient amount of time for the development of new regulatory tools, and it offered the opposing camps in the conflict an opportunity to blow off some steam.

3 The Changing Context of the Debate: Links between Biotechnology & General Disputes about Agriculture

Diverse as they were, the different economic, social and ideological contexts of the debate on biotechnology played a decisive role in its development. Already during the early 1980s, biotechnology became embedded in a variety of different discourses. To limit the debate to a mere 'scientific discussion on risk' would neglect the social reality that surrounds these issues. Things had become more difficult, and even attempts at launching a 'sober debate about risks and benefits' – which many promoters of biotechnology were willing to engage in – turned out to be unrealistic. Agricultural biotechnology had to confront the same problems that plagued modern industrialized agriculture as a whole. Therefore, and in contrast to a commonly held opinion, the lack of proper performance of – and public trust in – European institutions responsible for the oversight of food safety was not the only cause for the difficulties biotechnology was facing. The BSE crisis, as well as a variety of other food scandals, had highlighted not only the problems of food safety, but also those plaguing the general food production system in the E.U. If the only role of agriculture were to produce food at a reasonable price, farmers would have abandoned their profession in many areas in Europe a long time ago. However, agriculture serves many other functions, for example the maintenance of strategic reserves to produce enough food in times of crisis, conservation of the rural landscape for tourism, provision of a source of income for a population that wants to maintain a rural way of life, the prevention of environmental degradation, the maintenance of

an adequate water supply, and so on. Some of these functions conflict with the enduring pressures to maximize productivity.

In particular, productivity demands conflicted with the image of agriculture in some European countries, where many urban dwellers still have relatives in the countryside. Rural areas are easily accessible from the big cities; they literally start in the suburbs and often serve recreational purposes. There is far less of a spatial segregation between pristine natural areas like national parks, etc. – if such things exist at all – and agricultural production sites. Although areas with large farms do exist, in mountainous countries such as Austria, typically, agricultural production tends to be rather small-scale. This makes it difficult to develop economies of scale.

Besides, farmers' interests have traditionally been given a prominence far beyond what could be justified by their share in the Gross Domestic Product or in the population. Especially conservative political parties have their roots in the countryside and their policies tend to be geared towards the preservation of a rural lifestyle and small-scale agricultural economies. Farmers welcome any opportunity to secure their income, and in times of over-production there are only two ways to do so: by lowering the costs of production, or by developing products for new niche markets. The first choice would involve increasing productivity; yet, this is often impossible, especially where the natural environment is less suitable for intensive agriculture. The alternative strategy, *i.e.,* seeking new market niches, can be challenging, too.

Nevertheless, some European farmers managed to do just that, and they have found a new niche in organic produce. However, in order to achieve a higher price, it is necessary to convince consumers that the organically grown foods are of a superior quality. This is not easy, given the fierce competition from industrialized agriculture, and it is only feasible if the product has a property that exceeds the intrinsic, material quality of the product. The fact that in many European countries the sale of organic produce has risen steadily demonstrates the esteem of the images that are attached to such products: they are perceived to be more 'natural' and free of adulteration, to be produced in an environmentally-friendly way, and to support a sustainable way of conducting agriculture that does not push small farmers out of the market.

Whether such perceptions can be substantiated or not is not the question here, and there are indeed reasons for doubts, for example regarding the 'family farm' nature of enterprises devoted to organic production. Yet, they do shed light on the multiple functions of agriculture in the perception of consumers, and in particular, of the urban population. Although some romanticism surely exists, one may question the sensibility of producing large amounts of food in an industrial setting, as such production methods might compromise the product's taste, notwithstanding the fact that these products would probably be as healthy as other, similar products produced in small-scale enterprises. In some countries, especially in France and Italy, there is also strong national pride attached to the

respective cuisines and, consequently, to the national produce. Hence, the fear of adulteration must also be seen as a source of additional national diversity within the European Union.

For biotechnology, there is a problem with respect to the marketing of its products. Genetic modification is perceived to be 'unnatural,' and this stands in striking contrast to consumer demands that food be unadulterated. This is a social fact, as has repeatedly been shown in surveys, and it is unlikely that it will change in the near future. Furthermore, biotechnology tends to serve as a quid pro quo for the increasing pressure towards the industrialization of food production. In this way, it is a sounding board for concerns that go far beyond mere risks that can be assessed by scientific means; it is a proxy for what many consumers do *not* want to have.

The European Commission subscribes to the view that agriculture fulfils multiple functions. Yet, at the same time, it states its intention to foster biotechnology as a means to solve urgent problems; in other words, it is keen to 'make biotechnology happen.' The commission sees as the benefits of the technology increased productivity – which would reduce the demand for subsidies – and its contribution to a 'better' environment. Compared to possible benefits, risks – for example through unintended gene transfer – are considered to be remote, or are assumed to be manageable by putting in place proper risk assessment procedures.

However, the concept of 'risk' has acquired several meanings. Apart from risks to human health and/or to the 'natural environment' (which in itself is a contested concept), risks to the many intended practices of agriculture are also subject to debate. What risks should an assessment deal with? The determination of what a risk is, and above which threshold a phenomenon has to be considered a risk, have paralyzed European debates and regulation for years. Scientists held that only risk as measured by scientific means should be assessed, but despite such consensus, scientists from different member states assessed the same products in diverse ways, due to a lack of agreement on basic assumptions (Levidow *et al.* 1996). This resulted in different policies, which were hard to reconcile on the supranational level; ultimately this lead to a regulatory gridlock. The answer was to call for a 'sounder' scientific approach to risk assessment, which biotechnology opponents interpreted as a call for a less rigorous procedure. However, the frequent reference to 'sound science' did not improve the situation, as scientists appeared incapable of bridging discrepancies rooted in different value perceptions.

In fact, it is hard to reconcile the U.S. approach of 'sound science only' with the European approach of 'sound science plus.' It appears as if it is the 'plus' that causes the troubles, rather than the science or its soundness.

In light of the severe gap between the E.U. and the U.S. (Van Beuzekom 2001), new tools were needed that would finally make biotechnology happen (European Commission 2000). This time, the European Commission took a different approach, compared to the more closed-shop strategy applied ten years before to devise the old *Directive 90/220/EEC*. (European Union 1990) This 'new style' included stakeholders and the general public under the umbrella of "governance" (European Commission 2001a). To integrate actors that would be subject to a planned regulation had always been a strategy applied by the European Commission (Behrens 2002), but it was extended now. Internet-based and open hearings added to the decision-making process (European Commission 2002).

A major tool for meeting critics' demands was to explicitly base the upcoming regulation on the 'precautionary principle' (PP). Although especially U.S. trading partners were strongly against the term, the Commission chose to adopt the PP as a general policy principle. In a communication labelled 'informal', they elaborated on their understanding of the contested concept (European Commission 2001b). Officials were not always outspoken about what exactly was meant by it; yet, at least it was acknowledged that, in the case of uncertainty over severe risks, they would not wait until there was scientific evidence, but would take appropriate measures despite the lack of full proof (Torgersen 2001). However, the contemplated *Directive 2001/18/EC* on deliberate releases and the marketing of GM products (European Union 2001) contained so many measures seen to be precautionary in themselves that the need to apply the PP appeared very unlikely. Ironically, by implementing elements of precaution, the Principle itself was rendered obsolete, and the most precautionary aspect about including the PP seemed to prevent the use of it!

Other important novelties were mandatory monitoring and the granting of approvals for only a limited time-span. These measures emerged as attempts to remedy the problem of the lack of data for risk assessment, in cases where possible events (such as unintended gene transfer) could only be expected to occur at very low rates. Another reason for the introduction of these procedures was to assess the appropriateness of containment or resistance management measures. Critics held that mandatory monitoring would increase the costs of growing GM crops and impose an additional burden without a scientific rationale, which, in turn, would diminish the gain in productivity. Resistance management, however, is considered sensible also in the U.S.

Furthermore, the European Commission required that GM products be labelled, which was a departure from the principle that there must not be any criteria other than risk. Labelling was introduced in order to secure freedom of choice for consumers; the label does not pretend to say anything about risk

per se. Of course, in a world where, together with the prevention of litigation, this is the only purpose of a label, such labelling is nonsense. If, however, value judgements are considered legitimate, irrespective of the question whether or not this met scientific approval, labelling makes sense. An immediate consequence is segregation, and, in order to be credible, this requires means to trace back 'improper' ingredients. This again opens up the possibility to sue polluters for contamination, so liability is extended from 'scientific' issues (such as risks to human health) to quality criteria (such as purity).

In order not to jeopardize the Common (although now segmented) European Market, the solution to the problem of distinguishing risks and value choices entailed a whole range of new regulations, which in part have yet to be worked out. One of the problems of all these bits and pieces, for example the regulations on food and feed, is that they depart from the horizontal approach that had been the hallmark of both the old and the new *Directive*. In fact, they introduced elements of the product-oriented regulation the U.S. had always demanded. On the one hand, the distinction between GM and non-GM is the *raison d'être* of the Community regulation and the foundation of the whole exercise of labelling and traceability. On the other hand, specifying the demands according to different product categories allowed a more flexible handling of product marketing applications.

As a means to centralize responsibility for risk assessments, a new E.U. Food Agency was created. Being an outcome of the BSE crisis and various other unpleasant experiences with divergent risk assessments, it was founded with a view to provide the ultimate scientific authority for decision-making on food safety. Again, it is an indicator for the growing importance of product-related institutions. It also indicates a diminished importance of environmental issues that had long been dominating the agenda. It not only implies that other Directorates General have more to say, but also that other councils of ministers will deal with issues of biotechnology. Hence, one may speculate that the new *Directive*, with all its complicated provisions, is far less important for the future of agricultural biotechnology than the extended debate would suggest.

5 Conclusions: The Future of Agricultural Biotechnology in Europe

Time will tell whether – and, if so, how – the new regulations will work together. The *Directive 2001/18* (European Union 2001) alone is so complicated that it will take a while before civil servants become accustomed to its use. It could well be that the different pieces are like gears with non-fitting teeth, or worse, with no teeth at all. In the worst case, the different bits and pieces will hinder each other, with the result that none of them are really able to fulfil expectations. In the early 1990s, there has been a more or less comparable situation in the U.S., where it took several years to sort out the competencies of different regulatory

bodies. This is a problem for product-based regulations, where it is not entirely clear exactly which aspect is at issue. Patience with the new regulation is required, and it is unlikely that we will experience a 'Big Bang' after years of silence.

If the WTO had not been involved, several (European) domestic issues would have decided the future of agricultural biotechnology in Europe. The most important one is how a competitive technology will fare in a precautionary market. Where will consumer preferences move to? Will second-generation crops bring a predicted turn around, *i.e.,* will they convince consumers of the benefits of biotechnology? Will there be a spill-over from medical biotechnology in terms of a better image, or, instead, will agricultural biotechnology stain the image of medical biotechnology as soon as there are personal disadvantages to take into consideration? What should a product look like, and which properties should it have, in order to be acceptable for consumers and, hence, to garner a significant market share? So far, research on desirable attributes for consumers has been neglected, in favour of studies on the lack of desirable ones, *i.e.,* risks. It is about time to give up the narrow focus on what people would not be allowed to reject on the grounds of a lack of risk, and to start examining what they would deem acceptable.

A second question is how the positions of different member states will evolve. For example, for the time being, there is little indication that France will increase its current lukewarm support for agricultural biotechnology and return to its pre-1997 policy. The present line of thought in Scandinavia, one of the areas most sceptical in matters of biotechnology, is changing, however. For example, the right-wing government in Denmark has tried to overcome the local tradition of environmental concerns. Germany has a Green Party minister, but it has hardly any interest in a pronounced policy on this matter. Austria has a right-wing government, but prefers to keep waiting. Britain argues that it must wait for the results of the farm-scale trials, although the government has repeatedly declared its support for agricultural biotechnology. National strategy-building will probably resume as soon as the set of regulatory gears has been put into motion again, and it will surely continue to promote national interests and values.

A third question is how new E.U. member countries will position themselves. Some of them are major agricultural producers with a relaxed attitude to agricultural biotechnology. U.S. companies have a strong position in these countries, as they do not run into the kind of troubles they frequently encounter in the Western part of Europe. Environmental NGOs, if they exist at all, have more pressing concerns to worry about than GM crop technology, as there is severe industrial pollution from the era of socialist rule to be cleaned up. In fact, Bulgaria, and, to a lesser degree, Romania have been testing-fields for U.S. companies for years, and they harbour significant acreages of transgenic crops. These countries are next in line for membership, and they are slowly adopting European regulations. It will be interesting to see whether the new members will be willing and able to shift the majorities on questions of agricultural biotechnology. For some of

them, this is doubtful. Poland, for example, has recently taken over as the main E.U. supplier for rape-seed oil, after Canada switched over to transgenic crops, so it has significantly profited from the E.U. ban (Lheureux *et al.* 2003).

The main question will be how Europe, and in particular the European public, will take up the WTO challenge. Even before the U.S. had filed a formal complaint, the climate had already started to worsen. U.S. Congressmen have long demanded that the moratorium be fought and that the E.U. be taken to the WTO, in order "to send a clear and convincing message to the world that prohibitive policies on biotechnology, which are not based on sound science, are illegal" (Dennis Hastert, Republican representative from Illinois, quoted in Pegg 2003). Yet, the European side seems to gear up as well. In a newspaper comment on the WTO Doha Round negotiations, Commissioner Fischler (2003) alleged that the U.S. denied other countries any legitimacy to pursue "questions of the environment, of food safety, of the security of food supply and of protecting rural life," together with agricultural policies. Many countries in the world are similarly afraid – but not willing – to become victim to the "crusade in the name of free agricultural trade, in order to fully implement their [*i.e.,* the export-oriented countries'] undeniable comparative advantages."

We have heard such tunes before, at previous rounds of trade wars in different fields, from steel to hormone beef. Agricultural issues have always been a favourite arena for such battles, and biotechnology seems to have finally become part of them. In other words, it has arrived in the trans-Atlantic normality, even if this means that it is accepted as an issue in international trade wars. The phase where it played a role of its own has come to an end. In the future, we will be talking agribusiness, and no longer biotechnology.

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4 Angles of Vision: Stakeholders & Human Embryonic Stem Cell Policy Development

Robin Downey, Rose Geransar, & Edna Einsiedel

1 INTRODUCTION

ONE OF THE REVOLUTIONARY ADVANCES in the 1990s has been the successful derivation and culturing of human embryonic stem cell (hESC) lines, which have the capacity for self-renewal and which give rise to other cells and tissues of the body (Thomson *et al.* 1998). While heralding potential advances in the treatment of various diseases, hESC research has also generated considerable controversy, which has affected the trajectory of policy development in many countries, including Canada. A variety of stakeholder groups have attempted to shape policy developments, galvanized by the social and ethical issues associated with stem cell transplantation, and by the implications of hESC research on views of life and death.

Stakeholders contributing to the development of policy around hESC research have included patients and patient-based organizations, scientists and physicians, entrepreneurs, the general public, ethicists, pro-life groups, religious communities, and politicians. While the scientific community, patient groups, and many academic commentators were focused on the benefits of the technology and supported Canadian research and development in regenerative medicine, opposition voices were found primarily among pro-life supporters. The controversy surrounding hESC research has largely been played out in policy meetings and debates, with little broad public input.

An examination of the development of stem cell policy in Canada gives us a good opportunity to examine the attempts by stakeholder groups to shape legislation. Previous research on AIDS activists has demonstrated how patient-based organizations can contribute to more collaborative forms of innovation

in the field of biomedicine (Epstein 2000). The impact of such stakeholder groups – as patient organizations illustrate on a broader level – may be considered "democratization struggles in the biomedical sciences and health care" (Epstein 2000, 24).

Stakeholders from various points on the opinion spectrum have used a variety of means to influence policy and, indirectly, scientific developments. These groups have influenced policy through letters to MPs, presentations in the Standing Committee on Health, press releases, protest letters to groups with opposing views, and by encouraging their members to meet with MPs at key times during policy development. The Stem Cell Network, for example, is a venture that brings together more than fifty scientists, clinicians, and ethicists to investigate the therapeutic potential of stem cells (Networks of Centres of Excellence 2004; Stem Cell Network 2004). The organization also collaborated with patient advocacy groups in the early stages of the issue formation (Stem Cell Network 2004). Cooperation among these stakeholders was prominent. Approaching the issue from the opposite perspective, the pro-life movement has used rhetoric associated with both cloning and abortion controversies, to prompt cautionary media coverage and in directed campaigns to supporters of stem cell research. Some patient-based organizations responded to these campaigns by supporting policy developments, such as the guidelines from the Canadian Institute of Health Research (CIHR) and Bill C-13, the proposed legislation on new reproductive technologies. At the same time, without proper legislation, these groups were more likely to limit any funding to adult stem cell research projects, explicitly excluding hESC research. Although some patient groups seemed to be somewhat silenced by the aggressive tactics of the pro-life movement, others took active and innovative approaches to influencing policy.

The nature and extent of controversy reflects important scientific distinctions. Stem cell research is only controversial if human embryos or foetuses are the subjects of research, whereas adult stem cell research is much more widely accepted and was supported by pro-life groups in Canadian policy discussions before legislation was passed. While most patient-based organizations tended to support the moderate position that only embryos originally intended for reproductive reasons should be used for research, some groups support the use of therapeutic cloning. There are already industry discussions about the benefits of embryonic research (Campbell *et al.* 2004; British-North American Committee 2004). Canadian scientists have expressed the need for openness towards human embryonic research, recently worrying that a potential Conservative victory in the 2004 federal election might bring hESC research in Canada to a halt (Munro 2004). While there is no doubt that pro-life groups had some success in influencing the moderate approach to regulating hESC research that has been adopted by the Canadian government, the strong network of stakeholders that support continued research is likely to have an influence on future developments.

2 THE SCIENTIFIC CONTEXT

2.1 *What are Stem Cells?*

Some technical background is necessary, because moral and policy positions often reflect a range of scientific developments and distinctions. The potential for curing diseases is a driver for scientific inquiry into stem cells, despite controversy regarding the use of human embryos in research. The uniqueness of stem cells arises from the fact that they have both the ability to divide rapidly into cells of their own types and the flexibility to differentiate into a variety of functional cell types and tissues, given the appropriate chemical stimulus. This 'plasticity' confers the potential to treat large numbers of patients with a variety of diseases and disorders. For example, it is thought that hESCs may have potential applications in treating Parkinson's and other brain disorders, ALS (amyotrophic lateral sclerosis), multiple sclerosis, muscular diseases (such as muscular dystrophy), heart disease, spinal cord injury, blood diseases (such as leukemia), diabetes, stroke, and infertility (*New Scientist* 2003a, 2003b). Furthermore, stem cell research also offers an alternative way of exploring embryonic development, making this a particularly exciting area of basic research (National Institute of Health 2004).

However, there are a number of scientific problems currently associated with the use of stem cell transplantation as a therapeutic approach. One of the biggest issues is the lack of homogeneity of tissue cultures. In order to be used in clinical trials, all cells in a tissue culture must be of the same type or lineage. Currently, tissue culture conditions are being improved in order to stimulate all the stem cells in a particular culture to differentiate into the same cell type (*e.g.,* brain or bone cells). Otherwise, transplantation of cells from a non-homogeneous cell culture may result in the development of cancer (Campbell *et al.* 2004). Another problem is that millions of cells are required for transplantation, and large-scale growth of stem cells is difficult to achieve. Prolonged culture periods can slow cell growth and increase the chances of cells acquiring genetic abnormalities (Pilcher 2004). Currently, large-scale growth of stem cells using bioreactors is being explored (Sen *et al.* 2004).

2.2 *Sources of Stem Cells*

Three potential sources may be used to harvest stem cells for research: adult tissues, foetal tissues, and embryos. Adult stem cells are found in small numbers in most organs, including the liver, blood, bone marrow, and the brain. These are known to have the potential to differentiate into a limited number of tissue types. Although the use of adult stem cells is non-controversial, scientific evidence with regard to their efficacy *is* controversial (Ruder 2004). Foetal stem cells have greater plasticity than adult stem cells and may give rise to many different types of tissues, a quality referred to as 'pluripotency.' However, the main source of foetal tissues is aborted foetuses, making this a seldom-used and controversial source of stem cells. Umbilical cord blood also provides an

excellent non-controversial source of tissue-matched pluripotent cells, and its potential is currently being harnessed in umbilical cord blood banks (Cord Blood Registry 2004).

Embryos are considered to be the most versatile source of stem cells for research, because the embryonic stem cells (ESCs) derived from them are totipotent, *i.e.,* they have the ability to differentiate into any tissue type found in that organism (Daar and Sheremeta 2002; National Institute of Health 2004). ESCs are derived from embryos that are between five and seven days old, from the polarized 'inner cell mass.' This derivation process necessarily destroys the embryo, making hESCs one of the most controversial sources of stem cells for research.

There are three potential sources of embryos for human embryonic research, including stem cell research: excess embryos left over from fertility treatments, which were created through in-vitro fertilization (IVF), cloned embryos generated from so-called somatic cell nuclear transfer (SCNT), and embryos generated through a process called parthenogenesis.

In IVF, the sperm and egg from consenting donors are used to create an embryo; in Canada, this can only be legally done for the purpose of facilitating conception. However, an excess number of embryos are usually created, and leftover embryos may be discarded, frozen and kept for future use, or donated for research purposes upon the provision of free and informed written consent by the gamete and embryo providers. Use of IVF embryos for hESC research is plagued with ethical issues with regard to the permissibility of destroying embryos, donor privacy and confidentiality, as well as worries regarding commercialization and commodification of the human embryo (Ad Hoc Working Group on Stem Cell Research 2000).

In somatic cell nuclear transfer (SCNT or therapeutic cloning), the somatic cells of an individual are used to extract the nucleus containing that individual's full genetic code. This nucleus is transferred to an enucleated egg (provided by a human donor), generating a zygote that is genetically identical to the parent somatic cell. This embryo may potentially be used as a source of stem cells. From a clinical perspective, this may be desirable, since it provides the possibility of tissue-matched treatments (U.S. Department of Health and Human Services 2001). There are scientific risks associated with this process, including the possibility of developmental defects (Daar and Sheremeta 2002), ethical issues, such as the acceptability of cloning for therapeutic purposes (Ad Hoc Working Group on Stem Cell Research 2000), economic and logistical issues, such as the allocation of health-care resources for such technologies, and socio-legal issues relating to equal access to treatment (Faden *et al.* 2003).

Parthenogenic embryos may be created by chemically inducing an unfertilized egg to replicate. In some lower animals, this process may lead to the development of a complete organism; however, in humans, parthenogenic

embryos do not have the potential to develop to term. Because of this, the use of parthenogenic human embryos in research may prima facie avoid the ethical problems associated with use of viable human embryos. However, there remains much controversy surrounding the use of viability as the criterion for moral consideration (Jones 2003).

2.3 *Historical Background*

Canadian science has long played an important role in stem cell research, although policy developments have proceeded more slowly than in other countries. Scientists in Toronto and Montreal discovered stem cells in the 1950s, and these pioneers trained generations of Canadian scientists in stem cell research (Networks of Centres of Excellence 2004). This leadership has created a collaborative and cohesive research community in Canada (Networks of Centres of Excellence 2004). Though ESCs were first derived from mice twenty years ago, scientists have struggled with the challenge of maintaining these cells in tissue culture. In 1998, two independent research groups in the U.S. simultaneously reported that they had successfully isolated and maintained stem cells in tissue culture (Shamblott *et al.* 1998; Thomson *et al.* 1998). This was a pivotal discovery in the field of regenerative medicine, and undoubtedly one that created the need for a regulatory framework.

For the purpose of discussing the influence of Canadian stakeholder groups on policy development, it is useful to identify three main areas of stem cell research, which correspond to specific stakeholder positions. These are: adult stem cell research, research on leftover IVF embryos, and research on cloned embryos. Although the vast majority of Canadian researchers currently work with adult stem cells, the headlines have been dominated by the ethical controversies concerning the source and use of human embryonic stem cells for research (Networks of Centres of Excellence 2004).

3 THE EVOLUTION OF CANADIAN STEM CELL POLICY

3.1 *Chronology*

Canadian stem cell policy was stitched together from legislation originally intended to regulate human reproductive technologies. Proposals to regulate reproductive technologies were adapted to accommodate the specific issues raised by hESC research, as scientific progress made such concerns relevant.

This evolution (summarized in table 4.1) began in 1989 with the establishment of the Royal Commission on New Reproductive Technologies. In 1993, in a report entitled *Proceed with Care*, the Royal Commission recommended immediate regulation of assisted human reproduction. The Commission made 293 specific recommendations regarding reproductive technologies, the majority of which required action on the part of the federal government (Hébert *et al.* 2002). The same year, the Working Group on Reproduction and Genetic Technologies

(RGT) was established with the support of Health Canada to advise the Deputy Ministers of Health. Their recommendations resulted in the announcement of a voluntary moratorium on some applications by the Health Minister in 1995. This prohibited, among other things, sex selection for non-medical purposes, buying and selling of human gametes and embryos, human genetic engineering, cloning of human beings, ectogenesis (development of the embryo outside the womb), and the creation of human-animal hybrids (Ad Hoc Working Group on Stem Cell Research 2000).

In 1996, the Minister of Health established The Advisory Committee on Reproductive and Genetic Technologies (RGTs) to advise Health Canada on moratorium compliance. Bill C-47, *The Human Reproduction and Genetic Technologies Act*, was also proposed that year by the Minister of Health, prohibiting specified RGTs. Health Canada also released a discussion paper proposing a regulatory framework for RGTs (Health Canada 1996). Based on the recommendations of the Royal Commission, Health Canada extended the list of prohibited activities in Bill C-47 to include research on human embryos after fourteen days of development. Other activities added to the list of prohibitions included the use of human gametes or embryos for any purpose without informed consent of the donors, creation of human embryos for research purposes only, and offering to provide or pay for prohibited activities. However, Bill C-47 died on the Parliament of Canada *Order Paper* at the 1997 call for an election (Ad Hoc Working Group on Stem Cell Research 2000).

In 1998, the Medical Research Council (MRC), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC) – Canada's three research-granting councils – put forth the *Tri-Council Policy* (TCP) *Statement: Ethical Conduct for Research Involving Humans*. These guidelines covered ethical conduct for research on embryos in general, but made no specific reference to hESC research. This was the same year that hESCs were first isolated and cultured and in which the necessity for legislation governing human embryonic stem cell research first became evident. The TCP guidelines established a series of requirements for research involving human beings, including the need for ethical approval by a research ethics board (Graham 2004).

By 1999, Health Canada had prepared an overview paper on RGTs. In the fall of 2000, the CIHR established the ad hoc Working Group on Stem Cell Research to write a discussion paper setting forth recommendations on how current policy could be applied to stem cell research. These included the proposal that the CIHR should fund research on existing hESC and other pluripotent human cell lines as well as research involving the derivation of hESC from leftover IVF embryos. The Working Group also recommended that the CIHR place a moratorium on SCNT, the utilization of stem cells to create human embryos, and combination of human stem cells with animal embryos or vice versa (Canadian Institute of

Health Research 2002). By 2000, Health Canada released a discussion paper outlining options for legislation, defining two categories of activities in assisted human reproduction: "regulated" and "prohibited."

On 3 May 2001, the Minister of Health invited the House of Commons Standing Committee on Health to conduct a full review of the Government of Canada's *Proposals for Legislation Governing Assisted Human Reproduction*. In December 2001, the Health Committee presented its report and one of its multiple recommendations was that legislation be introduced on a priority basis. The next milestone in legislation, Bill C-56, the proposed *Assisted Human Reproduction Act*, incorporated many but not all of the Committee's recommendations. One significant change recommended by the Committee – and reflected in the proposed Act – is the establishment of the Assisted Human Reproduction Agency of Canada, a regulatory body for the licensing, monitoring and enforcing of the Act. The Act proposed to prohibit a range of activities deemed by many Canadians to "run contrary to human dignity or societal values" (Hébert *et al.* 2002), while regulating other activities. It also introduced Clause 40(2), which indicated that in order for the Agency to grant a license for research on embryos, applicants must have demonstrated that no other category of biological materials would suffice for the purpose of the proposed research (Bill C-6, 2004).

In March 2002, in the absence of legislation, and with the scientific community growing more impatient, the CIHR issued its official guidelines for federal funding of hESC research. This was intended to fill the policy gap until legislation was enacted. These guidelines prohibited the use of federal dollars to conduct any type of human cloning, but allowed the use of leftover IVF embryos for hESC research to a 14-day limit, based on a number of conditions: (1) the leftover IVF embryos must have been created for the purpose of fertility treatments, and not for the purpose of stem cell research; (2) free and informed consent must have been provided on behalf of the gamete and embryo providers; (3) no commercial transaction must have been involved in obtaining the embryo; (4) there must have been a demonstrated health benefit to Canadians from the research (Canadian Institute of Health Research 2002). Although these guidelines did not apply to privately funded research, many patient-based organizations chose to abide by them voluntarily (Canadian Cancer Society 2002; Parkinson Society Canada 2002). Pro-Life groups, however, withheld their support. According to Campaign Life Coalition (CLC), CIHR appeared to be "pushing the envelope in order to get its own way rather than waiting for the government to introduce legislation to be debated and voted upon" (Campaign Life Coalition 2002a).

In September of 2002, Bill C-56 died on the *Order Paper* in Parliament, but was reinstated in October as Bill C-13. One of the changes to Bill C-13 was the addition of Clause 40(3.2), which precluded the Human Reproductive Agency of Canada from issuing a license for research on embryos unless free and informed consent had been provided by the embryo donors, in accordance with the CIHR

Table 4.1
Canadian Policy Events Related to Human Embryonic Stem Cells*

Date	*Policy Event*
1989	The royal Commision on New Reproductive Technologies was established.
1993-96	A Federal/Provincial/Territorial Working Group on Reproductive and Genetic Technologies (RGT) was established with Health Canada support, to advise the Deputy Ministers of Health.
1993	The Royal Commission produced a report entitled *Proceed with Care*, making 293 recommendations.
1995	A voluntary moratorium on specific RGTs was announced by the Minister of Health.
1996	The Advisory Committee on Reproductive and Genetic Technologies was established by the Minister of Health.
	Bill C-47, the proposed *Human Reproduction and Genetic Technologies Act*, was introduced by the Minister of Health to prohibit specified reproductive and genetic practices.
	• Prima facie prohibited: the maintenance of human embryos outside the human body (with no acceptable time limit specified), cloning or transplanting cloned human embryos in humans, creation of embryos for purpose of research, creation of hybrids or chimeras, genetic engineering, and sex selection.
	A discussion paper entitled *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* was released by Health Canada.
1997	Bill C-47 died on Parliament of Canada *Order Paper* at the call of the 1997 federal election.
1998	The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* was produced jointly by the MRC, NSERC, and SSHRC.
1999	Health Canada prepared an overview paper on reproductive and genetic technologies to further the discussion on the proposed regulatory framework.

guidelines. This restriction applies only to hESC research, unlike Clause 40(2), which applies to all embryonic research. However, Bill C-13 also died on the Parliament of Canada *Order Paper* in 2003 (Hébert *et al.* 2004).

Finally, in February 2004, Bill C-13 was reinstated as Bill C-6, *An Act Respecting Assisted Human Reproduction and Related Research*. Thirty amendments by the Committee made it to the Bill, and seventeen additional amendments were

Date	*Policy Event*
2000	Health Canada released a discussion paper that outlined options for potential legislation, including both prohibited and regulated activities.
2001	The Government of Canada's *Proposals for Legislation Governing Assisted Human Reproduction* was presented for study to the House of Commons Standing Committee on Health and produced a report in December.
2002	The Canadian Institute of Health Research (CIHR) issued guidelines governing CIHR-funded embryonic stem cell research. Bill C-56, *An Act Respecting Assisted Human Reproduction,* was introduced. • Prohibited the activities listed under Bill C-47, but defined the terms "chimera," "hybrid," "therapeutic cloning," and "reproductive cloning"; refined clauses. • Proposed the establishment of an Agency to license, monitor and enforce the Act, which would only license research on in vitro embryos if their use was proven necessary for the purpose of the proposed research. • Introduced a 14-day limit for developing an embryo in vitro. Bill C-56 died on Parliament of Canada Order Paper. Bill C-13 (the reinstated version of Bill C-56) was introduced, first reading. • Precluded the Agency from issuing a license for embryonic stem cell research without the written consent of the original gamete providers and the embryo provider, in accordance with the CIHR guidelines. Bill C-13 was rewritten.
2003	Bill C-13 died on Parliament of Canada *Order Paper.*
2004	Bill C-6 (the reinstated version of Bill C-13) was introduced, and was passed by the House of Commons, Senate. No major changes were made to the Bill and it received Royal Assent in March.

⁂ *Source:* Health Canada (1996); Ad Hoc Working Group on Stem Cell Research (2000); Canadian Institute of Health Research (2002); Hébert *et al.* (2002; 2003; 2004).

made by the House of Commons at Report Stage (Bill C-6 2004). The bill was passed by the House of Commons and Senate by 3 March, and received Royal Assent on 29 March 2004. No major changes were made to the legislation, and as a result, hESC research is regulated as proposed in Bill C-13 (Hébert *et al.* 2004). Some of the major regulated and prohibited activities covered by the legislation are summarized in table 4.2.

Table 4.2
Summary of Primary Prohibited and Regulated Activities in Bill C-6*

Prohibited Activities

- Creating a clone through any technique, or transplanting a human clone into another human being.
- Creating IVF embryos for any purpose other than IVF treatment.
- Making animal-to-human or human-to-human chimeras.
- Creating any type of hybrid.
- Maintaining an embryo past the 14-day development stage.
- Sex selection (except to avoid sex-linked disorders).
- Human genetic engineering.
- Transplanting a non-human gamete or foetus into a human being.
- Advertising the doing of any of the above listed activities.

Regulated Activities

- Research on leftover IVF embryos, including HESC research.
- Manipulation of human gametes for the purpose of creating an embryo.
- Production of human-to-animal chimeras (to create transgenic animals as model systems for study of human diseases).

* *Source:* Bill C-6 2004.

3.2 *Criticisms of the Assisted Human Reproduction Act*

For many years, the lack of social consensus and the governing Liberal Party's commitment to consensual decision-making had immobilized the policy-making process (Montpetit 2002). Many would agree that legislation governing assisted human reproduction – over ten years in the making – was long overdue in Canada. However, pro-life groups such as Campaign Life Coalition, and Life Canada insisted that the passage of Bill C-6 was a hasty decision prompted by the federal election call (Campaign Life Coalition 2004).

Although the development of legislation in this respect has been a process that has involved a great deal of deliberation, consultation, and debate, various aspects of the legislation as it developed were subject to much criticism. Inadequate justification for statutory bans on therapeutic cloning was one major area of concern. It had been argued that therapeutic cloning should be a regulated activity (rather than being prohibited outright) because it was not clear how the use of this technology violates core values and/or human dignity (Caulfield 2002). There had also been general concern regarding the wording of the Bill, and its provision of definitions. At one extreme, Campaign Life Coalition had even criticized legislators for not defining the term "human being" in the context of this Bill (Campaign Life Coalition 2004).

Another major criticism has been that it is not clear how the proposed framework would meet challenges associated with the diversity of public opinion, particularly if public opinion were to shift in response to scientific and clinical developments (Ad Hoc Working Group on Stem Cell Research 2000). While the enactment of legislation cannot absolutely depend on the establishment of social consensus, there is concern that statutory prohibitions of certain activities may have been excessive, given the wide divergence of public opinion (Caulfield 2002). From an economic perspective, advances are rapidly being made in the field; thus, an inflexible policy may also have a stifling effect on innovative capacity (Knowles 2004).

The Standing Committee on Health maintains that there is consensus regarding the view that prohibitions on activities like SCNT are required. Several different types of stakeholders were invited to the Standing Committee on Health to give presentations, which contributed to the amendments that were eventually made to the bill (White 2003).

4 THE CANADIAN PRO-LIFE MOVEMENT STIRS CONTROVERSY

Groups opposing hESC research present a complex profile. The U.S. National Bioethics Advisory Committee found that there is little consensus within and among religious communities with respect to the moral permissibility of this research (*cf.* Shanner 2001). However, there is generally a preference for avoiding embryonic research if possible (Shanner 2001). The Presbyterian Church U.S.A. and the Reform Jewish movement, for example, have expressed support for limited hESC research (Lampman 2001). However, many Pro-Life groups, religious and non-religious, have taken a united stand against any form of embryonic research. In Canada, these groups include Campaign Life Coalition, Campaign Life Catholic, Life Canada, and the Catholic Civil Rights League. Moreover, some research shows that Christian conservatives in Canada have become increasingly political on abortion and other related issues (Hoover and den Dulk 2004). Guidelines released by the Canadian Institute of Health Research in 2001 were quite controversial: then Canadian Alliance leadership candidate Stockwell Day expressed disapproval of them as they were announced: "After years of a voluntary moratorium, the CIHR has chosen to allow controversial research which destroys human embryos to proceed." The pro-life movement would later use this type of moral argument to construct its case against hESC research.

Conservative religious groups were especially vocal during the hearings of the Standing Committee of Health. They were also actively involved in letter-writing and awareness campaigns (Campaign Life Coalition 2002b; Life Site 2003). Campaign Life Coalition distributed posters electronically and encouraged letters to be sent to MPs and to other interested groups. The media in Canada and the U.S. reported on these groups and their tactics: "Highly vocal critics

of the new research in the U.S. have likened the use of embryonic stem cells to the use of human skin for lampshades in Nazi Germany" (Foss and Fox 1999). The posters that CLC made available on their website suggested that cloning could occur in Canada and that experimentation on embryos was possible if Bill C-13 were to be passed.

Pro-life groups became active in their opposition over these issues. Campaign Life Coalition was especially worried about the allowance of certain techniques in the legislation: Nuclear transfer using diploid primitive or immature germ line cells; twinning or fission; parthenogenesis; de-methylation experiments in which a new human embryo is formed; use of male and/or female pronuclei to clone; DNA-recombinant germ line gene transfer; mitochondrial cloning (Campaign Life Coalition 2002c). There was a shared fear that this would be a worrisome direction and that this course had to be altered:

> The draft bill therefore – despite the fact, I might add, it is paraded up front that there are prohibited activities – allows, with ministerial permission, embryo splitting, nuclear transfer cloning – and I repeat, nuclear transfer cloning is allowed – recombinant DNA transfer, and germ cell alteration, which is the technique used for eugenic enhancement (Standing Committee on Health 2001a, Dr. John Shea, Consultant, Campaign Life Coalition).

Some politicians did take a strong stance against allowing embryo research, especially as it relates to cloning. Campaign Life Coalition is an organization that was formed to be engaged in political issues of interest to the pro-life movement (CLC informant 1, July 2004). In a recent interview, CLC informant 2 mentioned a number of strategies that his organization used to promote this issue. For example, they provided scientific and policy information on their web site. They also produced a CD-ROM for MPs, and engaged in more direct interaction with politicians (CLC informant 2, July 2004). Comments of a Member of Parliament who had been a vocal opponent of embryo research demonstrate this linkage between positions against the two technologies:

> If Bill C-13 is to achieve anything, it must ban all forms of cloning, all manners and all techniques, and it does not…. In Clause 5(1)(c) the bill states: "No person shall knowingly for the purpose of creating a human being, create an embryo from a cell or part of a cell taken from an embryo or foetus, or transplant an embryo so created into a human being." That is a difficult clause to understand, but the problematic phrase in the clause is "for the purpose of creating a human being." One is prohibited from doing that if the purpose is to create a human being. What happens if the purpose is not to create a human being? What happens if the purpose is

> to just do research? All of a sudden, if someone's purpose as a researcher is simply to create this embryo for research purposes, then the bill does not ban that activity (Hansard 2003; Paul Szabo, Liberal MP).

Amendments were eventually made to the wording of the bill:

- Create a human clone, or transplant a human clone into a human being (First Reading)
- Create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device (Third Reading) (White 2003).

Rhetorical tools from debates on abortion were often used in this debate. They were also used to some extent when stating their opposition to the Standing Committee on Health:

> No human being, including the embryo, should ever be used as a means to an end. No human being, no matter how tiny, can be killed to help another. No human being should ever be considered spare or surplus (Standing Committee on Health 2001b, Dr. Mary Lou Cranston, Director, St. Joseph's College Ethics Centre; Member, Catholic Health Association of Canada).

Many of the pro-life arguments were focused on cloning, abortion, and eugenics, all of which are attached to existing moral controversies. Pro-life groups often likened research on stem cells to Nazi experiments, and associated it with the spectre of human cloning on the horizon. Cloning always raises moral quandaries in the public eye, and is often associated with eugenics (Einsiedel *et al.* 2002) and opposition groups were not averse to linking therapeutic cloning with eugenic experiments . They also focused on the murdering and killing of embryos, much as they did in abortion debates. In general, their opposition reflected a sense of the relevant scientific distinctions and embodied the same moral rhetoric that they brought to bear on other issues. The pro-life movement produced a moral campaign against all forms of hESC research, which was effective, yet in the end unsuccessful.

5 PATIENT GROUPS & POLICY STRATEGIES

Many groups support ongoing stem cell research, citing the potential that it holds for curing diseases. Advocates of hESC research include patient-based organizations such as the Juvenile Diabetes Research Foundation (JDRF), the Canadian Cancer Society, the National Cancer Institute of Canada, the ALS Society of Canada, he Parkinson Society Canada, and the Muscular Dystrophy

Association of Canada (MDA), as well as the patients affiliated with these organizations, and the Disabled Women's Network (Ontario Disabled Women's Network 2003; Downey and Einsiedel 2004). Many of these organizations in Canada have been actively involved in supporting the enactment of Canadian stem cell policy through awareness campaigns, by writing letters to Parliament, and by making presentations to the Standing Committee on Health. Likewise, many physicians, scientists, and entrepreneurs (with some overlap between these groups) view stem cells as having scientific, therapeutic, and economic potential. In particular, Canadian researchers have played an essential role both at the science-policy interface and in creating media awareness of the field (Networks of Centres of Excellence 2004).

Patient groups have played a significant role in lobbying policymakers in this area. Patient-based organizations responded to the controversy by cautiously lobbying for legislation to be passed and for only funding adult stem cell research in the interim. Other groups, such as the Juvenile Diabetes Research Foundation were more active in their campaign, remaining hopeful that therapeutic cloning would one day be an option for further research. The Muscular Dystrophy Association, the Parkinson Society Canada, and the ALS Society of Canada engaged in active partnerships that were focused on sharing information and strategies. The efforts of these groups are worth considering, because of the innovative nature of some of their tactics and the range of their experiences, both positive and negative, while breaking new ground regarding controversial issues. Several of these groups faced quite vocal opposition, which resulted in a variety of responses that ranged from silence to protest.

The high degree of controversy over this issue is perhaps a central reason why patient groups have engaged in a broader range of strategies to try to ensure that legislation that would allow research on embryos would be passed. Patient-based organizations were also quite vocal around the stem cell research. Representatives from five of these groups were interviewed in early September 2003, as Parliament returned to session: (the Canadian Cancer Society/the National Cancer Institute of Canada; the Juvenile Diabetes Research Foundation; the Parkinson Society Canada; the ALS Society of Canada; and the Muscular Dystrophy Association of Canada). In some cases, this was the organization's first foray into issues of controversial research and policy. These groups were not accustomed to being involved in controversial issues. In the words of an officer for the Canadian Cancer Society and the National Cancer Institute of Canada, "our organization wasn't used to taking controversial public positions" (CCS informant, September 2003). The Canadian Cancer society did not become particularly active for just this reason. All of these groups had received some mail that indicated that they could lose funding support from members because of their support for the CIHR guidelines and Bill C-13, with key events leading at times to a "wave of letters and contacts from those opposed." For example, some

letters made statements such as this: "I'm not going to give to you because you have a position: you're supporting the murdering of babies." (CCS informant, September 2003).

According to a Muscular Dystrophy Association representative:

> As soon as we publicly voiced those opinions – as soon as our presentation to the Standing Committee on Health was made public – we began to hear, particularly from those outside our organization, on what seemed to be a fairly organized basis, their strong displeasure and anger about the position we were supporting (MDA informant 1, September 2003).

The controversy seemed to affect the activities of some patient groups, effectively discouraging them from participating in political lobbying. For example, a JDRF representative admitted that:

> [a] lot of charities have been very hesitant to come out on this issue from a patient advocacy perspective because of potential backlash from donors…. So it definitely has had an impact. (JDRF informant, September 2003).

One common response to the controversy, illustrated by the Cancer Society, was to develop a risk strategy:

> What we have changed is how we deal with controversial positions. At the point where we took a position on stem cells, we didn't have a process for risk analysis. After that, we put together this process called RIO or Risk Issues and Opportunities (CCS informant, September 2003).

These examples demonstrate that patient-based organizations were caught in a controversy that, to some degree, prevented some of them from participating in the policy discussion.

However, some patient groups engaged in more active tactics, centred on empowering members to take an active stance: "[We] empower, assist, support, and encourage persons with neuro-muscular disorders, as they are comfortable and as the resources permit, to move towards an active role of advocating on their behalf through our organization" (September 2003). This type of lobbying through empowerment was seen as something new: according to an official for Muscular Dystrophy Canada, "[members were given] clear directions, including a lot of support materials: form letters, suggestions of what they could do, or how they could do it, or when they could do it." This led some patients to become

involved in the stem cell issue and to gain expertise in the area. One effect of active engagement in this controversial area was an increased awareness of the policymaking process:

> We've learned about the political process because it's been one of our first forays out there in terms of policy development. At what time do we pick up the guns and what time do we stroke nicely? At what time is it appropriate to exhibit which behaviour? (MDA informant 2, September 2003).

Reflecting the attitude of other proponents of hESC research, this informant also emphasized that there is a need to engage, not only with other patient-based organizations, but with other interested stakeholders: "We need to empower and engage our stakeholders in the debate…. That includes a lot of information about where we stand, what our position is, what kind of help we need" (MDA informant 2, September 2003). The MDA was also actively encouraging patients to become more politically involved. This resulted in one patient delivering a presentation to the Standing Committee on Health (MDA informant 2, September 2003).

Illustrating this increased attention to the realities of policy-making, the Juvenile Diabetes Research Foundation encouraged children to visit their local MPs, and encourage the support of Bill C-13 in September 2003. The JDRF had a similar event the year before when they took over sixty children to Kids For a Cure Lobby Day to lobby on Parliament Hill, so this was not their first venture into this sort of political lobbying. However, rather than only focusing on clarifying Type One and Type Two diabetes, this effort was also focused on stem cell research policy. The JDRF had timed this event to be synchronized with legislative discussions on Bill C-13, a strategy that was seen as very effective:

> When I came back [to Ottawa], it was a lot easier to talk to some of these MPs. And that day we were actually able to change the minds of a couple of MPs who, prior to that day, did not support embryonic stem cell research (JDRF informant, September 2003).

In terms of the impact that these groups will have on research in the future, their lobbying and communication activities are essential. Web sites have provided another way for groups to stage their messages and to form alliances. The ALS Society of Canada had a form on their web site for keeping track of individual efforts to influence policy. Several groups mentioned active support of research projects with adult stem cells, but one of the representatives was clear that researchers were not likely to go ahead with research on embryos without legislation: "We hear that researchers are chomping at the bit … but researchers are apprehensive, rightfully so, of going ahead with anything … in the void of legislation" (MDA informant 2, September 2003).

The experiences of these patient-based organizations highlight the complexity of lobbying regarding controversial issues. On the one hand, calculations of risks and benefits play an important role. The public is generally more likely to support a technology that will be beneficial for health: "health is the magic word for gaining agreement. Health, or, more precisely, the promise of health, opens doors, elbows aside resistance, [and] brings public support and money" (Beck-Gernsheim 2000, 125). According to surveys and focus groups, the Canadian public would go further than the CIHR guidelines to support therapeutic cloning. For example, the 2002 Ipsos-Reid poll found that 61% of Canadians approve of the creation of cloned human embryos for collecting stem cells). Recent focus group data found strong support for the technique: 23 out of 27 participants supported the use of cloning for research purposes (Reid 2004). On the other hand, however, vocal opposition regarding controversial issues can derail more utilitarian considerations. In the face of the very vocal pro-life movement and the MPs that support them, these patient groups have needed to develop innovative strategies to lobby government, to try to ensure that this somewhat restrictive piece of legislation went through. At the same time, however, as one informant noted, controversy can have potentially beneficial effects on research:

> Given the lay of the land today, when these controversies pop[ped] up,… legislation pulled away, because the votes might not be there. In the absence of this legislation, I think innovation can just hit the roof because it leaves it quite open for researchers to undertake a lot of different types of research. The research community can then have all this freedom. It puts the ball in the researchers' court, in terms of what they want to do (JDRF informant, September 2003).

Now that legislation has achieved somea degree of closure, research opportunities are confined to research on embryos that were created for reproductive reasons. However, it is likely that patient-based organizations and other interested stakeholders will continue to push the boundaries of this research.

6 THE INTERNATIONAL CONTEXT

The role that stakeholder groups play in shaping policy on stem cell research varies between countries. Governing institutional structures can foster both public and stakeholder participation in technology policy. In this sense, there are different national policy cultures for technology development (Klüver *et al.* 2000, 31). Of course, stem cell policy has a direct impact on the innovative capacity of biotechnology industry. Some national policy cultures demonstrate significant stakeholder involvement in stem cell policies, while others, such as those of Korea and Iran, show very little.

There is no consensus with regard to therapeutic cloning within the United Nations. In 2003, a U.S.-led group of more than sixty nations supported a ban on

all forms of human cloning, including therapeutic cloning. A second proposal, introduced by Belgium and backed by more than 20 nations – including France, Germany, and Japan – opted to ban only reproductive cloning and to leave the regulation of therapeutic cloning to individual nations. The lack of consensus led to a decision to delay the vote on the issue of cloning until September 2004 (Tamkins 2003). In the meantime, national policies regarding hESC research and human embryonic research continue to shift.

In the U.S. the issue of stem cell research has become extremely politicized in recent months, due to the pending presidential elections. While the U.S. has no federal legislation to govern hESC research, it has relatively restrictive guidelines regarding federal funding of human embryonic research, put in place in August 2002 by president George Bush. Today, there are 15 hESC lines eligible for U.S. federal funding (NIH Human Embryonic Stem Cell Registry 2004). At the state level, laws vary tremendously. Even in California, a state with relatively flexible stem cell policies, politicians are sharply divided regarding stem cell research, with Republicans recently voting to reject a proposal that would lead to U.S. $3 million in funding for hESC research (Kaiser Network 2004). Presidential Candidate John Kerry proposes to lift the current federal restriction and to increase funding for hESC research (Berkshire Eagle 2004).

Within the European Union (E.U.), hESC research has been a source of tremendous controversy: policies among member countries vary widely, from prohibiting all embryonic research (in Ireland and Austria), to allowing therapeutic cloning for the purpose of generating embryos for hESC research (in Belgium and in the United Kingdom). In some countries, such as Germany, the production of human embryonic stem cells is prohibited, but some research is permitted on imported cell cultures already developed from stem cells in other countries (Stafford 2004). Other countries, such as The Netherlands, Denmark, Sweden, Finland, Spain, Greece, and, recently, France, allow only research on leftover embryos from fertility treatments (Knowles 2004). The U.K. recently granted its first license allowing scientists to clone human embryos as a source of stem cells (*New Scientist* 2004). According to the Chairman of Germany's National Ethics Council, the U.K. decision underscores the different opinions within the E.U. and forces all other members to review their positions (Burgermeister 2004).

Asia is moving rapidly in hESC research, with countries such as Singapore, China, and India leaning strongly towards allowing therapeutic cloning. In South Korea, scientists for the first time derived hESCs from cloned human embryos (Hwang *et al.* 2004), a breakthrough that is reflective of the country's policies on embryo use and creation for research purposes. The rarity of organ donations in South Korea has been claimed to fuel innovations in regenerative medicine (Pearson 2004). Japan has also recently voted to adopt policy recommendations that would allow the creation of embryos for research purposes, either through IVF or SCNT (*Japan Times* 2004). In the Middle East, there is little controversy involving research on leftover embryos from IVF treatment, with this type of

research generally allowed, but therapeutic cloning and other means of generating embryos for research remain highly controversial (Daar and Al Khitamy 2001). Among Islamic countries, Iran was the first to produce, culture, and freeze a hESC line (Royan Institute 2003; *Payvand News* 2003). Israel has established a very strong research community in this field, but research remains limited to the use of IVF embryos, although policies are currently being revisited and may potentially allow for therapeutic cloning (Knowles 2004).

These global policy patterns direct where research is done, and, therefore, they play a role in determining both how funds are allocated and the extent to which local biomedical and biotechnology industries in this field prosper. Currently, the U.K., Israel, and many Asian countries including China, South Korea, Japan, and Singapore, are less restrictive of innovation in hESC research (Pearson 2004; Yang 2004). As developments in this field skyrocket, a great deal of stem cell collaboration is likely to take place within the next decade, an effort in which the CIHR will play an ongoing role (Hagen 2003). This type of scientific networking is reflected in the International Society for Stem Cell Research, which is an independent, non-profit organization that has been established to "promote and foster the exchange and dissemination of information and ideas relating to stem cells" (International Society for Stem Cell Research 2004). Such organizations and programs promote cooperation rather than competition within this field. Even so, the ability of any country to participate and contribute to the pool of knowledge depends on its accumulation of scientific competence in this field, as promoted or prohibited by its policy. It is useful to survey hESC policies within the international context, in which Canada strives to be an innovative and active contributor and competitor. The most recent Canadian legislation has placed Canada in a position to maintain an innovative edge in hESC research, and to continue to shape a field that is at the forefront of medical research agendas worldwide.

7 CONCLUSIONS

The trajectory of Canada's hESC policy demonstrates the challenges that arise with controversial technologies. A committed association of stakeholders – that believes stem cell research has the potential to revolutionize our approach to the treatment of many diseases – has formed around this issue. In addition to the activity that patient groups have engaged in, the scientific community has been very committed to the development of this research. Almost twenty per cent of individual researchers in this field have appeared as expert witnesses during the committee stages of Bill C-13 (the Assisted Human Reproduction Act), and there have been more than two hundred media appearances by researchers over a one-year period (Networks of Centres of Excellence 2004). These proponents of stem cell research development have been successful in their endeavour to push this legislation through. However, it was tempered by very vocal opposition.

In the face of moral protest from the pro-life movement, patient-based organizations and the scientific community were successful in moving the line beyond adult stem cell research as the legal limit. The recent policy developments around stem cell research provided a number of points at which stakeholders could make a case for their positions, and it provided a focus for a wide range of lobbying efforts. The Standing Committee on Health provided a forum where dialogue and debate between the two extreme positions could be focused. However, some organizations from both of these positions also engaged in other more active strategies. Patient advocacy organizations have been pushing for enactment of legislation governing hESC research, despite tremendous pressures on all proponents of the research by pro-life groups. In the process, patient groups have developed political expertise that they may be able to use in their continued push for medical advancements. Their degree of organization and coordination, and their broad range of lobbying tactics – including the effective use of new communication technologies and of strategies for empowering their members – have prepared them for potential engagement with future issues. Stem cell research was an issue that many of these groups could collaborate on, and they may continue to use their collective force in the future.

The range of motivations that shaped the lobbying efforts of various stakeholders underlines the complexity of issues affecting policy decision in this area. Values central to Canadian society suggest that respect for potential life should be balanced against endeavours to improve the quality of life (Royal Commission on New Reproductive Technologies 1993). In this respect, Canadian legislation has been successful; it has taken an intermediate route that promotes innovation by allowing research on IVF embryos, while maintaining democratic accountability by prohibiting the most controversial types of activities using human embryos, such as therapeutic cloning. However, it is worth noting that – like in other countries, and unlike earlier debates on this legislation that focused on reproductive technologies – feminist perspectives are largely missing from the debate on stem cell research (*cf.* Williams *et al.* 2003).

In general, it is important to balance attempts to gain a competitive international edge with respect for core Canadian societal values. Determining just what Canadian values are and how policy satisfies them has proven to be a challenge, and, according to some ethicists, this process will be on-going and will remain a matter of contention. Whether this ongoing challenge will undermine the long-term validity of the legislation will be seen in the years to come. What is clear so far is that the policy-making process has ceased to be immobilized by lack of consensus: Canada now has standards governing hESC research within both public and private sectors. While some critics argue that the legislation is flawed, many observers – both within and outside the policy arena – agree that Bill C-6 is an important step towards clear and effective regulation of hESC research in Canada (Graham 2004).

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Part 3

From Public Perception to Public Participation

Consumer Choice & Decision-Making

5 Involving Communities: A Matter of Trust & Communication[1]

Béatrice Godard

1 INTRODUCTION: THE CARTAGENE PROJECT

THE CARTAGENE PROJECT AIMS to map genetic variation in a large sample of the adult population of Quebec. The CARTaGENE resource will allow large-scale medical, pharmacogenomics and public health studies – including association studies of common diseases or 'protective' phenotypes – and is expected to lead to the discovery of new susceptibility genes. The demographic component of the project will determine mutation frequencies in the different regions of the province, and, thus, guide the establishment of medical genetic services tailored to the needs of the regional sub-populations. In more general terms, the goal of the research is to provide information required for an optimal use of genetic knowledge and technology in the health care system.

The investigators of the CARTaGENE project propose the following:

1 Random selection of 50,000 adults between twenty-five and seventy-four years of age, representing 1% of the population in each of the respective age groups. The recruitment will be unbiased as far as disease and ethnic origin are concerned, and will be representative, not only with regard to the diversity of the population, but also with respect to its density. The population of Quebec is homogeneous in certain aspects, but heterogeneous in others. Approximately 55% of the population lives in southwest Quebec, in the vicinity of Montreal, which is, with its nineteen languages, more heterogeneous than the rest of the Quebec population, which is composed mainly of French Canadian descendants.

2 Anonymization of personal, medical and sociological data of consenting participants, as well as of biological samples obtained at the time of interview.

3 Provision of comprehensive knowledge of genetic variation in a large population.

4 Contributing to the development of tools and strategies for detailed phenotyping.

5 The organization of public consultation and the encouragement of citizen engagement.

CARTaGENE will be in the public domain and accessible to researchers, be they national or international, and public or private. It will operate in a standardized public health network. For the benefit of the participating population, a public authority, the Institut de Populations et de Génétique (IPEG), has been created as the steward of CARTaGENE.[2] Already in 2001, CARTaGENE had an information session with representatives of Quebec's Access to Information Commission (Commission d'accès à l'information du Québec, or CAIQ) in order to explain the framework in which the investigators would present their request to obtain permission for access to the Quebec's Health Insurance Authority (Régie d'assurance maladie du Québec, or RAMQ) list of enrolees and medical data. The members of the CAIQ did not foresee insurmountable difficulties in eventually granting such an agreement. Discussions are still ongoing with representatives from the Ministry of Health and Social Services of Quebec, who are endorsing the project.

As soon as funding has been acquired, a demonstration phase will be conducted. The ultimate goal of this preparatory phase is to obtain the approval of the CAIQ with regards to (1) the security of personal data, (2) procedures pertaining to privacy and anonymization, as well as (3) authorization to the RAMQ to provide nominative data (such as people's address information, for example) for recruitment. The preparatory phase also includes fine-tuning of the public consultation protocol, as well as the completion of the IPEG incorporation. Ethical evaluation and acceptance of the project will also be sought. Once this preparatory phase is finished and funding is available for the finalized and publicly accepted CARTaGENE project, the recruitment of the participants will start, which will be spread over four years.

2 THE COMMUNICATION STRATEGY OF CARTAGENE

The communication strategy of CARTaGENE has two components: communication with the public and with participants, as well as communication of the results of the research to the scientific community.

2.1 *Communication with the Public and with Participants*

The communication with participants and the public consists of two parts: (1) a communication plan to inform and involve both citizens and participants prior to and during the research project, and (2) public consultation – via citizens' forums – to promote exchanges between researchers and citizens, and to ensure that the latter's opinions and views are taken into account. These two approaches will be based on qualitative and quantitative research on social perceptions of the CARTaGENE project.

2.1.1 *Social Perceptions Research*

The recruitment of fifty thousand individuals for CARTaGENE will require in-depth knowledge of the social perceptions of the project and its approach. Some of the issues we want to address, for example, include the following: what are the risks perceived by lay people? Are there differences in perception among geographic areas or among cultural communities? Furthermore, what are the major challenges of recruitment? In order to develop a coherent strategy – especially given the presence of a variety of ethical and social concerns in Quebec's pluralistic society – it is essential that social perception research be carried out, and that relevant and effective approaches be developed (*cf.* Cragg Ross Dawson 2000; Weijer and Emanuel 2000; Human Genetics Commission 2001; People, Science and Policy 2002).

This research will allow us to expand on our findings about public perception with regard to genomics, by analyzing them in the context of the broader ethical and social issues of which they are part. In each region, activities in support of the social perceptions research will precede the actual recruitment by six months; this will serve as a foundation for the planned subsequent development of the sociological research, as well as for the logistic coordination of the project in that region.

An initial *qualitative phase* will involve twenty-seven focus groups of six to eight participants each. They will be distributed throughout Quebec, according to qualitative criteria with respect to the linguistic, the cultural, and the regional diversity in the population. In order to ensure that the sample is representative, participants will be chosen randomly. The use of the focus group technique will allow us to identify the social, scientific and ethical issues as observed in the population (Graves *et al.* 1998). Subsequently, a report featuring the analysis of the tape-recorded results will allow us to gain a deeper understanding of the socio-ethical implications of the social representations aspect of the project.

In order to explore the expectations of the population with respect to the CARTaGENE project, in November 2001 four preliminary focus groups, each with different socio-demographic characteristics (*i.e.,* either young [age twenty to thirty-five] or old [age thirty-six to sixty-five], and either a low or a high level of education), have been conducted in Montreal. Overall, the focus group participants were of the opinion that scientific research is desirable. Projects

such as CARTaGENE are seen to hold promise for society. Importantly, however, reported across all groups are concerns regarding confidentiality, respect for the individual, transparency, and the right to feedback for the donors. These concerns will now be addressed in more detail.

Confidentiality and Respect for the Individual. It appears that, in general, individuals favour the idea of donation for the 'greater good,' but they want to be assured that they will benefit from this donation, and that their personal information will be respected. Not surprisingly, there is a considerable degree of concern about the ways employers and insurance companies might use human genetic information. Many fear that, if others have access to their genetic information, they will know too much about them. Indeed, genetics can be a very useful diagnostic tool, but in most cases the diagnosis of disease, disability, or condition depends on probabilities. It is not clear how accurate genetic data will be as indicators of an individual's health or disease. Irrespective of the probabilistic nature of such genetic information, the public will need assurances that any results of research that makes use of genetic database information will be handled in a responsible way, and that the public's best interests will be taken to heart. Furthermore, the public should be made aware of the fact that the very purpose of these studies, at least initially, is to combine genetic information with genealogical, demographic, environmental and medical data.

Transparency. Concerns about transparency were raised, especially concerning the issue of informed consent. It is important to explain to the public why the sample collection is being set up and how the samples will be used. Furthermore, it is important to seek explicit consent for access to an individual's medical records. In keeping with the principle of transparency, it will be necessary to make clear to donors that their samples could be used in ways that currently cannot be foreseen.

The Right to Feedback. The donors' right to feedback is another universal concern. They need to know what sort of feedback they will get on what sort of diseases, if any at all. Many members of the focus groups view feedback as an important potential motivator for participation. They have expectations that the results of research or tests will provide them with a cornucopia of personal information.

Public Ownership. Some members of the focus groups raised the issue of the ownership of medical and genetic databases. There was a concern that exclusivity of research resources would have negative implications, such as restriction of the access to data and the commercialization of the results of the research. Consistent with this concern, we found an extensive degree of support for the notion of public ownership of these databases.

A subsequent, *quantitative phase* will lead to an internal validation of the questionnaire administered to the participants of the focus groups. The questionnaire will be modeled after the views and concerns expressed by the focus group participants. A telephone survey will be conducted in all eighteen regions

(2100 questionnaires) to validate the results obtained through the twenty-seven focus groups. The results of this second phase will be compared to the results of the qualitative phase, hence allowing an assessment of the qualitative results in light of the quantitative ones. In turn, this will help assess (1) how perceptions are distributed, (2) the explanations as gleaned from focus group findings for positions identified in the surveys; and (3) what effect information and discussion sessions have had on the perceptions of the CARTaGENE project.

2.1.2 *The Communication Plan*

CARTaGENE's team strives to establish a long-term partnership and a constructive dialogue between the scientific community and society. This requires that the public be informed and that participants be consulted. This discussion and partnership approach, although so far not fully realized in population genomics, is in line with the team's efforts to create transparency and open-mindedness at all levels of the project (Habermas 1992, 1997). The partnership approach favours values such as integrity, ethical pluralism, mutual respect, respect for others, and democracy (Health Canada 2000; Thibault *et al.* 2000). This approach does not adhere to a passive conception of citizenship, but, instead, integrates an active and collective one, where preoccupations and interests of citizens are taken into account (Kymlicka and Norman 1994; Emmanuel 1996; Gutman and Thompson 1997; National Institutes of Health 2002). In addition to facilitating recruitment and retention of participants, increasing participation can also contribute to the identification and minimization of the risks associated with research. Hence, both researchers and participants have a mutual interest to take on the project together and as partners (Goggin 1986; Sclove 1998; May 2001). The information and consultation processes will be transparent. They will be either periodic or continuous, depending on the different methods planned. The communication and consultation plans require the development of procedures and mechanisms for the implementation of information and consultation campaigns. Different techniques have been implemented or are planned to inform and involve citizens, both during the research project proper, and before its launch.

Prior to the Start of the Research Project

- June 2001: First semi-public workshop on the project and its ethical and legal aspects: 125 professionals in ethics, law as well as decision- and policy-making attended the workshop.
- From July 2001 onwards: The web site of the Quebec Network of Applied Genetic Medicine (Réseau de médecine génétique appliquée, or RMGA) has been updated to inform the public about CARTaGENE's nature and its ethical and social framework. CARTaGENE has also created its own web site (CARTaGENE *n.d.*). It contains mass media articles published about the project, and it has a readership of 600,000 to 800,000 individuals.

A large number of inquiries for participation have been received. The web site will be adapted to address more specific communication needs as the project evolves.

- From August 2001 onwards: Newsletters have been published regularly to facilitate liaison with experts, the media, and the public. So far, four have been produced, which are available on the CARTaGENE web site. During the course of the project, the newsletters will particularly be of interest to participants in the research. They will also be emailed to Quebec research networks and weekly magazines.
- Ongoing: Press releases and media presentations have already informed the population about the project's objectives and its public communication strategy. A press release has been seen in November 2001 and more than 2.5 million readers have had the opportunity to be informed about CARTaGENE. The CARTaGENE project has also been presented to various key authorities in Quebec: The Information Access Commission, the Director Committee of the Ministry of Social Services and Health, the Statistics Institute of Quebec and the Ministry of Technology, Science and Research. Furthermore, a presentation to the Ethics Commission of the Ministry's Council has been scheduled.
- June 2003: A second semi-public workshop with professionals in ethics, law, decision- and policy-making was held in order to update these specialists about the developments on the project and its ethical and legal aspects since the first workshop two years earlier. The ethical and legal aspects of the CARTaGENE project have also been discussed during the Third International DNA Sampling Conference held in Montreal, in September 2002. Besides, in 2002 the RMGA has drawn up a *Statement on the Ethical Conduct of Genetic Research Involving Populations* (Réseau de médecine génétique appliquée 2002). All RMGA members are bound by this *Statement*.
- Six months before recruitment: A '1-800' information hotline will be set up to facilitate public inquiries and to communicate information about the project. An information leaflet as well as posters will further promote the dissemination of information about the project's objectives and approaches to the general public and to the participants in the research.

During the Research Stage

- During recruitment: Information sessions (general sessions in the different regions, as well as ones dedicated to specific indigenous peoples and ethno-cultural communities) will help to inform the population and will endorse a representative and diversified participation.

- Ongoing: Press releases and media presentations will provide the public with up-to-date information about the project. The 1–800 information hotline will be maintained for inquiries from research participants and the general public. On the CARTaGENE web site, comments and articles, news updates, as well as a follow-up to the citizens' forum recommendations will be available to the public. On the web site of the Human Genetics Commission, a deliberative electronic forum, called "PopGen," will list the FAQs about public population genomics projects.
- Ongoing: In accordance with its mandate, which guarantees a decision-making process that ensures the public and social mission of CARTaGENE, the Institut de Populations et de Génétique (IPEG) will endorse the citizens' forum recommendations and guidelines for communication of the results of the research, after having sought advise from an independent ethics committee and a scientific advisory board. During the research project, IPEG will support the Citizens' Committee for ongoing consultations regarding the progress of the project, in order to maintain a partnership approach.

2.1.3 *The Public Consultation Plan*

Obtaining the public's opinions cannot be achieved through information sessions alone. Consultation mechanisms favouring exchanges between researchers and citizens have been planned to ensure that their opinions and views are taken into account, as established by CARTaGENE's partnership approach (Jennings 1990; Reiser 1991).

A *citizens' forum*, made up of a diverse group of people, will be organized, which will provide them with opportunities to learn about the project, to examine its ethical and social aspects, and to formulate an ethical opinion report about the project. This transparent consultation mechanism will allow citizens to get actively involved in the evaluation of the project and will give them the opportunity to submit an informed public opinion to the researchers, who, in turn, will need to respond to the issues publicly (Grundahl 1995; Smith and Wales 1999, 2000). The schedule will be as follows.

- Six months before the recruitment of CARTaGENE's participants: Creation of an independent committee to select candidates according to the established criteria (representativeness for gender, age, education, occupation, urban versus rural residence, ethnicity, values, and interests).
- First three months: Forum meetings. Selection of witnesses by experts and lay people retained to inform the citizens' forum, prior to the drafting of opinion.

- First month: Selection of fifteen citizens by the independent committee; assembly of a list of potential witnesses; first information session for chosen citizens, and delegation of consultation process organization to the forum.
- Second month: Second weekend information session. Proposition of a list of witnesses.
- After six months: Actual citizens' forum (one weekend): expert testimony; ethical and social aspect report drafting; press release on citizens' forum opinion.
- Ongoing: Citizens' forum meeting, which becomes a citizens' committee that maintains ongoing consultations regarding the development of the project.

In addition to the citizens' forum, the above-mentioned *deliberative electronic forum*, "PopGen," on the web site of the Human Genetics Commission will provide opportunities for permanent discussion and exchange of information and ideas on ethical and social aspects of the project, and will allow citizens to express their points of view. Moreover, articles regarding the ethical, the social and the scientific aspects of the project will be made available on the web site.

2.2 *Communication of the Results of the Research*

Guidelines for scientific communication will be published, in order to address a number of social, cultural, and ethical issues relevant to the communication of the research results, since genomic knowledge is susceptible to interpretation according to different mental schemes, and is framed according to different (cultural and other) values. For example, the issues of stigmatization and discrimination of sub-populations are fundamental, since some of the research will be done and interpreted in terms of regions (due to the sequential structure of the project). How can we prevent the development of regional prejudice? (Bouchard 1994). How can we ensure an accurate interpretation of genomic knowledge? (Mauron 2001; Pääbo 2001). The issue of public representations of genomics will have to be dealt with, since various conceptions of the importance of genomics to human self-understanding co-exist. Therefore, a multidisciplinary team will formulate scientific communication guidelines to assist CARTaGENE's researchers. These guidelines will tackle issues concerning (1) the social representations of genomics and the diversity of genomics' interpretations; (2) the perception of stigmatization and discrimination in population genomics; (3) popular genetics education; and (4) the development of ethical approaches for public communication of population genomics research results.

Public consultation of communities in genomics research is still in its infancy. Researchers are just beginning to work with named populations and they are not legally required to conduct consultations within communities. While ethical review boards often consider the implications of the research project for the community, community consultation is not required in the Research Ethics Board (ERB) approval process. There is no agreement about the ethical and policy goals that public consultation can achieve and about which methods best address these particular goals. Neither is there much agreement regarding the types of issues on which consultations should be held, nor with respect to the standards by which oversight bodies should evaluate them (Weijer *et al.* 1999).

Though not legally required, many factors impel investigators to engage communities. It is difficult even for highly knowledgeable people to understand the nature and purpose of large-scale genetics databases. Moreover, due to the scale of these databases, the risk of group harm gives greater urgency to ensuring that communities understand the project, and to seeking their input regarding how the project and the groups are described and the data used. There is a growing public concern about protection for communities in genetic research, hence, initiating a dialogue with a community is imperative if we truly are to consider participants as partners (Shickle 2001). With that in mind, policy recommendations have recently been issued (National Institutes of Health 2002; Réseau de médecine génétique appliquée 2002; Commission de l'éthique de la science et de la technologie 2003).

There are clear advantages to involving communities. An ongoing dialogue creates greater comprehension and it addresses potential concerns of the public. Community involvement increases the robustness of the individual consent process, essentially making it an informed decision-making process. As stated by the National Institutes of Health (2002),

> …community consultation may achieve goals not attainable through individual informed consent and standard ethics review.… Community consultation is also intended to elicit feedback regarding potential participants' relevant values, preferences, concerns, or judgments. As partners in, rather than simply as subjects of, the research activity, consultation increases the likelihood that community members will feel empowered rather than exploited" (National Institutes of Health 2002, 6).

However, conducting community consultations for genomics research is a delicate matter; issues of representativeness, social identity, internal politics, and cross-cultural differences abound (Juengst 2000). Conflicts may arise when individual and community interests conflict. For instance, if the community

consents to research participation, individuals may still refuse to participate. On the other hand, if the community does not consent, then individuals who are identified because they are members of the community should not be approached for study enrolment.

Finally, there is the question how community involvement may be encouraged. Even with the willingness to respect values such as fair representation, transparency, and accountability, there is still a risk that the public mistrusts researchers and simply does not participate in sufficient numbers. Other DNA and data-banking projects have failed because of public concerns. For example, a company called Autogen attempted to set up a genetic database using the entire population of Tonga, an island in the South Pacific. The Tongans opposed the establishment of the database because of concerns about informed consent, and about the lack of prior public discussion (Burton 2002). Consequently, the project was halted. Likewise, in the U.S.A., the National Heart, Lung, and Blood Institute refused, apparently due to community concerns, to allow Boston University to close a deal with a private company for the use of the publicly acquired data from the well-known Framingham community study (Philipkoski 2001). This disregard for public opinion led to suspicion of the initiators and their motives. The founders of CARTaGENE are not immune from such risks.

4 CONCLUSIONS

CARTaGENE researchers aim to integrate an active and collective partnership approach, where preoccupations and interests of citizens are taken into account. They also aim for transparency and openness at all levels. In fact, initiating a dialogue with a community is beneficial to researchers and the public alike. Community involvement promotes a two-way communication between investigators and the community: on the one hand, investigators can inform the community about the research and its outcomes, and, on the other, the community can inform investigators about their interests and concerns. Although there are no guarantees that a community consultation will prevent harm on the basis of research findings, openness to discussion creates a forum for members to learn how to deal with scientific conclusions and potential outcomes of research.

Notes

1 This work was part of the Genomics in Society: Responsibilities and Rights project, funded by Genome Quebec and Genome Canada.

2 IPEG is a public non-profit organization, created for the governance, administration and regulation of CARTaGENE's activities.

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6 Canadian Attitudes to Genetically Modified Food[1]

Michele Veeman, Wiktor Adamowicz, Wuyang Hu, & Anne Hünnemeyer

1 INTRODUCTION

IN THIS CHAPTER, WE PROVIDE AN OVERVIEW of some of the findings from a study of consumers' perceptions and choice behaviour for genetically modified foods in Canada. The research reported here is one component of a Genome Prairie research project, titled "The influence of social interactions and information on risk perceptions and attitudes towards genomic technologies." It is motivated by the lack of knowledge on how consumers process information about agricultural biotechnology and how their risk perceptions and product choices are affected by information.

There is a very diverse range of perceptions of agricultural biotechnology. For example, advocates of this technology refer to the many potential benefits of genetically modified foods in terms of improved quality and availability of food, and the potential for less agricultural dependence on chemical pesticides. Such benefits are contested by critics, who argue that knowledge of the implications of genetically modified foods for human health and the environment is insufficient, and that important ethical and moral questions remain unresolved. The attitudes of many members of the public may be less clearly defined. The effects of different types of information on these varied perceptions are not known. Yet, a proper understanding of this issue is critical for policy-makers and others. For public policy to be effective in governing genetic technologies in the food sector, it is important to know how consumers become informed, which sources of information they prefer and trust, how they process information and, ultimately, how information translates into consumer choice behaviour.

The importance of wording in reflecting and potentially influencing people's perceptions of genomic technologies is well recognized. Reference to modern biotechnology as 'genetic modification' has become common and we follow that practice in this chapter. However, it is known that the alternate wordings of 'genetic modification' and 'genetic engineering' may not be viewed as identical, with 'genetic engineering' being seen as more pejorative than 'genetic modification.' Thus, in striving for neutral language, in the course of our study – both in the focus groups and in the wording of the text of the survey – we consistently used the wording 'genetic modification/genetic engineering' and the abbreviation 'GM/GE' where this was appropriate.

2 THE STUDY: AN OVERVIEW

This study builds on other attempts to explain and predict consumer attitudes towards genetically modified foods. The communications literature investigates consumers' underlying attitudes about – and perceptions of – these foods (Frewer *et al.* 1998; Grunert 2000; Bredahl 2001; Hossain *et al.* 2002; Marks *et al.* 2002; Roosen *et al.* 2003; Evenson and Santaniello 2004). The importance of product information has been recognized in several studies (Finlay *et al.* 1999; Noussair *et al.* 2002, 2004; Rousu *et al.* 2004), as has the role of trust in information sources (Hunt and Frewer 2001; Huffman, Rousu *et al.* 2003). Some previous economic studies, using the approaches of 'stated preference' or 'experimental auctions,' have assessed how attitudes may translate into actual market behaviour, by estimating consumers' willingness to pay for genetically modified foods (Lusk *et al.* 2002; Chern and Rickertsen 2002). In addition, several studies (Shogren *et al.* 2002); Van Wechel *et al.* 2003) specifically analyze how varying information content about genetically modified foods (either positive or negative information) affects consumer preferences. The contributions of our study include components of its methodology, its documentation of the heterogeneity in attitudes to genetically modified foods, and its analysis of the effects of different labelling scenarios.

The study involved a Canada-wide survey of 882 participants, conducted in January 2003. The survey, which was developed with the aid of several focus groups, encompassed two statistically designed experiments, applied on a split-sample basis. Each of these experiments focused on the effects of different types of information – in a manner that simulated hypothetical purchase situations – for a selected food product. Pre-packaged sliced bread was chosen as the product for this purpose for several reasons. As a basic food product for many Canadians, bread is consumed in almost all Canadian households; wheat is one of the major agricultural commodities of the country; and, at the time of the survey, genetically modified wheat had been proposed – but not approved for production or sale – in Canada.

Following an introductory section of the survey, which determined the characteristics of bread that each respondent normally purchased, each individual

was randomly assigned to one of the two experiments. Subsequently, each person also completed questions that probed his or her knowledge of agricultural biotechnology and elicited assessments of the importance of different food safety and environmental issues related to agriculture and to genetically modified food. Survey participants were also asked to indicate the extent to which they trusted various sources of information on genetically modified food, as well as the extent of their agreement or disagreement on a variety of attitudinal statements relating to agricultural biotechnology and genetically modified foods. In order to facilitate comparisons across time and across populations, several of the questions that had been asked by other researchers in other contexts were incorporated into our questionnaires. A final section of the survey provides information on socio-demographic and economic characteristics of respondents.

One of the two experiments undertaken in the survey focused on the influence that different types of information, from different sources, had on respondents' choices between particular bread products. These were described in terms of major characteristics, including health and environmental attributes, which could be associated with genetic modification. The second experiment focused specifically on the effects on choices of genetically modified food in the context of different types of labelling policy for this product. The use of choice-behaviour experiments in this study reflects the disciplinary focus of economics and the belief that it is particularly useful to study consumers' perceptions of product quality or risk in the context of the trade-offs that are made relative to product prices, rather than solely interpreting risk perceptions in terms of people's stated opinions, since these may not always reflect behaviour. The study is also informed by the literature and methods of sociology and psychology, reflecting the major influence of these disciplines on the study of peoples' behaviour relative to risk. The survey was designed and applied in a computer-based interactive form. An international marketing firm was contracted to apply this to a sample drawn from their Internet panel of approximately 40,000 Canadian households; that panel is considered to be representative of the Canadian population.

Our sample of 882 respondents is reasonably (but not completely) representative of the Canadian population, in that the average respondent in our study was slightly older, wealthier and more educated than is the case for the population as a whole. However, the benefit of using computer-aided survey technology is the increased specificity that could be achieved in the questionnaire in presenting reasonably realistic scenarios to a large sample of respondents. Specifically, the computer technology enabled respondents to 'build' their own choice of bread, reflecting their preferred choice of characteristics at the very beginning of the survey. This could be used as the basis of a modified 'switching model' in the first experiment, based on whether the respondent continued to prefer this initial choice, or chose another bread type (or chose neither), as attributes of an alternate offering (and information characteristics) were changed. For

the second experiment, determination of the characteristics of the normally preferred bread type provided a reference point for these characteristics, for each person, allowing an assessment of labelling scenarios.

3 PRELIMINARY FOCUS GROUPS

In order to gain information on attitudes to GM food and to test preliminary versions of the survey, several focus groups, each consisting of seven to nine people, were conducted in Edmonton in 2002. Four groups were mainly composed of University of Alberta students. Two further groups consisted of primary household grocery shoppers, formally recruited from the general Edmonton population by University of Alberta's Population Research Laboratory. The main objectives for the group discussions were to identify the product attributes relevant for consumers' choice decisions, to gain an understanding of contentious issues relative to GM food, to test components of the survey experiment, and to assess individuals' comfort with an internet-based survey.

In each of the groups that focused on bread, including the two public groups, different samples of pre-packaged sliced breads were displayed, and the initial focus of group discussion was to identify the characteristics of individuals' preferred bread choices. In addition to price, the relevant bread attributes and levels of peoples' preferences crystallized as: brand name (national brand versus store brand), the type of flour (white, partly whole wheat, whole wheat or multi-grain flour), colour, consistency, and the thickness and shape of slices. Focus group participants also identified 'freshness' and 'presentation' of bread as important for their choice decisions. The identified choice criteria were either incorporated as attributes in the experimental design, or standardized in the product description for the experiment (as with freshness and presentation in the first experiment, and all attributes except price, brand name, and type of flour in the second experiment).

Possible benefits and risks of applications of genetic modification, both in general and with regard to food, were also discussed in the focus groups. Many of our findings from this process mirrored those of other studies, in Canada and elsewhere. There was a wide range of knowledge and attitudes towards issues associated with genetic modification through biotechnology. Participants identified health and environmental issues as areas of major concern for genetically modified food, mainly due to the large degree of uncertainty associated with long-term effects of these foods. Even so, some participants explicitly pointed at possible positive effects, citing increased food supply for developing countries, drought resistance of crops, the creation of food with health improvements, or a view of genetic modification as a process involving general advancement of technology that is likely to pave the way for beneficial applications. However, as has generally been found elsewhere, respondents expressed less hesitation towards medical biotechnological applications. In general, focus group participants showed little specific knowledge of genetically modified food technologies,

and, with the exception of some individuals with fairly strong opinions, many participants were reluctant to voice a clear opinion in favour of or against these new products.

A preliminary version of the survey instrument for bread was also tested in two focus groups. This specifically explored respondents' purchase intentions for breads containing genetically modified ingredients, and their specific attitudes and concerns regarding this technology. In these focus groups, we asked respondents whether they would buy bread with genetically modified ingredients that contained specific health and environmental benefits at a price discount. Approximately 50% of the focus group participants chose to switch to GM bread that provided health and/or environmental benefits. The focus group findings were the basis for the experimental designs that were adopted for the two experiments.

4 RESPONDENTS' VIEWS OF FOOD & AGRICULTURAL RISKS

In the attitudinal component of the survey, the 882 respondents were queried on their assessments of the degree of risk associated with each of a number of identified food health risks. As with all questions in this section of the survey, these were presented in random order. Respondents were asked to rate each of the identified issues in importance from 1 ("very high") to 4 ("almost no risk") or 5 ("don't know). As in the other blocks of questions in this section of the survey, the order of presentation was randomized across respondents. Although genetically modified foods were believed to be very risky by an appreciable number of respondents, overall this issue was seen as less risky for food safety than most of the other listed food risks. The most risky issues for food were thought to be: bacterial contamination (cited as being very risky by 41% of the respondents); pesticide residuals (41%); use of antibiotics in food production (36%); BSE (mad cow disease) (32%); use of hormones in food production (32%); fat and cholesterol in food (25%); use of genetic modification/engineering in food production (21%); and use of food additives (15%).

Respondents were also queried on their assessments of the levels of risk for the environment that are associated with a number of listed agricultural-related issues. A similar four-level scale and the option of "don't know" applied in each case. The most risky issues for the environment were viewed to be: water pollution by chemical runoffs from agriculture (viewed as very risky by 61% of respondents); herbicide/pesticide resistance (50%); agricultural waste disposal (41%); soil erosion (28%); genetic modification/engineering (27%); and adverse effects of agriculture on biodiversity (26%). Overall, the respondents in this survey tended to see agricultural biotechnology as somewhat more of an environmental risk issue than as an issue of food safety. There were relatively few "don't know" responses to these two sets of questions.[2]

Table 6.1
Knowledge of Agricultural Biotechnology

True / False Statements	*Correct Answer*	*% of Respondents that Answered Correctly*
"Genetic modification/engineering can only be applied to plants, but not to animals."	False	83%
"By eating a genetically modified/engineered food, a person's genes will also become modified."	False	73%
"Canola, corn, soybean and potato are amongst the genetically modified/engineered crops currently produced in Canada."	True	67%
"Genetically modified/engineered food items are currently available in Canadian supermarkets."	True	89%
"All of the food items in Canadian supermarkets contain genetically modified/engineered ingredients."	False	81%
"Canadian food regulations require the labelling of food items which contain genetically modified/engineered ingredients."	False	51%

5 Respondents' Knowledge of Agricultural Biotechnology

In order to assess the respondents' knowledge on the topic of genetic modification, we asked them the following six true/false questions. As noted in table 6.1, a relatively large number of respondents believed, incorrectly, that Canadian regulatory policy required labelling of food containing genetically modified/genetically engineered ingredients.

Respondents were also asked to assess their own knowledge of genetic modification in terms of how well informed they felt about the subject. Overall, 3% of the subjects indicated that they were "very well" informed on the topic, 42% specified "somewhat informed," 44% chose "not very informed" and 11% reported "not at all informed."

6 Trust in Sources of Information on Agricultural Biotechnology

Using a four-level scale, we asked respondents to assess the trustworthiness of different groups as sources of information about genetically modified/engineered food products. The percentages of respondents indicating ratings of "very trustworthy" and "not trustworthy at all" are listed in table 6.2.

Table 6.2
Trustworthiness of sources of information on genetically modified/engineered food products

Groups	*Very trustworthy*	*Not trustworthy at all*
Research institutions	41%	1%
Consumer associations	32%	3%
Family/friends	10%	10%
Federal government	10%	11%
Farmer's associations	9%	8%
Food industry	4%	19%

These responses show relatively low trust in "the food industry," "farmers' associations" and "the Canadian Government," on the one hand, and high levels of trust in information from "research institutions (*e.g.,* universities)" and "consumer associations," on the other. The lowest level of trust in information from the queried institutions was for the food industry, which was rated as "not trustworthy at all" by nearly one-fifth of respondents.

7 Attitudes & Perceptions with Regard to Risks & Benefits of Agricultural Biotechnology

In the block of questions on attitudes to agricultural biotechnology, respondents were presented with thirteen attitudinal statements and asked to indicate their agreement or disagreement with each of these. A four-point rating was used ("strongly agree," "somewhat agree," "disagree" or "strongly disagree"); a "don't know" option was also available. The statements are listed in table 6.3. In this table, the "agree" and "strongly agree" responses are summed together as "tend to agree," while the "disagree" and "strongly disagree" responses are aggregated as "tend to disagree." One striking characteristic of the responses to these questions is the relatively high proportion of "don't know" responses to a number of the statements.

An initial non-parametric analysis was applied to the responses to the attitudinal questions cited above, in order to assess any common groupings of questions and respondents. Responses to the thirteen attitudinal statements were reduced into factor scores using a factor analysis with the method of principal components extraction. Two factors were identified (based on Eigen values greater than one) and these account for 51% of the variation among the data for the thirteen perception questions. These two factors can be described as:

Table 6.3
Attitudes and Perceptions Regarding Possible Risks and Benefits of Genetically Modified Foods

		Response		
	Statement	*Tend to agree*	*Tend to disagree*	*Don't Know*
	Concerns about GM/GE foods related to human health:			
1	"The human health benefits of GM/GE crops outweigh the human health risks."	32%	43%	25%
2	"Foods derived from GM/GE crops are less risky for humans than foods derived from GM/GE animals."	23%	43%	34%
	Concerns about GM/GE foods related to the environment:			
3	"The overall benefits for the environment of GM/GE crops outweigh the overall environmental risks."	32%	44%	24%
	Concerns about GM/GE in animal production:			
4	"Overall, I am more sceptical of GM/GE applications in livestock than in crops."	55%	31%	14%
5	"Feeding animals with GM/GE feed is not a concern."	33%	56%	11%
6	"GM/GE applied to livestock will worsen animal welfare."	38%	35%	27%
	Concerns about GM/GE foods related to market structure:			
7	"Increased GM/GE crops in Canada will lead to a harmful concentration of corporate power."	42%	34%	24%
	Overall assessment of GM/GE foods:			
8	"GM/GE in agriculture is unnatural."	54%	37%	9%
9	"Foods derived from GM/GE animals are simply not necessary in Canada."	47%	36%	17%
10	"I would sample foods from GM/GE crops to find out whether I like them."	55%	35%	10%
11	"I would prefer cheaper foods derived from GM/GE crops over more expensive GM-free products."	33%	57%	10%
12	"Canada should advance the general field of GM/GE technologies to prevent or cure diseases."	67%	21%	12%
13	"All things considered, benefits of GM/GE in food production outweigh risks."	37%	43%	20%

1 Forecast of a bright future (this groups together questions 1, 2, 3, 5, 10, 11, 12, and 13). Individuals with higher scores for this factor generally perceive a bright future for the technology of genetic modification, based either on potential individual benefits or the benefit of society as a whole.

2 Concern about the application of genetic modification (this groups together questions 4, 6, 7, 8, and 9). Individuals with higher scores for this factor generally see genetic modification as unnatural and have concerns about various aspects of its application.

Stratification of the higher and lower ends of these two factor scores indicates four types of strong views or attitudes of individuals in our sample, as in the first four rows of table 6.4.

As can be gauged from this table, 7% of the 882 respondents believe that

Table 6.4
Representative Consumer Groups Based on Factor Analysis

Attitudes	*Number of Individuals*	*Percentage of the Sample*
Concerned, but Bright Future	59	7%
NOT Concerned and Bright Future	91	10%
Concerned and NO Bright Future	128	15%
NOT Concerned, but NO Bright Future	105	12%
No Strong Views Regarding Biotechnology	499	57%
Totals	882	101%

agricultural biotechnology is useful (*i.e.,* that it has a bright future), but are also concerned about its potential adverse impacts. Approximately 10% support the development of this technology without any obvious concern. The highest percentage of respondents that expressed consistently strong views across the attitudinal questions fell into the third category, which includes the 15% of respondents that did not consider the technology of agricultural biotechnology to be beneficial and were concerned about its application. The fourth category of respondents, 12% of the total, did not view agricultural biotechnology to be useful, but were not particularly concerned about this issue either. Of those respondents that had strong views on whether or not agricultural biotechnology constituted a concern, the numbers of "concerned" and "not concerned" respondents were relatively equal (about one-fifth each). However, as is shown in table 6.4, overall, 57% of respondents (*i.e.,* those with factor scores that fell within the upper and lower groups of the two factor scores) did not express strong views either for or against genetic modification, in terms of their attitudinal responses to the questions outlined previously in table 6.3.

Table 6.5
Activism, Actions and Attitudes Regarding Labelling with Respect to Genetically Modified Foods

Statement	*Response*		
Stated Actions:	***Yes***	***No***	***Don't Know***
"The possibility of GM/GE content affects my food choices."	40%	53%	7%
"I purposefully buy food at organic stores to avoid GM/GE food."	11%	87%	2%
Stated Activism:			
"I donate money to organizations which oppose GM/GE foods."	4%	92%	4%
"I donate money to environmental protection organizations."	25%	73%	2%
"I have lobbied against GM/GE foods."	3%	96%	1%
Views on GM/GE Labelling & Regulation:	***Tend to Agree***	***Tend to Disagree***	***Don't Know***
"The public is sufficiently involved."	13%	80%	7%
"The right to know warrants mandatory labelling."	88%	10%	2%
"The labelling decision should be left to experts."	57%	39%	4%
"No labelling is needed if the final quality is the same."	14%	83%	3%
"Voluntary labelling might be used as a marketing tool."	71%	25%	4%
"Stricter regulation is better than mandatory labelling."	61%	34%	5%
"Mandatory labelling is preferable over voluntary labelling."	90%	8%	2%

8 Activism, Actions & Attitudes with Regard to Labelling & Policy

A further block of attitudinal and opinion questions assessed views on attitudes and activism regarding genetically modified food, and opinions on labelling and related policy issues. A summary of the questions and responses is given in table 6.5. Overall, a slim majority of respondents indicated that their food choices are affected by genetically modified content, but relatively few respondents indicated that they purposely avoid genetically modified food; even fewer indicated that they donate (4% overall) or lobby (3%) against genetically modified

food. Approximately one-quarter of those surveyed donate to environmental protection groups.

The responses to questions concerning labelling and policy summarized in table 6.5 were based on a four-point scale ("strongly agree" to "strongly disagree"). As was the case in several of the previous tables, the responses overall are aggregated, so that "tends to agree" includes "strongly agree" and "agree," while "strongly disagree" and "disagree" are combined into "tend to agree." It must be recognized that the nature of the responses to this group of questions is likely to be influenced by their wording. There are relatively few "don't know" responses. Respondents indicate a strong desire for public involvement, vote even more strongly for mandatory labelling, and disagree that labelling is not needed if the product's quality remains unchanged. An appreciable majority of respondents expressed a degree of scepticism concerning the use of voluntary labelling. A majority expressed a preference for stricter regulation over mandatory labelling, but about one third of respondents disagreed with this.

9 Experiment 1: Introducing Product Improvements & Alternate Information Scenarios with Regard to Agricultural Biotechnology

This experiment applied a structured, internet-based 'stated choice' experiment, using a modified 'switching task' approach, to investigate choice behaviour for a genetically modified food among 447 consumers across Canada. Respondents were asked to choose, in a sequence of tasks, between their previously specified favourite bread purchase and the same product with additional environmental and/or health benefits, which could be specified to be the result of genetic modification of wheat, at varying price levels. Each respondent that was offered a genetically modified product was provided with a basic definition of genetic modification.[3] The experimental design allowed respondents to voluntarily search for additional product information, which included different types of information from varied sources on the safety of GM foods, for human consumption as well as for the environment. The preliminary results of this component of the study are as follows:

1 In the absence of product improvements, overall, the average respondent was less likely to purchase bread containing genetically modified wheat than regular bread, all other attributes held constant. However, if it was indicated that genetic modification would generate a positive health effect ("bread rich in healthy vitamins" as a result of genetic modification of the wheat), overall, consumers' aversion to genetically modified bread declined. The specification of an environmental attribute ("produced in an environmentally friendly manner") also tended to reduce the aversion to the genetically modified product, and this was of importance for

a subset of respondents. Overall, however, the product choices made by respondents indicated that the incorporation of a health attribute based on genetic modification tended to be valued more highly than an environmental attribute.

2 There is considerable preference heterogeneity among individuals in the sample relative to respondents' aversion to genetically modified food. The effects reported in the preceding paragraph are based on the average respondent. More detailed statistical analysis of respondents' product choices indicates that a sizeable group of individuals was unaffected by the presence of genetically modified product in terms of their likelihood of purchasing bread, while another sizeable group was strongly averse to the purchase of genetically modified product, regardless of the attractive levels of the other attributes. The variation in preferences for genetically modified food does not appear to be strongly linked to demographic characteristics. This heterogeneity makes it difficult to generalize about consumers' attitudes towards genetically modified food.

3 In the course of this experiment, respondents could choose to access additional information[4] on genetic modification and on the health and environmental attributes, through the mechanism of a 'mouse click.' This voluntary access to information forms part of the data collected in the course of the experiment. Approximately half of the respondents chose to access more information, while the rest did not seek further information.

4 Preliminary analysis shows an association between information access and respondents' choices. For example, the group of respondents that did not make an effort to acquire further specific information (but was exposed to the general initial health and environmental information statements noted above) tended to be less strongly opposed to the presence of genetically modified ingredients than those who did access information. Further, those respondents exposed only to advocating (*i.e.,* positive) information about genetic modification technologies tended to be rather less averse to the genetically modified product than those exposed to both advocating and critical information about genetic modification. Further analysis is being pursued on these data.

10 Experiment 2: Alternate Labelling Policies for Genetically Modified Food

A total of 437 respondents were assigned to this computer-aided, online 'structured choice' experiment for specified bread products. The usual bread choice of each respondent was identified in terms of specified product attributes (including price), providing a set of reference points that was applied in subsequent analysis. Participants were randomly assigned to product choice situations that

simulated either mandatory or voluntary labelling regimes. Thus, in the course of the survey, consumers were introduced to simulated market choice situations in which they could choose to purchase particular bread products that varied in price, brand name, type of bread flour and whether or not it was labelled as containing or not containing genetically modified ingredients. In each choice situation, consumers also had the option not to purchase any of the designated alternative products.

An economic model was used to examine consumers' preferences for bread that may contain genetically modified ingredients, in the context of different types of labelling policies. Again, there was much heterogeneity among respondents in the extent of aversion to genetically modified food. With mandatory labelling, and in situations where there were no product improvements, consumers tended to react negatively to declarations that the product contained genetically modified ingredients. In the voluntary labelling context, consumers were willing to purchase bread labelled to indicate that it contained no genetically modified ingredients at a price premium. However, our research also shows that the *loss* in consumer welfare associated with identification of the presence of genetically modified ingredients is proportionally higher than the consumer welfare *gain* associated with identification of the absence of genetically modified ingredients, where welfare gains and losses are expressed in terms of economic measures of utility. This interesting finding of asymmetry in consumers' responses relative to gains and losses may reflect the strength of the adverse perceptions of genetically modified bread held by some respondents.

11 CONCLUSIONS

Each of the various components of this study indicates that there is significant diversity amongst Canadians in their views on genetically modified food. For approximately one-third of our respondents, choice behaviour indicated a very high level of aversion to genetically modified food. However, the choice responses of a relatively large group (about 50%) of respondents did not demonstrate a particularly high level of aversion. When the genetic modifications involved health benefits or environmental benefits, and information on these issues was accessed, choices tended to be affected. However, only about half of the respondents who could have accessed further information actually chose to do so. In general, those who chose *not* to access information tended to be less opposed to genetically modified food.

The two labelling contexts that have been investigated in this study confirm that, in the absence of product improvements, identification of genetically modified foods (as under a mandatory labelling system) had negative effects on purchases of that product. Compared with a base case, mandatory labelling of genetically modified ingredients in bread products significantly lowered the perceived value of the products. Providing for labelling only of products that do *not* contain genetically modified ingredients led to welfare gains and

price premiums for these particular labelled products, but, overall, this effect was less than the welfare losses and discounts associated with label statements of genetically modified contents. This could be interpreted in the light of the strength of the concern about genetically modified food expressed by some consumers, as well as of consumers' scepticism that the voluntary labelling statement "does not contain genetically modified ingredients" tends to be used for marketing purposes, as was indicated in the 'voting response' question on this issue (see table 6.4).

The future directions for our continuing research on Canadian consumers' responses to information in the context of genetically modified food include emphasis on the analysis of the heterogeneity in responses and choices observed in the current study. Also of particular interest is the question why some consumers choose to access more information and others do not. Yet, another issue involves the investigation of the factors that contribute to asymmetry in people's responses to different GM labelling contexts. The social, economic, demographic and attitudinal reasons that seem to underlie respondents' relative tolerance of, or aversion to, genetically modified food is of considerable interest and will continue to be a focus of our future research.

Notes

1 This research was supported by funding from Genome Canada, Genome Prairie, and the Alberta Agricultural Research Institute.

2 There were some variations between different regions in Canada in these and some other responses to the survey. However, these fall outside the scope of this chapter and are not discussed further here.

3 This was: "Genetic modification, also called genetic engineering, is a recent development in modern biotechnology. This technique involves the transfer of a piece of genetic material from one organism to another. Through genetic engineering it is easier to produce new traits without changing other traits in the plant or animal. It is also possible to introduce traits from outside the species, something that is not possible with traditional breeding methods."

4 The statistical design encompassed differences in information content, specifically positive and negative information, in addition to a 'no information' treatment.

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Part 4

Framing the Gene

The Media Sphere

7 Media Representations of Genetic Research[1]

Tania M. Bubela
& Timothy Caulfield

1 INTRODUCTION

GENETICS AND RELATED TECHNOLOGIES get considerable attention from the popular press. Almost weekly, the media carry a new genetics story, ranging from the discovery of a new disease gene, or the role of genetics in behavioural characteristics, to commentary and speculation about the social impact of the genetic revolution. Some commentators have suggested that media representations exaggerate both the benefits and the risks associated with genetics and genetic technologies, a phenomenon that has been called *genohype* (Holtzman 1999; Caulfield 2000; Fleising 2001).

Some authors argue that the research community and policy-makers should be concerned about genohype, because the public is interested in science and technology (Optima Consultants 1995; National Science Foundation 1998; Yann Campbell Hoare Wheeler 1999; U.K. Office of Science and Technology 2000; Pollara Research and Earnscliffe Research and Communications 2001; International Research Associates 2002) and receives most of its information on science and technology from the media (Heijs and Midden 1996; National Science Foundation 1998; Yann Campbell Hoare Wheeler 1999; Cragg Ross Dawson 2000). At the same time, public understanding of science and technology is minimal (Optima Consultants 1995; Hartz and Chappell 1998; National Science Foundation 1998; Wellcome Trust 1998; Einsiedel 2000a; Ipsos Reid 2000; International Research Associates 2002). Those in the scientific community argue that a proper understanding of a basic set of scientific concepts is an important prerequisite for public participation in the discussion on science and technology (National Science Foundation 1998). Media exposure may work in concert with low levels of public awareness or interest to increase the potential impact of

genohype on public perceptions of the risks and benefits of biotechnology, in turn, reducing the ability of the public to participate in policy discussions in an informed manner (Ransonhoff and Ransonhoff 2001; Geller *et al.* 2002).

However, it is overly simplistic to state that public opinion, particularly public concern, is based on a combination of ignorance and misinformation. Proponents of genetic technologies and products use this argument to delegitimize public opposition. Media sensationalism is "blamed for amplifying and exploiting that public ignorance" (Priest and Gillespie 2000, 530). Public opinion surveys show a correlation between level of education and support for biotechnology. However, this correlation is not universal, but, instead, is mediated by the demographic and socioeconomic characteristics of the respondents and the specific genetic technology or product in question (Einsiedel 2000b). Others call the public ignorance argument into question and suggest, instead, that the media merely *reflect* – rather than *shape* – public discourse and opinion (Condit 2001). In the end, however, there is no doubt that the media exert some influence on the complex interactions between regulators, the scientific research community and the public, regardless of the question whether or not the media play an active role in the formation of public opinion.

In a democratic society, the lay public can exert substantial influence on its public representatives, who, in turn, fund or regulate scientific research and the use of science-based technologies (Condit 2001). At present, public unease, augmented by distorted media reporting of sensitive issues, has resulted in a general mistrust of government regulators and politicians (Einsiedel 2000a; International Research Associates 2002). Public representatives may also ban or criminalize scientific research that is perceived as dangerous, immoral, or unjust. Thus, public policy makers have a responsibility to develop a well-informed regulatory framework that is not distorted by overly positive or negative public attitudes about genetic research and its applications.

One substantial set of studies have estimated that public opinion, as measured by polling, becomes functioning law about two-thirds of the time (Page and Shapiro 1992). Hence, it is not surprising that stakeholders, such as the research community, have a vested interest in shaping public opinion to support biotechnology research, and the media may be one important tool in this endeavour.

In this chapter, we discuss how researchers interact with the media and how well the media translate scientific research for the lay public. We critically examine the generally held view that any distortion of information or genohype originates with the media. This view is reflected in the public's lack of trust in the media, compared with its high level of trust in the medical profession and in non-industry researchers (Page and Shapiro 1992; National Science Foundation 1998; Yann Campbell Hoare Wheeler 1999; Einsiedel 2000a; Market and Opinion Research International 2000; U.K. Office of Science and Technology 2000; International Research Associates 2002). We question whether these polarized levels of public trust are warranted. Recent studies show that sensationalism

and inaccuracy may not originate with the media but, instead, may emanate directly from scientists and public research institutions, through interviews and press releases (Schwartz *et al.* 2002; Bubela and Caulfield 2004). This begs the question whether there is any evidence at all that media hype influences public opinion. In order to explore this issue, we conducted our own analyses of recent newspaper articles from several English-speaking countries. We will conclude this chapter with a discussion of the results of our research and recommend increased involvement of the public in the debates about genetic research.

2 DOES THE PUBLIC TRUST THE MEDIA TO NOT SENSATIONALIZE GENETIC RESEARCH?

The low level of trust in the media may be indication enough that the public believes in genohype. This perception was indeed supported by survey data (Yann Campbell Hoare Wheeler 1999; U.K. Office of Science and Technology 2000; Millward Brown 2001; International Research Associates 2002). However, the public did not solely put the blame with the media (Millward Brown 2001); there is also a general sense that the field of biotechnology is changing too rapidly and in an uncontrolled manner.

The belief that the media hype genetic research is not only found among the general public, but in the scientific research community as well. Scientists recognize that journalists play a crucial role in the communication of information about developments in genetics and biotechnology to the lay public. Yet, at the same time, they believe that media coverage is too sensational, too dramatic, and too speculative, and, furthermore, that it is unbalanced, *i.e.,* that risks are overemphasized, at the expense of the coverage of potential benefits (Gunter *et al.* 1999).

Several studies have shown that, while scientists are willing to communicate with the media and are relatively satisfied with the reporting of their individual research, collectively they remain convinced that the media sensationalize science (Wilkes and Kravitz 1992; Gunter *et al.* 1999). They also believe that the media have a detrimental impact on the public's comprehension of science and, hence, on public opinion with regard to the research in question. Scientists are dissatisfied that the media do not obligingly rely on expert opinion and uniformly act as cheerleaders for scientific innovation (Market and Opinion Research International 2000). Scientists believe that they should communicate directly with the public, especially on the social and ethical aspects of their research, but consider themselves insufficiently trained and equipped to do so (Market and Opinion Research International 2000).

3 DO THE MEDIA HYPE GENETICS RESEARCH?

3.1 *How Do the Media Report on Genetic Research?*

Is the mistrust in the media warranted? In general, research has shown that, for their stories, journalists rely primarily on research articles that appear in top-end

journals or on papers that are presented at major scientific conferences (Conrad 1999). The majority of research articles that appear in these top-end journals are covered by at least one media source, with journalists relying heavily on the peer review processes of these journals in ensuring accuracy (Entwistle 1995; de Semir 1996). Peer review is regarded as a quality filter and safeguard, so that additional comment is not necessary.

In selecting which research to cover, journalists also rely on press releases from journals, research institutions, funding bodies, and conference organizers, as well as on web sites and tip-offs from journals, universities, and other research institutions (Entwistle 1995). Yet, these sources are generally considered as introductions to a story and are not relied on as the basis for the media story (Entwistle 1995). Instead, most journalists base their stories on the primary scientific research article, recognizing the danger of relying on press releases. Articles are selected for press releases for their perceived newsworthiness, but the press releases do not routinely highlight study limitations or the role of industry funding. Data are often presented using formats that may exaggerate the perceived importance of findings. However, press releases may have a disproportionate impact by influencing the selection of research articles. Journal articles described in press releases, in particular those described first or second in the press release, *i.e.,* those given greater prominence, are more represented in the popular press (Woloshin and Schwartz 2002).

Abstracts at scientific meetings also receive substantial attention in the high-profile media, but there is a concern that the results of scientific studies presented at conferences may be reported prematurely, *i.e.,* before undergoing rigorous peer review (Schwartz *et al.* 2002).

One other factor influencing the choice of science story is fashion or stereotype (de Semir 1996). Stories with a ready pop-culture reference such as "Jurassic bacteria" may be covered instead of more newsworthy or more important research. Journalists also have a tendency to imitate each other (de Semir 1996). Newspaper offices monitor rival and global media, and major newspapers are used as sources and inspiration.

Journalists have a high level of confidence in the science community; in fact, it is higher than that in their own professional community (Hartz and Chappell 1998). Journalists often contact senior or well-respected researchers or administrators of research institutions; indeed, "[j]ournalists preferred to quote respected leaders in the field, and trusted contacts who had previously supplied lively comments" (Entwistle 1995, 921). 'Lay' opinions may be sought more often when the research relates to a segment of the population whose advocates are organized, such as patient groups, or gay rights activists in the case of the "gay gene" (Conrad 1999). Occasionally, a human element to the story is presented by interviewing 'sufferers,' for example, obese people, about their reaction to a gene discovery or potential treatment option (Bubela and Caulfield 2004). Where possible, this 'human interest' approach is preferred by the British press.

Even where there is controversy, opinions critical of the scientific validity of the research itself are seldom quoted (Conrad 1999). Some journalists are concerned that contrary or critical opinions may be due to a lack of familiarity with the journal article in question, or might be prejudiced by rivalry, and, hence, might weaken the story by questioning the claims made. Space limitations may also be a factor; it is difficult to summarize a research paper in a few hundred words and "having to summarize comments on it as well, with no extra word allowance, is even harder" (Entwistle 1995, 921).

The scarcity of investigative journalism may be partly blamed on the fact that there are only a small number of specialist journalists devoted to covering science and technology. For example, in Canada, there are only eighteen full-time science reporters, and most of them are focused on health issues. Eighty-two per cent of Canadian dailies do not assign anyone to cover non-medical science full-time, and, even more significantly, there are no science reporters employed by the Canadian wire services (Addario 2002). The average number of science journalists assigned to science news (including health) within the news organizations in one U.S. study was 1.6 (Hartz and Chappell 1998).

Most alarmingly, science stories are not necessarily assigned to specialist journalists. In February 1999, when a genetically modified (GM) food story broke, there were no news articles on GM foods written by science journalists (U.K. House of Lords 2000). Instead, 45% were written by political journalists. Commentary came largely in letters to the editor, editorials, and opinion columns, while none came from science writers.

On occasion, authors of research papers are contacted in order to check comprehension, to humanize the research by including quotes, and to obtain stronger statements than appeared in print. While scientists tend to be cautious in their professional journal articles, they will frequently make broader claims in news interviews. Such interviews allow the scientists to elaborate on the meaning and implications of their study, which often become quoted in the news stories (Conrad 1999; Bubela and Caulfield 2004). Typically, journalists encourage experts to 'speak with enthusiasm' about their research. In some instances, scientists may simplify and/or inflate their claims during interviews, and such statements are considered 'fair game' by the media (Bubela and Caulfield 2004). In such situations, the media and the scientific community may be inadvertent 'complicit collaborators' in the subtle hyping of science stories. Both scientists and journalists may perceive – consciously or unconsciously – short-term benefits from allowing the 'hype' or oversimplification to persist. The perceived benefits for the journalist are a more readable story, and, for the scientist, a degree of media attention for his/her research. However, most journalists specializing in science writing are aware of the risk of inciting undue optimism or pessimism *among* their readers, especially in a medical context (Entwistle 1995).

The final factor that plays into the equation is that the media operate as a commercial enterprise. Journalistic science stories need to address the issue of

relevance to the reader, listener, or viewer, often because the nature of science research is 'complex' (Hartz and Chappell 1998). The primary aim of science journalists, as with any journalist, is to get their stories into the newspaper or radio or television program, despite the fierce competition from other journalists (U.K. House of Lords 2000). However, the news media underestimate the public if they assume that the public prefers stories about scandals to stories about major challenges confronting science and technology. The biggest obstacle to balanced coverage of science and technology may not be the journalists themselves, but the "myopia of newspaper management who underestimate the public's interest in science news, and devote insufficient resources to cover this area" (Hartz and Chappell 1998, 33).

3.2 *Do the Media Hype Genetic Research?*

A number of studies deal explicitly with the degree of accuracy in the reporting of scientific research in the print media. None of these have found a high level of inaccurate reporting (Loo *et al.* 1998; Bubela and Caulfield 2004). Instead, more subtle forms of media hype may be prevalent. For example, the framing of stories on genetics may be overly optimistic and may distort some findings. New discoveries of genes may be announced with great fanfare, but when the most promising claims cannot be replicated and are subsequently retracted, the optimism may persist in future news stories on the same genes and the prior stories may not be retracted (Conrad and Weinberg 1996; Petersen 1999; Conrad 2001; Conrad and Markens 2001).

Hype or bias may be less reflected in the *accuracy* of the reporting than in the *selection* of the research to be reported on; this is likely to be especially consequential for those stories that are not selected for coverage. The media rarely report on conflicts of interest (Schuchman and Wilkes 1997). Information may be withheld or not properly explained by scientific research sources, for example, due to pressure from funding bodies or corporate sponsors. There is also a bias against reporting on studies with negative results (Koren and Klein 1991; Conrad 2001; Geller *et al.* 2002). The omission of facts of a story is another form of hype or bias. For example, while most media stories may be technically accurate, omissions may leave readers with the overly optimistic impression that the discovery of new genes can have immediate implications for broad segments of the population, including improved treatments or prevention (Bernhardt *et al.* 2000).

Furthermore, journalists have been accused of acting as a cheer squad for the scientific community (Petersen 2001). Genetics stories are framed as ones of hope, with scientists depicted as warriors or heroes. The influence of non-genetic factors and 'multifactorial' interactions on disorders may be underreported. Nor is there much questioning of the goals, the direction, the methods, and the value of genetic research.

Bubela and Caulfield (2004) found that the majority of newspaper articles were faithful to their scientific journal paper source. Only a minority (11%) presented claims that were exaggerated or went beyond those made in the concluding paragraphs of the scientific journal paper, where some speculation is often made by authors about the possibilities of further research or about the human benefits of the research. The study found that – in an attempt to increase readability and excitement – the media may over-emphasize 'sexy' or 'bizarre' news topics, thereby sacrificing the accuracy of the news items covered and ignoring other, more scientifically worthy ones altogether (Bubela and Caulfield 2004). For example, newspaper articles were more likely to by hyped if the topic was behavioural genetics (*e.g.,* sexual orientation, alcoholism, mental illness, or criminality genes); genetically modified organisms (*e.g.,* glow in the dark rhesus monkeys or a genetically modified killer pox virus); longevity (*e.g.,* clock genes); or reproductive technologies (*e.g.,* the transplantation of the nucleus of an egg from one woman into the de-nucleated egg of another). Newspaper articles on diseases such as obesity were also more likely to be hyped while articles on life threatening and prevalent diseases such as cancer, stroke, and heart disease were not.

One of the areas of inaccuracy identified in the reporting on medical (Moynihan *et al.* 2000) and genetic (Bubela and Caulfield 2004) studies is the difficulty of reporting on the costs and benefits associated with the research, stemming from a lack of comprehension – both by the public and by journalists – with respect to the differences between absolute and relative risks and with regard to the nature of basic probabilistic analysis. Condit (2001) has shown that lay people have difficulty in dealing with numerical risks, or, at least, that they *assess* those risks differently than do professionals. Similarly, risks may be underreported, *i.e.,* they may be discussed without addressing side effects or harms (Cassels *et al.* 2003; Bubela and Caulfield 2004). In contrast, benefits are emphasized in both scientific and newspaper articles, contributing to a general hyping of genetic research. This has the potential effect of inflating expectations of the general public and special interest groups such as patient groups and investors (Bubela and Caulfield 2004).

In summary, there is little evidence for blatant sensationalism of genetic research by the media. If anything, media coverage is generally supportive of, and optimistic about, genetic research, at least in a medical context. Media studies tend to bear out the concerns of media critics, but not those of the research community, *i.e.,* the media act as an uncritical cheer squad for genetic research. The forms of media distortion (as opposed to hype) are more likely to be found in overly positive and uncritical framing, omissions of fact, selection of research stories with a bias against negative findings, and the likelihood that disconfirming studies will not be reported. Contrary to the journalists' own code of relying on the peer-review process, covering research that appear in

reputable journals, the media do publish preliminary findings that may never be published from scientific meetings as if they were scientific fact. Due to such practices, the social and ethical debate is not being heard.

3.3 *Do Scientists Hype Genetic Research?*

Who has the most to gain from genohype? The media gain by presenting stories that are of interest to the public through increased readership, listenership, or viewership. Yet, what about the research community? If scientists have such a negative view of the media's ability to communicate their research to the public, why do they interact with the media at all?

Media interviews function in a public relations capacity (Nelkin 1995); they may help researchers achieve their overall professional goals, including improving their image, both within the lay and within the research communities. Media coverage may help researchers get funding (Wilkes and Kravitz 1992); is valued by institutions (Nelkin 1995); and increases awareness of research. Other advantages relate to esteem, academic rank, salary, promotion, and opportunities to collaborate (Market and Opinion Research International 2000). All of these are more likely if scientists promote themselves as making big advances in research (Wilkes and Kravitz 1992). Indeed, scientific research that generates media coverage is more likely to be cited by peers in the scientific literature than scientific research published in the same top-end journals that does not, suggesting that scientists are not immune from media representations (Phillips *et al.* 1991). Yet, scientists have a duty to act responsibly when dealing with the media, by avoiding the temptation to exaggerate the significance of their work (U.K. Royal Society 2000).

Scientific institutions and journals, too, have much to gain, including increased prestige, research funding for institutions, and high quality submissions and readership for journals (Wilkes and Kravitz 1992). Institutions and journals issue press releases that have been found to be inaccurate and incomplete. Press conferences are encouraged even in cases where the data being discussed are preliminary. Scientific organizations may invite the media to their press conferences without providing explanations of methodological and statistical concepts or without access to scientists who can critique the research project in question. Large and prestigious scientific conferences also receive substantial media coverage (Schwartz *et al.* 2002). However, as was stated above, retractions or disconfirming studies are rarely printed.

In summary, both the scientists and the media have something to gain from genohype (Sibbison 1998). On the one hand, scientists get caught up in the hype: the media are more likely to cover a big story, so there is a strong incentive for the scientists to make their research story appear more important than it really is. On the other hand, the journalist has a more readable story that is more likely to be selected by editors for prominent placement in the media.

Both sides may thus be complicit collaborators in overstating the advances in research (Sibbison 1998).

4 DOES GENOHYPE MATTER?

4.1 *Is There Evidence That Media Hype Influences Public Opinion?*

Media effects on public opinion are generally overstated. Yet, this does not mean that there is no effect at all. The media can focus public attention on some issues, and away from others ('agenda setting') and they can frame issues in ways that benefit some stakeholders but not others. However, there is little evidence that this occurs unilaterally. Journalists are heavily dependent on their sources, and those that are more prominent or better funded are more likely to receive coverage (Priest and Gillespie 2000).

That genohype matters is premised on the argument that the media play an educational role, by interpreting complex scientific research and translating it for the public. It is true that the public gets most of its information about genetics and biotechnology from the media. The next step is to assume that, if the media reports are sensationalized, this will influence public opinion to be either irrationally for or against genetic research. The research community often argues that lack of scientific literacy or knowledge in the public will somehow drive the public to irrationally reject new genetic technologies.

In the case of GM food, there is little evidence that the media have influenced public opinion on this issue (Gaskell *et al.* 1999). The general tone of press accounts on GM food in Europe and the U.S. has been very similar, and, if anything, European coverage may have been more positive. Thus, the more negative reaction in Europe cannot be attributed to the impact of a more alarmist media coverage. With respect to the argument that the media act as educators, it can be noted that there also appears to be strong opposition to GM foods in some countries with high levels of scientific literacy, thereby calling into question the hypothesis that public concerns are associated with public ignorance (Priest and Gillespie 2000).

Studies on whether media coverage of medical genetics shifts public opinion towards a more deterministic view of genetics (Nelkin 1995) have reached a variety of conclusions. One study found that the reason public opinion may not have become more deterministic is that present media coverage is no more biologically deterministic than its antecedents (Condit *et al.* 1998). In contrast, hyped and inaccurate media coverage of the genetic basis of homosexuality influenced public opinion towards greater acceptance of genetic determinism, with concomitant positive effects on substantive equality rights for gays and lesbians (Petersen 1999, 2001; Conrad and Markens 2001).

In summary, there is little evidence that the media play a predominant role in shaping public opinion. Other factors, such as the perceived utility of the application and the risks associated with it, combined with an innate sense of

moral acceptability, are more determinative of public opinion. Hence, we would like to argue that the media, rather than influencing public opinion, merely reflect it, being more optimistic in their coverage of medical genetics (with the exception of cloning) and more pessimistic in the way they treat agricultural biotechnology.

5 CONCLUSIONS

Scientists believe unjustly that the media are distorting their message. Research has shown that the media are accurately conveying the results of scientific research. In general, journalists select stories from high-quality and peer-reviewed scientific sources, supplemented by information acquired through direct interactions with researchers. Nevertheless, the public remains under-informed on biotechnology-related issues, and is suspicious that the media are sensationalizing scientific research. As a result, the public does not trust the media as a source of reliable and balanced information. Paradoxically, the public does trust the scientific community, which supplies the information to the media, despite the fact that scientists have more to gain from exaggerated research claims. However, the research community may eventually lose this position of trust, especially if it becomes viewed as overly arrogant, self-interested, and industry-oriented. The aura of secrecy and mystique that surrounds science, and the sense that work is being conducted 'behind closed doors,' breed public distrust.

The best way to foster favourable public opinion is to encourage open and inclusive public debate. The corollary is that the scientific community must be willing to accept that some research avenues are simply not acceptable to the majority of the public and should potentially be reconsidered. Rather than blaming the media – who are firmly presenting a pro-science position – scientists need to demonstrate the utility of their research, and they must provide a fair assessment of the risks involved.

Despite the fact that the media report fairly accurately on genetics and biotechnology, there is still a need for reform in their coverage of those issues. This stems from the conclusion that sensationalism is not the main form of media distortion, but that framing and coverage are. Contrary to the views of scientists, the reform needs to be in the direction of increasing the number of voices presented in the debate, including those of ethicists and other special interest groups. The media should question the rational and social implications of the research, and not merely report on seemingly disparate and isolated research discoveries.

The media should present coverage that puts the public in a position in which it is able to form a reasonable opinion. Instead of presenting coverage that is either entirely positive or entirely negative, the media must recognize that the public "sees and understands that the picture may be more complex, that there are uncertainties to what we know and much still remains that we don't know" (Einsiedel 2000a, 29) Media coverage should entail much more than educating

the public about scientific facts and methodologies; the public should be given a framework in which to place both breakthroughs and disasters, and everything in between. The public wants and deserves information that is "genuinely objective and distanced from the very many, often very powerful interests participating in the debate" (U.K. Office of Science and Technology 2000, par. 4.32).

Finally, the research community and regulators should be very concerned about the lack of confidence in public policy on genetics and biotechnology. Trust may be increased by involving the public in the development of research agendas, policies, and regulation. The media should, therefore, have an important role to play in encouraging public discourse and in explaining regulatory policy as it develops.

In conclusion, we return to the central question posed in this chapter, does genohype shape public opinion? There is little evidence of genohype; any media hype that may exist is more subtle. There is little evidence that media coverage is the sole factor responsible for shaping public opinion, but there is no doubt that it has at least some influence. At the same time, media coverage reflects public opinion, a conclusion that scientists involved in more controversial research may find difficult to accept. More research is now required to address the question of how politicians and regulators are influenced by the media and the public discourse reflected therein.

Notes

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8 Lay People Actively Process Messages About Genetic Research[1]

Celeste M. Condit

1 INTRODUCTION

GENETICS RESEARCH HAS RECEIVED SUBSTANTIAL attention in the popular media in the past several decades. Most of the coverage has been favourable (Conrad and Weinberg 1996; Condit 1999; Conrad 2001), while some of it has been highly sensationalistic (Henderson and Kitzinger 1999). A variety of scholars have worried that this coverage would lead the public to adopt inappropriate conclusions about the implications of genetics research and the role of genes in human characteristics such as health, behaviour, or abilities. Two concerns have been central. The first is that people would become more 'genetically deterministic,' that is, that they would assign genes the sole or dominant role in human outcomes. The second concern depends on the first. It holds that, as people come to believe that behaviour and abilities are genetically determined, they will become more discriminatory, because they will believe people are essentially and inevitably different from one another in a hierarchical, rankable manner.

In contrast, but in agreement with contemporary theories that argue for an 'active audience,' our recent research has found that a majority of people tend to resist messages and interpretations of messages that assign genes an exclusive or even dominant role in human characteristics. In this chapter I will briefly discuss the 'determinism problem,' and then review four studies that reveal active lay processing of messages about genes. The chapter will be concluded by outlining some competing values that lead the majority of lay people to interpret messages about genetics in a resistant fashion, or in ways that subordinate genetics to other factors.

A variety of scholars have worried that press coverage of genetics is excessively deterministic. The most highly quoted book about genetics is probably Dorothy Nelkin and Susan Lindee's (1995) *The DNA Mystique*. In this book, they argue that

> The images and narratives of the gene in popular culture reflect and convey a message we will call genetic essentialism. Genetic essentialism reduces the self to a molecular entity, equating human beings, in all their social, historical, and moral complexity, with their genes (Nelkin and Lindee 1995, 2).

Others have called genetic determinism "geneticization" (Hubbard and Wald 1993). Whatever name it goes by, the general belief is that press coverage, like other popular representations (such as science fiction [Van Dijck 1998]), portrays genes as the sole source of human characteristics. However, there is substantial disagreement about how important a role genes should be assigned in any given case. In part, these disagreements are due to the fact that genes arguably play a greater or lesser role in different human characteristics. For example, most people would grant that genes play a relatively large role in a disease like Huntington's chorea but a much smaller role in one's choice of companions. This indeterminacy is exacerbated by the fact that in all cases genes and the environment interact, so that one cannot truly say that genes exert 30% of the influence and environment 70%. Different environments enable the expression of different genes, and different genes simultaneously 'niche pick' different environments (Wilson 1998). Moreover, as E. O. Wilson (1998) has pointed out, in most cases one cannot ethically derive "norms of reactance" for humans to provide definitive answers to questions about the relative role of genes and environment.

The indeterminacy of the role of genes is further complicated by differences in attitudes toward genetics. Some scholars believe that, for socio-ethical reasons, genes should not be attributed any influence in almost any case, and that any mention of genes is tantamount to genetic determinism. Other scholars believe that genes do, in fact, play a substantial role, so that some mention of genetic influence is appropriate. For the latter group, genetic determinism occurs not whenever genes are mentioned, but only when genes are assigned an inaccurately large amount of influence.

As much as possible, our research group has tried to respect and understand both of these perspectives. To do this, we have tried to interpret lay understandings of genetics, not by comparison to either one of these implicit definitions of genetic determinism, but rather in terms of changes in lay attitudes over time. Thus, our focus has generally been on examining whether or not messages about genetics make lay people *more* genetically deterministic. After conducting several studies, we found that we were unable to increase people's level of determinism,

using a message that we thought was ethical or at least typical. We continue to try to do so, but this is not an easy task; the difficulties involved relate to recent developments in theories of media.

During the closing years of the twentieth century, much research in cultural studies was developing the tenet that lay audiences actively and selectively interpret the messages they receive from the mass media. Our findings cohere so neatly with these theories that we have integrated the empirical work with the theoretical perspectives inaugurated by David Morely (1980), Janice Radway (1984) and Stuart Hall (1999). These theoretically based lines of research have demonstrated that lay audiences often do not respond in a passive, accepting manner to mass media messages. Instead, they select those message components with which they agree, and they re-interpret or reject messages with which they disagree. This portrayal of mass media audiences is quite different from the one assumed by critics of genetics in the media.

Most critics of media coverage of genetics have presupposed a worst-case scenario. They assume that whatever constitutes the worst possible coverage of genetics in the media is the understanding of genetics that is adopted by the public. Barbara Katz Rothman, the author of two highly successful books about genetics, expresses that perspective when she writes:

> Those of us who have made this "our issue" read those articles carefully, pounce on the qualifications, the uncertainties that follow the headline…. But for everybody else for whom that is *not* the issue they focus on, we see the headline, glance at the article, get a sense of the issue, and fold the paper as the train reaches our stop (1998, 136).

This is a rather paternalistic view of the public. It presumes that if the public is busy, they will simply adopt whatever headline they see. Fortunately or not, people are much more conservative about their attitudes than that. They resist change or messages that conflict with their pre-existing attitudes. In the case of genetics, a series of studies we have done indicate that attitudes assigning influence to individual will, social nurture, and religion appear to serve as substantial sources of resistance to wholesale adoption of genetic determinism.

3 Four Studies of Lay Responses to Messages about Genetics

3.1 *The (Non)impact of Headlines*

Surely, few English-speaking Americans can avoid having seen or heard headlines about genetics. As several theorists have suggested (Tannenbaum 1953; Leventhal and Gray 1991; Pfau 1995; León 1997; Sheedy 2000), exposure to headlines raise two concerns. The first is that lay people will eventually be convinced, by the sheer number and presence of headlines, to adopt genetic determinism. Our

team is currently engaged in a 'multiple exposure' study to explore that possibility. The second possibility is that highly deterministic headlines 're-frame' the content of articles about genetics that may more accurately describe genetics. By exerting a 'framing effect,' some researchers have found that headlines can lead audiences to particular conclusions (Tannenbaum 1953; Pfau 1995), even if the article itself might not explicitly endorse such conclusions. In a recent article (Condit *et al.* 2001), we explored that possibility in two linked studies about a news article about genetics.

The two studies consisted of a quantitative message impact study, followed by an interview study, which we used to gain a more fine-grained understanding of people's conceptions of news articles as they read. In the quantitative message impact study we selected an existing news article about genes and diabetes, and then removed from the article any sentence or phrase that we felt was strongly deterministic. The resulting message assigns a role to genes in diabetes, but not a dominant or exclusive one. Then we gave the message the headline "Scientists Discover Gene that Causes Diabetes," or "Gene May Play Role in Diabetes Puzzle: Germs, Genes, and Diet All Contribute to Common Condition," or no headline at all.

If the deterministic headline re-framed the message to enhance deterministic understandings, then those readers who were exposed to the deterministic headline should have expressed more deterministic attitudes than those who did not. Moreover, at least those who were exposed to the deterministic headline should have increased their levels of determinism. In fact, neither of these possible outcomes was observed. There were no differences between groups by headline type, and participants in all three groups actually reduced their levels of genetic determinism to a significant degree ($p = 0.001$).

The interview study helped us to understand why the deterministic headline did not have the negative impact hypothesized by the passive audience perspective. First, our lay readers had little difficulty in understanding that diabetes was a complex disorder that was brought about by a multitude of causal factors, and that manifested itself in multiple ways. Here are some sample responses:

- It tends to say that there are still more questions than answers and even if these questions get answered, it will affect very few people that have diabetes.
- It means that they… well, not as strongly as I had thought to begin with… It's more complex than just genetics.
- It means that they have discovered a gene that might be one of the causes of diabetes.

Thus, lay people do not seem to assume that any mention of a role for genes means that genes played the only role. Additionally, participants were sceptical about headlines, and they did not let the headlines frame their understanding. Just

because the headline appeared to make a claim did not mean that they believed it, especially when that claim was not consonant with the article itself.

Although the results of this study are not definitive, they do not support the paternalistic view of audiences, and many alternative approaches to the issue need to be pursued as well. One other approach we have taken is simply to ask people what a particularly controversial phrase often found in headlines means.

3.2 *What Does 'a Gene for Heart Disease' Mean?*

In 2001 we conducted a series of thirteen focus groups with lay people and asked them, "What does a 'gene for' heart disease mean?" (Bates *et al.* 2003). We coded the discussion in order to explore their perceptions of the degree of influence genes had on the likelihood that a particular individual would get heart disease, and for the amount of additional risk this would give one. Of those who gave a relevant response, only one third (32%) said that the statement meant that genes were the only factor. The majority (57%) said that the phrase meant that genes were involved with other factors in causing heart disease. A surprising 11% rejected the statement altogether, saying that genes played no role at all in heart disease. Similarly, the participants tended not to see the genetic predisposition as absolute. Less than a third (28%) said that if you had a gene for heart disease, this meant that you absolutely were going to get heart disease. The majority (57%) said that it simply heightened your risk. The resistant group, this time 15%, claimed that it did not increase your risk at all.

Although there is clearly a substantial group in the public that might be labelled genetic determinists (less than a third, but more than a quarter), the majority of the population seems to interpret even statements that appear highly deterministic, such as 'a gene for,' as part of a larger framework in which they incorporate other factors such as nutrition, environment, and exercise. This is not really surprising, because members of the public also hear many messages from the mass media and other sources that tell them that other factors – such as diet, exercise, and environment – play a role too. In other words, lay people do not forget everything they have heard, and they do not over-react to a single statement. Instead, they tend to interpret the statement in a fashion that fits it into their larger frameworks of understanding. Of course, it is possible that this could be changed by repeated exposure, which might, over time, increase the perceived role of genes and decrease the perceived role of other factors. A naturally occurring experiment suggests that substantially more deterministic coverage than currently exists in the media would be required, to cause such a change.

3.3 *Public Response to Coverage of Genes and Alcohol*

In 1996, Peter Conrad and Dana Weinberg published one of the earliest and most systematic studies of the media coverage of genetics. In an article titled "Has the

Gene for Alcoholism Been Discovered Three Times?" these authors examined news coverage of genetic links to alcoholism from 1980 to 1994. They concluded that "the media generally adopt a 'genes cause alcoholism' frame, emphasizing genetic factors and de-emphasizing or minimizing criticism, disconfirming studies, and alternative environmental explanations" (Conrad and Weinberg 1996, 3–4).

As Conrad and Weinberg document, the public had been receiving substantial messages linking genes and alcohol for at least two decades. If the paternalistic view of the public were correct, we would expect the public to attribute alcoholism exclusively, or at least predominately, to genetics. A survey of poll data published by Singer *et al.* (1998) shows that that was not the case. These researchers reported several polls, which showed a pervasive tendency by the majority of the public to hold the view that both genes and the environment are important in human outcomes, but that, most often, the environment is more important. Specifically related to alcohol, they summarized a poll by KRC Research and Consulting Inc., conducted in 1997, indicating that only one in ten respondents (9% of the population) attributed alcoholism solely to genetics, while only 24% said that it was mostly genetic. The majority of the public said either that genetics played "some" role (44%) or no role at all (20%). Despite many years of media announcements that "genes cause alcoholism," the majority of the public had not been persuaded by that view. This suggests a strong resistance to genetic determinism. This resistance is even stronger with respect to topics of high salience for special groups.

3.4 *Rejecting Messages Linking Genes, Race, and Medicine*

Our studies suggest that the majority of the public is unlikely to fall into the 'genetic determinism' trap. The resistance to such a worldview appears to be even stronger when genetic determinism is directly linked to issues of discrimination among racial groups. In 2002, we conducted ten focus groups with lay people. In that study, we offered them a message about an imaginary drug, "Fairdil," and then asked them to discuss the message, which read:

> If you are of African ancestry and you have a heart condition, the best drugs for treating you may be different than the drugs used for people of European ancestry. Compared to other medicines, Fairdil has been proven to be more effective for more African Americans in treating high blood pressure. Talk to your doctor to see if Fairdil is right for you.

We coded participants' comments on the message in terms of their general reactions (Bates *et al.* 2004). Only 20% of the participants indicated that they agreed with the message. Almost half (47%) of the respondents expressed overt

resistance to the message, while 4% said they wanted to investigate the message more closely before making a decision, and 28% made non-responsive comments (for example, changing the topic).

Those who rejected the message cited many different reasons for doing so. The largest single reason, articulated by 19%, was that the message risked racial discrimination. Others indicated that races were not genetically distinct (8%); still others emphasized individual differences within races (9%), or suggested that it risked either genetic discrimination (4%) or unspecified discrimination (8%). A large group (19%) simply said that they rejected the message, without giving a reason, while 15% held the view that the message was part of a conspiracy by the pharmaceutical industry. This was clearly not a message that most of our participants accepted passively. It seems that issues with a potential for discrimination tend to intensify the rejection of genetic determinism, rather than acceptance of determinism increasing acceptance of discrimination.

This strong reaction illustrates the way in which pre-existing values are brought to bear upon the messages about genetics that people hear. Our participants did not trust the motives of pharmaceutical industries, and they did not trust messages that espoused biological distinctions among races. Hence, they rejected the genetic claims in these messages. Public sensitivities about racial topics are not the only values that lay people bring to bear when they hear messages about genetics. Other important and highly salient values include social nurture, individual responsibility, and religion, all three of which appear to play a strong role in rejection of genetic determinism by the lay public.

4 SOURCES OF RESISTANCE

So far, our team has conducted thirty-nine focus groups. When we have asked people to talk about genes and various kinds of human behaviours, or to respond to messages about genetics, we have routinely received answers that highlight the strong role of individualistic thinking in the rejection of genetic determinism. The most extreme example that we have found illustrates this line of thought most clearly. A participant in one of our focus groups said:

> Even though you might receive a gene for high tolerances … [an] alcohol gene, or anybody in your family [had] an alcoholic gene and was more likely to be an alcoholic, you have to make the choice to be an alcoholic. Or if you receive any kind of trait – I know my dad is stubborn and I am stubborn like him too, but … that means I can change my mind not to be stubborn all the time.

This idea, that individual will can trump genetic predispositions, was expressed in a more moderate form by other participants. One, for example, said, "Well, I mean if you are genetically predisposed to being an alcoholic, but you never

drink alcohol, then … you are changing the effect that your genes would have on you." This emphasis on individual choice can even result in a quasi-Lamarckian interpretation that suggests that new traits can be generated and passed on down the family line, as another participant's comments indicate:

> Education … if you have some kind of gene make-up where you don't learn as well or as quickly or easily as someone else, if you just start getting real busy reading and learning and … pass it on to your son and all of those things, it might develop into a very intelligent life form in the future.

Most lay people do not see 'bad' genes as insurmountable barriers to success. If you have a lack of natural ability, it is widely believed that you can compensate for that by choice and through focused effort. Even those who might say that a person can not completely overcome such predispositions tend to hold each person responsible for 'playing the hand they are dealt' in such a way that they 'win.' In the words of one of our participants, "I think anyone has the capabilities to do well. They're not going to be an Einstein, but they are going to be able to succeed." Another participant likewise indicated: "I don't think that everything is MAPPed out for you. I think you are given so much, and then you use your abilities to go and take your abilities to do something with it. … Do with it what you will."

The common lay emphasis on personal will and individual responsibility reflects the idea that the choices people make are a product of their values. These values are also frequently understood, not only as a product of personal choice, but also as a product of nurture by families, teachers, and other individuals who surround children as they grow up. One woman expressed this view by saying:

> [I]f we talk about things besides disease and want to talk about the achievement of people … I mean there are a lot of people who probably would never have measured very high on an IQ test, even maybe a very good one. But because of a nurturing environment, and maybe good teachers and good work habits and a certain drive to succeed or a certain caring about a certain cause, they achieved great things.

These attitudes are most common with regard to social characteristics like achievement or drinking. Lay people are more likely to attribute greater genetic causation to physical attributes, rather than to personality qualities or behaviours. Yet, even these physical features are seen as substantially a product of nurture. As another participant indicated:

> Well, height might be [genetic], but there are hundreds of different sports out there. So let's say a basketball player might not breed a basketball player or might not breed an athlete at all. It may be how … he may be genetically … every person may be genetically predisposed to be an athlete. It's how we nurture that child whether or not … that predisposition is going to be influenced or not.

Both the nurturing of others and acts of personal will are seen by members of the public as sources of influence that can override genes, making even admitted predispositions created by genes non-deterministic.

Finally, genetic determinism is not only negated by the very widespread beliefs in the role of nurture and personal will, but also by strong religious beliefs, held by a substantial group of people. A quarter to a third of the respondents in our surveys indicate that the impact of genes is overridden by intervention from a Higher Power, or that an individual can gain such intervention through prayer. In a community-based survey of 858 participants, 32% either "strongly agreed" or "agreed" with the statement, "I can influence the impact of my genes on my health through prayer" (see Parrott *et al.* 2004). Similarly, 28% agreed with the statement "A Higher Power than humans predetermines whether human beings get disease." Although this is not a majority of the population, for this substantial group of people, genes are not the final influence on human characteristics.

5 CONCLUSIONS

Most people appear willing to accept that genes play a role in a wide range of human characteristics. However, because they have a strong sense of individual responsibility, personal will, or divine influence, they do not believe that genes are determinative. Instead, for the most part, lay people perceive genes to exert an influence that can be overruled through good nurture, personal effort, or religious force. Messages about genetics that run counter to these beliefs are not easily accepted by most lay people. They are either rejected outright or re-interpreted so that the influence of the genes is understood to carry its own weight, but coordinated with or even subordinated to other forces.

The studies we have performed show this trend to be a strong one. However, a variety of additional issues need to be researched. It is not clear what the boundary conditions for these attitudes might be, that is, what kinds of messages about genes might have the most influence toward determinism or discrimination. How much repetition is required for these other attitudes to be modified? How dependent are these other attitudes upon reinforcement from other messages about religious force, individual will, or social nurturing? Human attitudes, even resilient ones, generally have their limits. One of these appears to be social status, as our surveys also suggest that persons with more social power – *e.g.,* white males with high income – are more likely to express genetically deterministic

views. This suggests that future research needs to explore the disparate impact upon public policy that results from differently distributed views about genetics. In any case, more sophisticated understandings of media effects need to be developed if we are to account for social changes that may result from the science of genetics.

Notes

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9 Telling Technological Tales: The Media & the Evolution of Biotechnology

Edna Einsiedel

1 INTRODUCTION

WHEN TECHNOLOGIES EVOLVE, THIS EVOLUTIONARY LIFE can proceed in different directions, a process shaped and reshaped by various social actors. At least some elements of this process unfold in the public sphere and such developments can be viewed through the media. Even the media assume the role of social actor in the way they narrate, highlight particular voices while ignoring others, or package stories within particular modalities.

Biotechnology has enough of a technological history to be able to discern patterns in the way the media have acted as social actors. This activity is often purposeful; that is, the media choose subjects to tell stories about, rely on or talk to particular sources (and ignore others), follow particular professional conventions in such narratives, and are guided by assumptions about their audiences. In addition, there is also a less conscious process of social construction, occurring as a compendium of stories over time, providing a portrait of media activities that emerge from a series of individual stories. One can then reconstruct a response to the question posed in this chapter: What roles have the media assumed in contributing to the developing trajectory of biotechnology?

Biotechnology, of course, is a term that encompasses a large number of subjects. The period covering modern biotechnology has typically been marked by the discovery that it was possible to transfer genes from one species to another. Since then, it has evolved into a variety of applications, with the most controversial being generically modified (GM) food.

The dynamics of media coverage of biotechnology in the elite press across many European countries has been extensively described earlier (see, *e.g.,* Gutteling *et al.* 2002). The approach in such studies has typically involved the developmet of a coding frame, working with pre-selected and predefined categories. In this study, which covered a twenty-four-year period, for example, a clear increase in attention to biotechnology was documented, with such attention marked predominantly by positive coverage, although the extent of the positive or negative tone differed among the fourteen countries involved. Positive framing was also associated with medical stories, while more negative slants occurred with GM food and crop stories.

A similar analysis was carried out in Canada (Einsiedel and Medlock 2001) with the corresponding finding that overall, coverage tended to be positive, that benefits tended to be more frequently highlighted than risks, and that business tended to be a dominant voice. This coverage pattern changed between 1996 to 2000, with increased attention to non-government organizations' opposing views towards GM food in particular. At the same time that this attention to more varied sources and points of view developed, Canadian pubIics during this period also became more cautious toward the technology (Einsiedel and Medlock 2001).

In addition to these patterns, what can we deduce from other studies on media coverage of biotechnology in terms of the roles the media play in how a technology evolves? What does the research say about what the media *do* in the social shaping of technology?

Our examination of the roles played by the media with regard to biotechnology can be summarized thus: in general, we have found that the media can set agendas for public discussion and consideration, they contribute toward *how* these issues are considered by means of their packaging approaches, they enlarge the dissemination channels by which information about science and technology is circulated, they contribute to shifting trajectories of innovation processes through their spotlighting and promotional functions, but they have also provided an important tool through which science dissemination patterns have changed. We will discuss each of these issues in turn.

2 SUGGESTING PUBLIC AGENDAS & PROVIDING LINGUISTIC RESOURCES

While much influence has been attributed to the media, a body of research has also demonstrated this influence to be mediated by other factors. While the media have been able to set agendas (McCombs 1981) – *i.e.,* suggesting to publics what they might think *about* – their influence has been more limited when it comes to telling publics *how* to think. Although this initial contention has been modified further, such a function of agenda-setting remains an important one.

As an elaboration of the notion of setting public agendas, Shaw and Martin

(1992) suggest that – in addition to setting the public agenda – inadvertently, the press may also provide a limited and rotating set of public issues around which publics and policymakers engage in discussions. As Shaw and Martin suggest, "The press does not tell us what to believe, but does suggest what we collectively may agree to discuss, and perhaps act on." This set of issues for discussion is limited to about seven, give or take one or two, which vie for public attention at any one time, although, with the rise of media niche markets, such a limit might be more expandable (Hertog *et al.* 1994).

Besides setting the agenda of issues, the media also introduce terminology to the public that can quickly become part of the public lexicon. Though difficult to recall, there was a time in the media coverage of biotechnology when the term 'DNA' had to be followed by the full scientific name 'deoxyribonucleic acid.' Today, DNA has permeated popular culture so fully (Nelkin 1987) that its acronym can be used in advertising taglines and audiences 'get it.' Such terms as 'cyberspace' and 'the information superhighway' have had similar experiences. In the U.K., the term "GM" came to be part of general parlance through the GM food debates in the 1990s, heavily covered by the British press (Durant and Lindsey 2000). Popular culture provides further resources that the media can draw on, using images that have quick resonance with audiences (Turney 1998). When Dolly the sheep was announced to the world, the newspaper stories in many countries utilized very similar cultural resources, from Frankenstein to biblical allusions (Einsiedel *et al.* 2001). Stakeholder organizations have proven adept at relying on similar cultural resources in the labelling game, wresting the framing initiative early on – for example, the "terminator seed" is one label utilized in the media that has become the short-hand for gene use restriction technologies.

3 FRAMING & PACKAGING STORIES

There is considerable literature on the notion of 'news frames' (see, for example, Gitlin 1980; Entman 1993; Iyengar 1994). The concept arises from the idea that the media can define public images through the production of persistent patterns of selection, emphasis, interpretation, or exclusion. Of necessity, these frames tend to be drawn from – and reflective of – shared cultural narratives (Iyengar 1994). In the case of television, because of the medium's emphasis on the episodic in contrast to the larger picture or contextualized narrative, such coverage may have an impact on choices people make, for example, in terms of their openness or aversion to risk (Iyengar 1994) or in the way social problems are defined and attributed (Shah *et al.* 2004).

A case study of media coverage of Dolly the sheep – the first mammal cloned from an adult cell – showed that the way the media framed this event went beyond a narrative on animal cloning, becoming instead a signal for the slide towards human cloning (Einsiedel *et al.* 2001). The story frames were predominantly of doom and secondarily of progress. In the case of the former, the story

of Dolly became a story about science's uneasy relationship with society, with the news stories' emphasis on the themes of 'run-away science,' the dangers of crossing boundaries and 'playing God', and the threats to human identity.

The contrast in public perceptions on biotechnology in the U.S. and in the U.K. has been attributed in part to the generally more positive framing of biotechnology in U.S. media, in contrast to that in the U.K. (Marks *et al.* 2002). Comparisons of U.S. and U.K. elite newspaper coverage showed U.S. media (in this case, *The Wall Street Journal*, *The Washington Post* and *USA Today*) devoting more coverage to GM foods' benefits (Marks and Kalaitzandonakes 2003). However, in 2000 and 2001, negative coverage increased in the U.S. press because of certain controversies, specifically the Starlink case and that of the monarch butterfly and Bt corn. In the U.K., on the other hand, attention to GM food risks in *The Times* and *The Daily Telegraph* was higher and occurred earlier than in the U.S. (Marks and Kalaitzandonakes 2003). Biotechnology stories in U.S. newspapers further showed a strong reliance on industry and scientific voices, underlining economic considerations and potential benefits (Hornig-Priest 1994).

The impact of media attention and framing has been demonstrated in reader judgments of the frequency or likelihood of events. Because we remember recent experiences or reports, the recollections of immediately available information such as items in the news can have a significant effect on judgments or decisions, a phenomenon called the "availability heuristic" (Kahneman and Tversky 1973; Kahneman *et al.* 1975).

4 DISSEMINATION, HYPE, & SALES

The media can become important instruments for extending the dissemination channels for scientific information. Is this a straightforward transmission or do stories get shaped and reshaped under certain conditions?

Bubela and Caulfield's examination of newspaper articles on gene discoveries in Canada, the U.S., the U.K. and Australia and their comparison to the scientific publications on which they where based (Chapter 7, this volume; also, Bubela and Caulfield, 2004) demonstrated that there was less hype than expected. Over 60% of the articles had no exaggerated claims at all, and only just over a quarter had slightly exaggerated claims. The articles tended to be exaggerated depending on the topic – with certain topics lending themselves to hype, such as behavioural genetics, GM organisms, longevity, or reproductive technologies – or if there were costs or risks associated with the research. Their finding that any sensationalism found in newspaper articles can be traced back directly to the scientists and the research institutions through interviews and press releases is telling, suggesting that the assumption, particularly among many in the scientific community, that sensationalism or exaggeration occurs only when the information is in media hands may not be entirely accurate.

On the other hand, sociological studies of media work demonstrate that news production is regulated by a culture of practices and systems of news

production, which also have impacts on the news product. Story-telling practices, news values (*e.g.,* human interest, conflict, consequences, etc.), and structural constraints (*e.g.,* deadline pressures), all contribute to how news is identified as 'newsworthy' and how it is produced. Part of this process is how relationships with news sources are developed and maintained. Reporting 'biases' or preferences do emerge. For instance, research with positive results tends to be reported more often than research with negative results. The great amount of coverage reporting a gene associated with alcoholism stood in striking contrast to the much more limited attention to stories suggesting the association could not be confirmed (Conrad and Weinberg 1996).

On the industry side, the media as a channel for advertising and promotion is an additional tool for industry to promote its message. Public opinion findings have demonstrated the differences between European and North American consumers, with the latter exhibiting less awareness and, overall, less concern than their transatlantic counterparts. This led to concern on the part of industry that in order to keep North American consumers from going the way of Europe, a large-scale campaign was required to keep U.S. and Canadian consumers "informed about the benefits of biotechnology." In April 2000, nine biotechnology companies including Aventis CropScience, BASF, Dow Chemical, DuPont, Monsanto, Novartis, Zeneca Ag Products, the Biotechnology Industry Organization (BIO), and the American Crop Protection Association launched the Council for Biotechnology Information (CBI) to provide such information (Krueger 2001) with a U.S. $50 million budget.

The Internet provides an important channel for information dissemination by particular actors. Monsanto, for example, established the Biotech Knowledge Center. This centre is a multilingual site, offering separate interfaces for users from different countries and regions. This site provides search functions (providing capabilities to access news items, technical reports, scientific documents, and press releases), a topic library providing information on country-specific subjects, on-line discussion sections in five different languages, forms for submitting questions and comments to the company and for signing up for periodic news updates by e-mail, links to a web site on biotechnology basics, and an on-line glossary of biotechnology terms (Biotech Knowledge Center, *n.d.*).

5 THE MEDIA IN THE KNOWLEDGE PRODUCTION & DISTRIBUTION SYSTEM

It is generally acknowledged that the media play an increasingly important role in how science is done. The impacts can occur – or at least can be viewed as occurring – at the funding end as well as in how research information is disseminated. One study found that 86% of scientists believed that publicity about their work sometimes helped them get research funds (Dunwoody and Ryan 1985). It will be interesting to see if this attitude today is more widespread. Additionally, researchers working on effects of electromagnetic frequencies (EMF) in the

context of public controversy over their risks indicated that a rise in research funds provided by the U.S. Congress could be attributed to media coverage of this issue over a two-year period from 1989 to 1991 (Newman 1992).

The media are playing an increasingly prominent role in the dissemination of new knowledge. While they previously played a role secondary to scientific publication, this has become more pronounced, with media dissemination sometimes taking precedence or at least occurring at the same time as journal publication.

There are examples to illustrate this pattern:

- A four-year race to sequence the breast cancer gene was carried out between a consortium headed by scientists at the University of Utah, other collaborating universities, and private sector support from Myriad Genetics (formed by the Utah researchers), on the one hand, and Eli Lilly and a mostly public sector effort led by scientists at Berkeley, University of Michigan, with support from the National Institute of Health (NIH), on the other. The race was 'won' by the Utah-private sector team headed by Mark Skolnick, the winner having been established by the 'first-to-publish' rule. To illustrate the importance of the media, a study detailing this race noted:

  > The article's publication was itself a media event and the discovery's disclosure rather unusual. The initial announcement was made on NBC News on 13 September 1994. The next day, *Science* announced that the article had been accepted for publication and, very atypically, sent it directly to the media. The National Institute of Health immediately scheduled a press conference publicizing the discovery and the contribution of its researchers. The news hit national newspapers on 15 September and appeared on the front page of the New York Times (Dalpé *et al.* 2003, 195).

- The story of Advanced Cell Technology and the company's announcement of the first human embryo cloning effort was similarly marked by publication in a new electronic journal with ties to the organization, *E-BioMed: The Journal of Regenerative Medicine*, coupled with an exclusive with *U.S. News and World Report* and *Scientific American* (Cibelli *et al.* 2002). This arrangement, while 'media-savvy,' was also considered by some scientists as "an unprofessional means of sharing scientific data" (Weiss 2001).

These recent examples belie the fact that the earlier years of modern biotechnology were similarly marked by information dissemination by means of press conferences. The discovery of a new recombinant DNA technique to produce human insulin became front-page news even before publication of the scientific

data (see Hall 1987). Similarly, a press conference provided the venue for the announcement by Biogen scientists of their success in cloning interferon-producing bacteria, with journalists receiving a draft of the scientific paper that was intended for submission to the *Proceedings of the National Academy of Sciences* (Van Dijck 1998). In expressing its disapproval of what it labelled "gene cloning by press conference," the *New England Journal of Medicine* warned then that such practices were bound to affect the public's perceptions of science in negative ways (Culliton 1981).

This is not to imply that the 'new' dissemination mode has replaced the more traditional approaches; rather, it is to suggest a keener sensitivity to – and savvy in – the use of media channels on the part of scientists, scientific journals, and research institutions to complement the more traditional publication paths. This is also not simply a case of the media used as tools by scientists; a symbiotic relationship often develops that is fruitful to both cooperants (Peters 1995).

6 MOBILIZING CAPITAL

Given the public interest in medical cures, it is not surprising that attention to medical biotechnology in the media has increased significantly. Cookson (2001) documented an almost tenfold increase in the number of articles in U.S. newspapers, from 124 in 1991 to 1,117 in 2000. Pharmaceuticals have also gained significant media attention, with stories in *The Financial Times* increasing in the same period from 783 to 3,092 items. In terms of resources, *The Financial Times* had a single reporter covering the chemical, pharmaceutical and biotechnology industries; ten years later, that number had increased to six (Cookson 2001).

The race to map the human genome highlighted the competition between the public efforts led by the NIH-supported team of Francis Collins and the private efforts led by Craig Venter of Celera Genomics. The need to establish a business model that would encourage use of its databases once completed required a strategy that would "communicate Celera's business model to support advances in drug discovery" and "build confidence in the value of Celera Genomics' data" (Holmes Report 2001). A public relations firm designed a strategy that consisted of:

- Educating target audiences on the significance of decoding the human genome for the future of medicine.
- Using each scientific milestone as a building block to educate audiences about the differences between Celera's approach and the 'shotgun sequencing method,' a reference to the public initiative approach.

These strategies were designed with so-called "media thought leaders" in mind, whom the company labelled "early adopters of covering the genomic revolution." Science writers such as Nicholas Wade of *The New York Times* and Justin Gillis

of *The Washington Post* were among these elite journalists (Holmes Report 2001). A key communicator for this strategy was Venter himself, who was described as never turning down an interview request, whether it was a small paper or an elite one (Holmes Report).

The company considered the impacts of these strategies to be a success. The coverage was so extensive and unprecedented that Celera no longer considered it a priority to track all the coverage. In terms of mobilizing capital, the company's quarterly report for July through September 2001 showed revenues rising to U.S. $18.3 million, in comparison to U.S. $8.3 million in the same period the previous year, an increase that was attributed primarily to new subscription agreements (Holmes Report 2001).

Even smaller companies needing to raise investment capital are adept at hiring PR firms to manage their promotional efforts. For example, Cambridge Antibody Technology Group (CAT), a U.K. biotechnology company, developed proprietary technologies in human monoclonal antibodies for drug discovery and development. The company needed to raise funds by issuing new shares. To do this successfully, it had to generate attention from the investor and business media communities. It had successfully negotiated a deal with the well-known Human Genome Sciences Inc. (HGS), which would support the company's work in further drug exploration. The public relations firm hired to design and carry out the communication strategy developed its plan around this deal with HGS. It then drafted press releases around this collaboration, targeted key financial reporters with phone calls and set up interviews with key company personnel, then set up further stories to be used in the "market report" sections of national newspapers following the share price announcements (De Facto Communications *n.d.*). The success of these efforts can be seen in these headlines: "Biotech frenzy boost Cambridge after announcing share offering" (*The Wall Street Journal*); "CAT shares leap 60% on genome link. U.S. link boosts Cambridge Antibody" (*The Financial Times*).

Even in the earlier days of biotechnology, the expectations of finding magic bullets provided the basis for capital investors to bet venture funds on various promised products. This was the case with the race to develop genetically engineered insulin. In the early days of Genentech, when the company needed venture capital to work on insulin, various stages of its work were publicized through press conferences. Their announcement of their discovery of somatostatin (a pancreatic regulatory hormone) was announced to the press, resulting in their raising a million dollars to carry out their insulin research. Their discovery of insulin, again announced via press conference, resulted in raising U.S. $10 million to do further work on interferon (Hall 1987). In his case study of Genetic Systems during the early 1980s, Robert Teitelman (1989, 29) observed:

> Talk of medical breakthroughs became pretexts to raise money. Capital accumulation was confused with speculation; rhetoric was mistaken for reality. Companies wielded complexity like a weapon.… The sheer distance from lab to clinic, from cell culture to human patient, created a sort of imaginative space and nurtured dreams of miracles and money.

The flip side of mobilizing capital is depressing capital. This might occur with a spate of negative stories, for example. While an economic study of the impact of media coverage of agricultural biotechnology news on the corn futures market found no such impact (Parcell and Kalaitzandonakes 2001), claims have also been made that a consumer backlash in Europe prompted sell-off of shares of Monsanto Europe (Teather 2002). This negative consumer reaction may have further led to the company pledging not to use genes from humans or animals in the food chain.

7 Signals for Controversy, & Technical Failures

Controversy is one of the news elements of value in news production. There are different kinds of controversies spotlighted in the media, including controversy over interpretation of the science, controversy over competing policy choices, or controversy arising from harmful consequences of an event. Sometimes, these controversies remain within the arena of particular communities such as the scientific community or the policy community. When the controversy is played out in the media, there appear to be a number of factors at play. Consider these examples:

- The controversy over StarLink corn grew out of the discovery that traces of genetically engineered corn (trade name "Starlink") – which had only been approved for use in animal feed – were found in human food. A consortium of environmental groups announced the results of their testing to the media and the outcry was immediate and front-page news (Barbosa 2000).
- The Monarch butterfly-transgenic corn controversy grew out of a letter to the journal *Nature*, which suggested that butterfly larvae did not survive after exposure to Bt corn pollen. This finding again created a significant stir in the media, with environmental organizations calling for moratoria on GM crops or further studies on environmental impacts of these crops, and scientists themselves participating in the extended debates playing out in the media over the science on the Internet (Shelton and Sears 2001) and in scientific publications (*e.g.,* Shelton and Roush 2000). The controversy that developed was blamed on such factors as greater public interest in

the issue because of the involvement of an attractive and sympathetic species, the Monarch butterfly; the public's environmental concerns; the involvement of environmental organizations already adept at garnering media attention; and personal interests and involvement among scientists themselves (see Shelton and Sears 2001).

These cases suggest that the features intrinsic to a story are one important factor in explaining media interest. In the monarch butterfly case, the combination of a glamorous indicator species and public interest in environmental issues provided one cue for coverage. However, this was occurring against the already prominent backdrop of attention to and interest in the issue of GM foods. With the additional push provided by environmental organizations, the story became tailor-made for front page attention. Without these features, it is unlikely that controversy within the scientific community concerning differences in interpretation of scientific data would be sufficient to generate such attention in the public arena.

8 CONCLUSIONS

It is clear that the media can exert important influences on technological trajectories, but these influences are not always unidirectional. The media enjoy certain degrees of freedom when they choose stories to play up or down or ignore but they also work in accordance with production practices of their profession and their conceptions of their audiences. While one could argue that the media are furthermore subject to the entrepreneurial skills of information providers – be they scientific organizations, scientists, or other advocacy groups –, such 'information subsidies' are not unwelcome, given the need to feed the media's daily content requirements. Publics are also active negotiators in dealing with such content (see Condit, Chapter 8, this volume) – the caveat is that not all publics are attentive or active information processors *all* of the time, creating opportunities for other sources to play some role in social constructions of what is 'real' about a technology.

In the context of scientific knowledge production, it is also evident that the media are increasingly playing a more prominent role in information dissemination at the earliest stages of the scientific research process. Given the changes in the environment within which scientists operate – including increased pressures to generate research funds, to commercialize scientific discoveries and to attract venture capital –, the various roles the media play can become central to the directions taken by biotechnology.

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Part 5

Second Thoughts

Ethical Issues

10 Ethical Analysis of Representation in the Governance of Biotechnology

Michael M. Burgess

1 INTRODUCTION

THE CENTRAL ETHICAL QUESTION FOR GENOMICS, or biotechnology,[1] is how to organize and regulate in the public interest. This raises multiple questions, including: How should one evaluate industrial, scientific, economic and moral interests? How should one compare and assess the interests of diverse people such as aboriginal populations, industry, consumers and citizens? And how should legitimate public participation be informed without being biased?[2] In this chapter, I will sketch an approach for the evaluation of ethical analyses of these issues, and describe the first step in attempting to inform ethical analysis of governance through an experiment in representation.

Practical approaches to ethics are well developed in health care ethics, particularly in consultation and analyses that support individuals making treatment decisions. Health care ethics also includes policy decisions, meso- and macro-allocation issues, as well as the governance of research. These issues pose problems of legitimacy and representation that are less relevant to case-based analyses. In the latter, experts present evidence about the uncertainties of a particular treatment for a particular patient, in order to ensure that the ultimate decision by the individual or appropriate proxy is as well informed as possible. Experts' interests in promoting their own practices, research, and interpretive perspective on the world become more apparent when the focus of ethical analysis is assessment of research and practices. Compounding the problem, the increasing alignment between research, industry, and public funding casts a shadow of concern about the 'objectivity' of expert opinion and research. At the same time, the range and relevance of non-expert – citizen and consumer – perspectives on policy related

to a technical topic is difficult to specify and evaluate. Hence, a central problem of ethics related to policy or governance is adequate representation and evaluation of diverse expert and non-expert perspectives. This is particularly true for people who hold a minority view or have poor access to the institutions with the power to set policy.

Genomics exemplifies these complexities, raising difficult issues related to intellectual property policy, prohibitions, public funding and benefit, market influence and international coordination. What, if any, are reasonable limits to scientific exploration or application through biotechnology? What represents appropriate use of public funds, and how should intellectual property be protected to promote innovation and the public interest? Should industry and science be required to establish environmental sustainability and safety for human consumption (precautionary principle) before being allowed to conduct research, trial applications or release products? And what are the effects of biotechnology on poverty and the growing concentration of wealth?

The notion of 'policy' is too narrow to cover this range of issues; thus, in this chapter, I will use the broader term 'governance.' Governments often lack the power that is necessary to enforce policy, and they have organized the provision of many public services through other, relatively autonomous organizations – including private entities – that operate either in partnerships with the government, or completely independently.[3] Combined with the proliferation of education and access to information, some commentators suggest that these factors might have beneficial effects, providing the conditions for multiple and novel opportunities to exercise citizenship (Stehr and Ericson 2000). Other analysts suggest that governance must include structures such as hierarchies, markets, networks, and steering mechanisms (Pierre and Peters 2000), as well as activities such as incentives, disincentives, education and coping (6 2003, 55). Perri 6 defines governance as:

> … the development and use of the principal means of power, insofar as this leads – intendedly (in the case of hierarchy and communities and certain kinds of networks) or unintendedly (in the case of markets and other kinds of networks) – to produce more, rather than less, orderly and coherent patterns of structures of social, economic and political life' (6 2003, 3; emphasis removed).

Appropriate governance is typically characterized as governance in the 'public interest,' which may be more complex than the basic notion of governance. Researchers focusing on ethics and biotechnology have been concerned with the malleability of the notion of 'public interest.' Sherwin (2001, 17) emphasizes the importance of "justly arbitrating among competing interests by establishing fair procedures that are responsive to the full range of interests at stake," and putting in place "an open and responsive process that will allow input from those whose

interests might often be overlooked or misunderstood." This includes avoiding the reinforcement of historical and structural inequalities (Sherwin 2001, 29). Sherwin (2001, 18) explains the distinction between 'consumers,' as stakeholders who need safe, reliable, affordable products, accurate information, and protection from exploitation, and 'citizens,' who are concerned with the broader social, cultural, or environmental effects of developing or distributing those products. She also summarizes important distinctions between protecting natural rights (the fair arbitration of competing interests), common goods (things of interest to all members of a society) and collective goods (things achievable only through collective action) (Sherwin 2001, 12–14).

Justice theorists Buchanan, Brock, Daniels, and Wikler (2000, 263) emphasize the importance of the "cooperative framework," within which competing interests need to be balanced. They point out that representing diverse public or citizen interests may require a more inclusive framework than is provided by the market or by elected officials. They state:

> Theorists of justice have not only failed to supply a principled account of how … conflicting interests ought to be balanced; they have almost without exception failed to identify the problem as one of justice. Instead, they have framed the first problem of justice as that of how to determine the fair distribution of the burdens and benefits of social cooperation, proceeding on the assumption that the basic characteristics of the cooperative scheme is given, and that most or all individuals to whom distributive justice is owed are participants in that cooperative scheme. There is a prior problem of justice, however … that of choosing the cooperative framework itself (Buchanan *et al.* 2000, 263).

Concern about adequate access or representation in the governance of genomics is not merely an issue of whether the electoral system is adequately representative, since many of the ethical issues related to biotechnology and genomics will be subject to other governing forces. What is at stake is how non-dominant or less powerful perspectives can be given fair consideration in the diffuse activities that govern biotechnology.

2 THE PROBLEMS OF REPRESENTATION FOR GOVERNANCE OF BIOTECHNOLOGY

Despite the inevitability of judgements about the relative weight of the interests and concerns expressed by various groups, including the public, in most industrialized countries there is a tendency to depend on experts to describe and assess the potential benefits and risks of research and development (Baird 1996). The motivation behind this reliance on experts is complex. In addition to the complicated nature of technical information, there is a web of relationships

that increasingly underlie corporate, political and university strategies, as well as the growth in universities and corporations of professional risk/benefit expertise. There is also considerable difficulty inherent in identifying the 'public interest' and a persistent belief that the public is ignorant of – and uninterested in – science (Kerr, Cunningham-Burley, and Amos 1998a).

Environmental consultation and risk assessment has a history of public consultation geared towards informing policy. Environmental risk assessment experts recognize that, while there is merit in having technical specialists make some judgements, their expertise does not extend to objective identification of what kinds of risks are important, or why. As McDaniels (1998, 132) puts it:

> There is no such thing as an objective characterization of risk. All risk characterizations and all analys[e]s are subjective and value-laden, including lay and expert views…. When technical specialists call for a more 'objective' characterization of risk, they are simply asking for a greater role.… [S]electing what risks are important, and why, are not solely technical judgements.

These (and other) factors mean that public policy relies on analysis that must make value-based assessments that are not technical judgements of risks and benefits. It is in this realm that dominant ideologies and powerful economic and political interests influence policy, as well as the more indirect forms of governance. It is also the realm where the public can bring substantial pressure to bear.

Condit (2001) characterizes the literature on lay attitudes in the area of genetics as consumer-oriented, dominated by researchers that work with small groups of people who use genetic technologies or information. There is a considerable risk that this approach to research will further confuse the distinction between consumers and citizens, leading to definitions of the public interest that reflect the concerns of consumers rather than those of citizens, which tend to involve longer term and more systemic issues. Failure to adequately consider citizen interests tends to be based on the presumptions (1) that the identification and evaluation of interests is already adequately governed by market-system competition (Malinowski and Blatt 1997), and (2) that the public simply needs to be educated about the safety and benefits of research in order to alleviate concerns and to deflate controversy (Cox and McKellin 1999; Ipsos Reid 2000; Harris Interactive 2001).

Participatory research and public involvement are responses to the recognition that risk assessment, electoral politics, and consumer influence on the market are insufficient to counter the powerful influence of corporate and international financial interests, and other politically or financially advantaged groups. The first challenge for the ethics of governance in biotechnology is to complement expert advice – by adding a sufficiently diverse set of perspectives – *i.e.,* to define issues

in ways that more broadly inform ethical analysis. Identifying interests – rather than positions on issues – will reveal the goals that participants want biotechnology or its regulation to serve, rather than highlighting conclusions about what biotechnology can do or what should be regulated. In line with such an approach, in section 3, I will describe the initial stages of an experiment designed to define issues for further research.

Theorists in justice and health care have expressed similar concerns about fair representation of interests in the definition of just health care. Daniels (1985, 2001) argues for the necessity of "equality of opportunity" as a substantive principle of justice in health care funding. Elsewhere, Daniels and Sabin (1998, 51) propose a procedural approach to just decision-making that is open to a wider range of principles and reasoning, and that is publicly accountable. They argue that decision-making processes should be "accountable for reasonableness" and be based on appeals to principles and reasons that are "not only … publicly available, but [are] also … those that 'fair-minded' people can agree are relevant to pursuing appropriate patient care under necessary resource constraints." According to these authors, four conditions must be met for a process to be accountable for reasonableness:

1 *Publicity*: the rationales must be transparent and publicly accessible.
2 *Relevance*: the rationales must be reasonable, *i.e.,* based on appeals to evidence, reasons or principles that fair-minded parties accept as relevant.
3 *Appeals*: there must be mechanisms for challenges, dispute resolution, and ongoing review and revision.
4 *Enforcement*: there must be public regulation to ensure that the first three conditions are met (Daniels and Sabin 1998, 57).

Daniels and Sabin build into the third condition an opportunity for increased representation beyond what was considered in the decisions about what services to fund. In part, because the purpose of biotechnology is less clear than that of health care, representation of the full range of interests is important before issues are defined and policies are proposed.

Much of the actual governance of biotechnology will come from consumer and citizen pressures, media and market accounts of consumer perceptions, international agreements with primarily symbolic or cultural authority, and opportunities arising from rapid developments in the market, research and application. So, while wide representation is important for setting the objectives of policy and formal governance, the effect of engaging citizens and consumers on stimulating informed consumer and citizen participation should not be underestimated. Independent of regulation, the less centralized aspects of governance can be enhanced if the processes and outcomes of a representative approach to ethics lead to better informed and motivated participation of all parties.[4]

As part of a larger project, we initiated a 'scoping' phase of research to set the scope for what issues we would examine in detail.[5] In this section, I will briefly summarize the analysis and describe the difference that scoping focus groups made to the project and to its participants. It is important to note that this exercise is not an attempt to conduct representative consultation; for that purpose, public forums are preferable to invited representatives, no matter how the latter are identified (Sclove 1995; Bauer *et al.* 2000; Sherwin 2001, 30). The goal of the scoping research was to attempt to describe a diversity of perspectives and interests that might not be represented in the current literature, and to create accountability to participants for how their interests are considered in subsequent ethical analyses. The scoping models a representative approach to ethics, by enhancing ethical analysis through engaging broad or neglected perspectives, and doing so in a manner that supports participants' own identification and representation of their interests.

It is important to distinguish *interests* (things in which people perceive themselves to have a right or a share) from *issues* (disputes about how interests should be distributed, controlled, or promoted). Defining *issues* tends to narrow the range of relevant interests to those that are directly supported or neglected by the candidate rules or decisions. Consequently, issue definition is where policy development begins to influence deliberations and/or consultations, by defining which interests are relevant to a policy decision. This means that the initial – and possibly most important – challenge to avoiding domination of policy discussions by experts is the creation of a framework that recognizes citizen interests and ensures representative participation. Identifying stakeholders (*e.g.,* environmental groups) based on the expert or authoritative definition of a policy issue (*e.g.,* safety of GMOs) is inadequate; it would result in an incomplete representation of the range of interests included in the evaluation of a policy. Participants will be engaged from – and limited to – the perspective of particular roles (*e.g.,* consumers) rather than as citizens with interests based on citizenship and rooted in the particularities of their lives (*e.g.,* concerns about their workplace, about resources for their children or about cultural practices).

In order to avoid either stimulating positional responses, or limiting what interests might be relevant, the objective of the scoping focus groups was limited to asking people to identify their interests related to genomics. We chose to use focus groups because they are well-suited for identifying a diversity of interests within a particular field, enabling participants to shape discussion, learn and respond to each other, leading to an increased exploration of the topics (Morgan 1988; Morgan and Krueger 1993; Padilla 1993). Recent work in the United Kingdom suggests that focus groups provide a context in which participants demonstrate considerable sophistication in their knowledge and

understanding of complex issues, minimizing the influences of the deficit model of lay expertise[6] (Kerr, Cunningham-Burley, and Amos 1998a–c). Recruitment by telephone was carried out by a research firm, using demographic characteristics – age, gender, and occupation – as control variables and, additionally, asking if respondents were familiar with genomics. (Most were not.) We organized the focus groups to enhance participant comfort and to simplify analysis; members of a given group either shared little or no direct interest in genomics, or had 'direct' interests (NGOs, researchers, regulators, public and private funders of research). We probed the focus groups for three categories of information: types of genome research, hopes, and concerns. Below, we will summarize the results for each of these categories.

3.1 *Types of Genome Research*

First, the focus groups addressed types of genome research. This initial exercise provided assurance that a major component of genomics was not neglected in the subsequent discussion of hopes and concerns within any group, yet assured that the topic came as a suggestion from within the group, rather than being imposed by the facilitator. The groups came up with a wide range of types of genome research. For human genomics, the topics included stem cells and cloning, as well as genetic testing and therapy, and even augmentation, behavioural control and forensics. For nonhuman genomics, mention was made of genetic modification, improved access and types of foods, and preservation of endangered species.

3.2 *Hopes*

We introduced the issue of hopes before we dealt with concerns, because addressing concerns first might discourage some participants from listing possible benefits of genomics (see table 10.1).

The expressed hopes could easily be separated into 'human health,' 'food production' and 'the environment,' *i.e.,* categories of research and products widely identified in media, regulation and marketing. The hopes also appeared to be particularly consumer-oriented, focusing on the kinds of products and services that individual participants might hope would result from genomic research.

3.3 *Concerns*

Concerns were the last consideration in the focus groups, and the groups often revisited the hopes or types of genome research and considered what concerns these raised, making the discussion on 'concerns' the most nuanced and reflexive one (see table 10.2).

Although in some instances the concerns identified were about issues related to product safety and privacy of information, the range of interests identified was rather diverse, and went beyond mere individual risks, and more focused on

Table 10.1 Hopes

Human Disease
Cures for disease including detection, prevention, elimination.
New/advanced treatments for disease: (*e.g.,* plant or animal hosts for drug production, less invasive, personalized).
Growing organs, tissue, body parts and xenotransplantation.
Diagnostics/screening: early detection and manipulation.
Gene identification.
Fertility and reproduction.
Stem cell research.
Improved general human health.
Human Enhancement/Social
Longevity.
Human augmentation.
Cosmetics.
Defeat of biological and chemical warfare.
Population control.
Forensics and crime.
Forensics and paternity.
Environment
Environment: repair damage.
Environment: green energy sources.
Environment: holistic perspective.
Environment: sustainability-more efficient use, reduce depletion.
Public
Informing the public: right to know, balanced perspective.
Public involvement.

the broader public interest than was found in the discussion on hopes. Many of the concerns were expressed as issues related to governance, where identifying a concern was something to be considered, but not necessarily the basis for a prohibition. Scepticism was also expressed about the ability of any governance regime to restrict or resist dominant market forces, perhaps showing cognizance of the complex nature of governance.

4 DID SCOPING MAKE A DIFFERENCE TO FURTHER RESEARCH?

As mentioned earlier, the focus group research was intended to set a scope for the subsequent research, and to suggest approaches and populations that would be important to involve. Three topic areas were selected; together with the analysis, they were presented to an international and interdisciplinary workshop.[7] Participants reviewed the analysis, identifying the range of interests and the

Table 10.1 (continued)

Broad Benefits

Creating Utopia.
Solving world problems.
Salvation.

Food

Food production: fewer pesticides, elimination of pests, pest resistance.
Food production: increasing nutritional value and quality.
Food production: optimizing and expanding environments.
Food production: increasing yield and access (*e.g.*, Third World).
Food: increasing shelf life.

Plants

Plants: increased protection from unintended GM transfer.

Animals

Animals: save endangered species.
Animals as models.
Animal efficiency.
Cloning: animals.

Science

Research: further understanding/science.
Research process: precautionary principle, government involvement.
Research: broaden focus.
Research: to inform decision-making.

Governance

New industry: popular genomics to increase funding.
Patents *vs.* gifts to humanity.
New business model for pharmaceutical companies (*e.g.*, boutique therapy).
Improved regulatory practices.

three topic areas. Tentative issues and important populations to include were described for each topic, so that workshop participants could evaluate how well the range of issues was covered by these choices.

In addition to helping set the scope and select topics, the analysis led to three directives for future research. These can be summarized as (1) the need to contextualize genomics, (2) the identification of governance of genomics as a topic in its own right, and (3) the transformative effects of the research.

4.1 *The Need to Contextualize Genomics*

The range of interests that was raised re-affirmed the requirement that future research must be contextualized: genome research must be considered in the context of its funding, applications, and consequences. To restrict the discussion to issues arising from scientific study of genomics would fail to address

Table 10.2 Concerns

Power

Control and access: *e.g.*, class, wealth, power, developing world, U.S. dominance or difference.
Relationship between science and governance.
Religion: *e.g.*, problem to genomics, influences decision-making, juxtaposing faith and science.
Control and regulations: who, how, speed of, global.
Patents and control.
Screening: confidentiality, discrimination.
Lack of an advisory council.

Moral/Ethical Issues

Ideological gap: moral disagreement.
Playing God: *e.g.*, soul in clones, animal cross-overs, natural order.
Screening and trait selection: Who has the right to make decisions? Threshold/draw the line?
Cloning: spare parts, soldiers, rights.
Cloning: right to choose or refuse.
Stem cell research: human being, viable *vs.* aborted.
Xenotransplants: concerns about crossing animals and humans.
Genetic modifications and augmentation: social programming, definitions of good and bad.
Standards of care: doctors' duty, parents' right to refuse, choice.

Public Knowledge

Public consults: representation and manipulation.
Public interested in genomics?
Marketing or promoting genomics: media, Hollywood.
Fear and ignorance as a problem.
Informing the public: general lack of information about genomics, need labels, lack of informed decision-making.

the hopes and concerns raised in this research. For example, it is only in the broader context of market pressure and salmon farming that genomic research on salmon will have consequences related to environment and human consumption. The overall acceptability of the genomic research on salmon was perceived as inseparable from assessments of the benefits and risks associated with the adoption of genetic modification in salmon farming.

4.2 *The Governance of Genomics*

Although the difficulty of governance is both a general problem and one that is thorny in any particular context, governance of genomics is itself a topic worthy of direct consideration. As a result of the analysis of the focus groups and the workshop discussions, one of the proposed research areas (xenotransplantation) was dropped, so that an explicit focus on governance could replace it in future

Table 10.2 (continued)

Outcomes

Unintended outcomes: unpredictable risks, accidents, interconnectedness of good and bad, new diseases, resistance.
Interfering with Mother Nature: complexity and unpredictability.
Longevity: *e.g.*, overpopulation, financial burden of longer life, stress on social system and environment.
Future generations – Our children are at risk?

Funding

Negative intentions.
Biological warfare.
Creating new problems.
Instant evolution.
Environmental impact: *e.g.*, cross-contamination, endangered wildlife, genetic pollution, reduced biodiversity.
Economic impact: *e.g.*, countries refusing gm food, unnecessary industries
Quality and nutrition of gm food.
Safety of gm foods.
Loss of individuality, diversity, adversity, good balance.
Less regard for human life, human drive.
Discrimination *e.g.*, toward diseased, disabled, "refusers" (*re*: children, GM foods) as minority, based on DNA.

Research Process

Irreversible: can't stop genomics.
Lack of holistic approach.
Vision: *e.g.*, why, way of thinking about genomics.
Moving too fast.
Distrust of motives and conflicts of interest.
Secrecy.
Rights, exploitation of research subjects, testing products–animals and humans.

consultation and ethical analysis. The focus groups raised hopes and concerns regarding governance (see table 10.1). For instance, one participant summarized the conversation in the focus group composed of regulators as follows:

> To better inform the policies, programs and legislation that government, industry, etc., would use to appropriately manage or direct the application of genomic research, I hope the research itself feeds into the process and informs the process in terms of policy-making, decision-making, and legislation.

A rural focus group participant expressed concern about manipulation of the public, whether by corporations, or even by the focus group research itself:

> [M]y fear is, bottom-line, that large corporations will use their ethics money or whatever to just do little token, you know, groups like this, and go "Thanks, thanks, and now I'll do what I really want to do." I don't know how much power… this type of group actually has in decision-making. You know, we give our opinions, we talk and discuss stuff, and then they take their little data…, but will it make any difference?

4.3 *The Transformative Effects of the Research*

Although the focus groups were primarily intended to be a means for the researchers to develop an understanding of the diversity of interests related to genomics, they also had transformative effects. Many participants found it interesting to hear the different points of view, and were surprised by how much the group knew or could figure out. Every group recognized that it had gaps of knowledge, and that this had important implications for defining its interests and the complexity of the issues; many individuals expressed a desire for more information. In some cases, the participants wanted to be more actively involved in the governance of genomics, after they completed their work in the focus groups. Although focus group methods are not the most transformative of consultation methods, the focus on understanding diversity of perspectives – rather than resolving issues – seems to have stimulated reflection that was respectful of participants' expertise and ability to understand and engage each other.

5 CONCLUSIONS

The engagement of participants is vital for recruitment for future research. Motivating people to participate in research like this can be difficult, if there is no direct input into decisions or policy. These focus groups are insufficiently representative to legitimate decisions, or even to represent a population's perspective. Without assurance that policy makers will hear and heed their reflections, participants may find the research insufficiently motivating, or even frustrating. This may be compounded by the objectives of this research, which are to compare ethical approaches and to evaluate integration of diverse non-expert perspectives into governance of genomics. At least some of the participants in the scoping phase found the participation to be rewarding, despite the indirect relevance to policy.

Participants' active involvement, and their desire to become better informed and more active, are vital for the evolution of ethical governance in genomics and biotechnology. Governance encompasses policy, citizen, and consumer behaviours, less formalized incentives and disincentives, as well as rapidly evolving research knowledge and applications. The focus groups created an environment of respect for diversity and the interconnectedness of interests, and recognition of the wider consequences of both technology and policy. Apparently, this

encouraged participants to develop a more sophisticated model of how to think about the issues, it incited their curiosity and it stimulated them to learn more. The participants (and those they influence) were encouraged to become more engaged citizens and consumers, influencing governance through policymakers, as consumers, and as citizens. Furthermore, instead of attempting to convince participants that a particular position is correct, this research encouraged them to form their own opinions in a manner that is sensitive to the interests of others, and is based on both current knowledge and recognition of uncertainty.

This research will produce accounts of the range and interconnectedness of interests and uncertainty of consequences related to genomics. The goal is to produce both a knowledge base of interests, and awareness of the unintended effects of biotechnology and governance, that can better prepare policymakers, consumers, and citizens to participate in governance through formal and informal mechanisms. The recognition of the diversity and interconnectedness of interests will facilitate further, continual scrutiny of policy and of the consequences of biotechnology. The authors of a recent report on attitudes toward biotechnology in the U.K. (Gaskell *et al.* 2003) hypothesize that the reason for the apparent ambivalence toward biotechnology is that what is at stake is not science, but the kind of society we could become with the developments available in science and technology. They write:

> And, here, the conflicts that emerge are about the fundamental questions, What sort of society do we want, and how can new technology help in achieving it? These are questions about ethics and social values; science alone cannot answer them. In this sense, any platform of public debate between autonomous and responsible citizens is to be applauded. And if socially sustainable technological innovation is a societal goal, appropriate platforms for such debates will need to be established (on nanotechnology for example), if we are to avoid reliving the type of conflicts that raged over biotechnology in the mid to late 1990s (Gaskell *et al.* 2003, 19).

The process and products of our research promote respectful and mutual understanding of interests and the effects of biotechnology, thereby encouraging consumer and citizen involvement. In some instances, ethical analysis might contribute to policies or other interventions, but, more often, ethical issues must be revisited, as new information and new technological possibilities arise. An overemphasis on the need to become an 'expert' in a particular application would neglect the expertise and responsibility we all have as citizens, to consider the effects of our actions on others, and to participate in and to respect the stakes of others in the kind of society we become. On the other hand, wholly uninformed

discussion is unhelpful and, at worst, misleading. So, public engagement should make technical information available, but it must not do so at the expense of the representation of the interests and perspectives of *all* members of society, and it should encourage respectful engagement and scrutiny of the scientific and technological perspectives as well. This means not only resolving debates where possible, but also avoiding inappropriate closure, and considering not only policy, but all forms of power that are used in the structuring of social and economic activities.

Notes

1 In this chapter, I will treat genomics and biotechnology as inseparable. The reasoning for this will be discussed later.
2 Additional questions are central to the ethical analysis: How can one assess the long-term and unintended consequences of technologies and their governance? How can one fairly handle uncertainty when there is such diversity of tolerance? Should citizens be directly involved in policymaking, and if so, how? These questions are also the topic of the larger project described at our website: *gels.ethics.ubc.ca*
3 This discussion of governance is based on an unpublished background document prepared for the research project by James Tansey (2003).
4 In research on the public understanding of science or public involvement, approaches to research that enhance citizen understanding and engagement are known as transformative methods.
5 A more detailed report of the analysis can be found in Burgess (in press).
6 The view that the public must be 'educated' before they can discuss issues and contribute to policy.
7 Participants in the workshop are listed on the project website: *gels.ethics.ubc.ca*

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11 The Regulation of Animal Biotechnology: At the Crossroads of Law & Ethics

Lyne Létourneau

1 INTRODUCTION

SINCE TIME IMMEMORIAL, HUMAN BEINGS have exercised their "domesticative action" over animals (Digard 1990, 249). Through domestication, humans have sought to satisfy their goals and purposes. As the historian Robert Delort points out, "one of the most important aspects of human-animal relationships that comes to mind is man's exploitation of the animal, an exploitation that has started with the very first civilizations" (Delort 1984, 123; my translation). Indeed, throughout the ages, animals have provided multiple goods and services that have sustained the development and evolution of human societies.

Today, animals remain inextricably linked to human affairs. With scientific advancement and the rise of biotechnology, it is highly likely that, far from regressing, humans' 'domesticative action' over animals will persist, and even increase, in the coming years.

The transfer of genetic information between animals, whether between members of the same species or between individuals of closely related species, is nothing new; it can be, and, in fact, has been, accomplished through traditional selective breeding practices since the very beginnings of animal domestication. However, as a result of the recent rise of genetic engineering (*i.e.,* genetic modification through the direct manipulation of genetic material), it has now become possible to transfer genetic information between non-related species without any recourse to sexual reproduction, a procedure known as transgenesis. Consequently, combining advances in biological knowledge and techniques, novel animal uses are being contemplated.

In medicine and research, these include not only the production of recombinant proteins with therapeutic potential from the milk, blood and semen of transgenic animals, but also the breeding of genetically engineered animals to provide cells, tissues and organs for human transplants; the development of model systems of disease; and the use of transgenic animals to discover the function of genes or to study the regulation of genes (George 1998; Animal Procedures Committee [APC] 2001; Royal Society 2001; Agricultural and Environmental Biotechnology Commission [AEBC] 2002).

In agriculture, genetic engineering of animals opens opportunities with respect to two broad categories of applications. The first category includes the development of applications intended to improve animal management. For instance, as Seidel (1998, 58) points out, "[m]any people feel that the biotechnological approach of choice for dealing with diseases [in livestock] is to breed for, or add, genes for generalized or specific disease resistance." The second category comprises applications designed to increase animal productivity: quantity and quality of meat, quantity and quality of wool, modification of milk content, etc. (Seidel 1998; APC 2001; Royal Society 2001; AEBC 2002).

These advances in animal biotechnology, which are occurring at an ever-increasing pace, have set in motion a process for the development of appropriate regulatory frameworks, both at the national and at the international level. At the heart of this process, however, lie the ethics of animal transgenesis. And the development of regulatory frameworks in animal biotechnology is almost inseparable from a reflection on the ethical issues raised by transgenic technology (Ministry of Agriculture, Fisheries and Food [MAFF] 1995, 6; Advisory Group on the Ethics of Xenotransplantation [AGEX] 1996, 4; Silverman 2000, 8).

Far from achieving unanimity, animal biotechnology is a source of significant controversy. In section 2, I will discuss the double ethical dilemma associated with the genetic engineering of animals. My purpose will be to show that animal biotechnology gives rise to a number of divergent ethical assessments, leading to a multiplicity of viewpoints.

Located at the crossroads of law and ethics, therefore, regulatory frameworks in the field of animal biotechnology are developing against the backdrop of a plurality of contradictory viewpoints. These viewpoints are often competing to be crystallized in legislation (Ossipow 2002, 51). As a product of human activity, indeed, there exists an undeniable relationship between ethics and the development of law, and "law is shaped by the values people have." (Lyons 1984, 61). As I will illustrate in section 3, with respect to animal biotechnology this means that each proposed and/or adopted regulatory framework will reflect a particular stance on the ethical issues raised by the genetic engineering of animals; in other words, each regulatory framework will express inevitable moral choices.

This inevitability of ethical choices has two consequences. The first one is related to the fact that all laws are subject to moral appraisal. Proposed and/or adopted regulatory frameworks are likely to be subjected to moral praise or

to moral criticism and, in the latter case, to be called into question as unjust, unethical, immoral, and thus, in need of reform.

The second consequence relates to policy-making in pluralistic, democratic societies, for the tension generated by the plurality of viewpoints and the inevitability of ethical choices create a formidable challenge for competent authorities: that of the legitimacy of the implicit moral choices reflected in regulatory frameworks.

As a first step towards exploring this challenge, in section 4, I will examine the practice of developing regulatory framework policies on the basis of the moral principles underlying current systems of regulation. This was the approach taken in Great Britain. It offers an alternative to directly confronting the widely differing views on the genetic engineering of animals. Yet, the latter seems to be the preferred method for establishing the ethical framework within which animal biotechnology should take place (see *e.g.,* AGEX 1996; APC 2001).

2 ETHICAL ISSUES IN THE GENETIC ENGINEERING OF ANIMALS

Standard critiques of animal biotechnology are based on ecologically-oriented arguments, on socio-economic arguments, or on animal welfare/animal rights arguments (Burkhardt 1998, 114). In addition to the environmental risks associated with the release of genetically modified organisms and the impacts of animal biotechnology on world trade and developing countries, there is considerable unease about the possible harm to the animals involved, the rights and wrongs of interfering with the 'proper' nature of animals, and the ethics of using animals as factories for pharmaceutical products or spare parts for transplantation surgery (Holland and Johnson 1998, ix).

A close analysis of these standard critiques reveals that, whereas some arguments relate to the acceptability of using animals as means to human ends, others deal with the acceptability of modifying animals through the direct manipulation of their genetic material. The ethical issues raised by the genetic engineering of animals thus form part of a double ethical dilemma: (1) Is it morally acceptable to use animals for the benefit of human beings? (2) And, if so, is it morally acceptable to modify animals through the direct manipulation of their genetic material for such purposes? I will address these respective issues in the following two sections (see table 11.1).

2.1 *The Use of Animals*

Animal biotechnology falls within humans' goal of securing benefits for themselves in medicine, agriculture, fundamental research, and other fields. At the heart of the vision of society that is articulated through the genetic engineering of animals lies the idea of animals at the service of human beings. Therefore, based on different conceptions of the relationship between humans and animals, a first set of arguments related to animal biotechnology amount to a special

Table 11.1
Arguments about the Morality of the Genetic Engineering of Animals

Use of Animals	*Genetic Modification of Animals*
Anthropocentrism (*or Humanism*):	*Utilitarianism* (*or Animal Welfarism*):
• Human interests are superior to those of animals. • Animals must be treated as humanely as possible.	• Genetic manipulation is acceptable if the benefits outweigh the costs.
Utilitarianism (*or Animal Welfarism*):	*Environmental Ethics* (impact on):
• Animals may be used, killed, or subjected to suffering, if the benefits outweigh the costs.	• Environment. • Biological diversity. • Genetic integrity of natural *species*.
Animal Rights Theory:	*Social Ethics* (impact on):
• Animals possess basic rights that should be respected, even if animal use would be beneficial to others. • Any practice that imposes costs on animals for the benefit of humans is unjustifiable in principle (even human use of animals as food).	• Human health. • Rural communities (in developed and developing countries). • The importance of commercial interests and transnational corporations. • Public trust in science and technology.

case of ethical concern about animal use. As such, these views are essentially continuous with the debates that surround intensive animal farming, animal research, hunting, and other traditional forms of animal use.

According to philosopher L. W. Sumner (1988), the animal movement can be divided into two branches: the 'animal welfare' branch and the 'animal rights' branch. As he explains:

> [These] branches are … united in their conviction that (some, if not all) animals have moral standing and that recognition of this standing would require far-reaching reforms in our current practices. But they are divided both by the interpretation of moral standing that they tend to presuppose and by the reforms that they tend to advocate (Sumner 1988, 162).

In addition to 'animal welfare' and 'animal rights' arguments, which are presented below, there exists a well-established belief in the west that humans are superior to animals. This belief, which denies that animals have any moral standing and, as a result, justifies a blanket acceptance of animal use, is related to 'anthropo-

centrism' (or 'humanism'), the doctrine which holds that the interests of humans are morally more important than the interests of animals – or of nature in its totality – are determinative (De Roose and Van Parijs 1991, 23). Certain theorists who are part of this tradition, such as Thomas Aquinas and Emmanuel Kant, nonetheless insisted that humans ought to treat animals humanely, because cruelty towards animals leads to cruelty towards humans (Aquinas 1989, 11–12; Kant 1989, 23).

'Animal welfare' and 'animal rights' arguments were formulated in response to the anthropocentric doctrine. Generally speaking, 'animal welfare' positions are broadly utilitarian in outlook (Sumner 1988, 162). According to legal scholar Gary Francione, "an animal welfare position generally holds that there is *no* animal interest that cannot be overridden if the consequences of the overriding are sufficiently 'beneficial' to human beings" (Francione 1995, 6).

There are many versions of 'animal welfare' arguments, depending, for the most part, on the weight that is assigned to animal interests in performing the cost/benefit balancing (Francione 1995, 6). In his 1975 book *Animal Liberation*, philosopher Peter Singer argues that, in assessing the consequences of our actions, it is necessary to take into account the interests of every being affected and to give these interests the same weight as the similar interests of any other being. For "there can be no moral justification for regarding the pain (or pleasure) that animals feel as less important than the same amount of pain (or pleasure) felt by humans" (Singer 1990, 15). This principle of equal consideration of interests constitutes the basis of the moral equality between humans and animals within the utilitarian doctrine.

The primary alternative to the 'animal welfare' approach is found in the 'animal rights' approach, according to which animals possess basic rights. For animal rightists, no cost/benefit balancing is relevant in order to determine whether the use of animals is acceptable in any particular case. Animal rightists tend to regard any practice that imposes costs on animals for our benefit as unjustifiable in principle.

The theory of animal rights that is regarded as most influential is found in Tom Regan's *The Case for Animal Rights*, published in 1983 (*cf.* Regan 1991, 1996). Regan defends a position which rests on a structure of basic moral rights (to respectful treatment and not to be harmed), which are shared equally by all individuals that possess an inherent value, be they moral agents or moral patients, humans or nonhumans.

In terms of practical implications, Regan's position is quite uncompromising: he unambiguously condemns the use of animals for food, hunting, trapping, education, testing, and research. According to Regan, the rights view requires the abolition of all these activities (Francione 1996, 18). Mainly, it is the impoverished judgement about the value of animals that these human activities convey that exposes them as morally wrong, as fundamentally unjust. Indeed, the routine

use of animals for food, sport, profit, and research involves treating animals as if they were merely *renewable resources* whose moral status in the world is to serve human interests – *renewable* because they are replaceable without any wrong having been done, and *resources* because their value is assumed to be a function of their utility relative to the interests of human beings (Regan 1983, 345). Because animal rightists tend to condemn all forms of animal use, they are likely to oppose genetic engineering of animals, on the ground that using animals as spare parts for transplantation surgery, model systems of disease, factories for pharmaceutical proteins, or agricultural products, etc. is morally unacceptable. In consultations in Great Britain, those who believe in animal rights put forward the following objection against new breeding technologies, including transgenesis:

> The view that animals are no more than raw materials, it would be argued, fails to take account of the fact that the natural world in general, and animals in particular, are worthy of our respect as possessing an integrity or good of their own, which we ought not simply to disregard (MAFF 1995, 12).

2.2 *The Genetic Modification of Animals*

Not all arguments in support of, or against, genetic engineering of animals are firmly situated within the boundaries of animal ethics. Other viewpoints deal not with animal *use per se*, but with animal *modification*, *i.e.,* with the acceptability of modifying animals through the direct manipulation of their genetic material. These arguments share some common features with the ethical concerns raised by selective breeding (Sandoe and Holtug 1996). Nevertheless, they go beyond the latter in trying to identify the perceived difference between animal biotechnology and previous practices.

An objection that is increasingly voiced against animal biotechnology is that it constitutes an invasion of an animal's species-specific nature, or telos (Holland 1998, 225). The point here is that there is something objectionable in the very process of genetically modifying animals (Rollin 1995, 21; Comstock 2000, 183). Other arguments pertaining to the acceptability of animal *modification* include the likely consequences (positive or negative) for the environment, biological diversity, human health, food safety, rural communities in developed as well as in developing countries, the growing importance of commercial interests and transnational corporations, and public suspicion of science and technology (Rollin 1997; Comstock 2000; Thompson 2000; National Research Council 2002). Considerations related to the health and welfare of animals are also expressed (D'Silva 1998, 92).[1]

Leading animal welfare scientist Donald Broom adopts a more nuanced point of view. He affirms that two important questions need to be answered before

any moral judgement can be made on the acceptability of using transgenic procedures on animals: (1) whether or not there are positive or negative effects on welfare; and (2) what the magnitude of those effects is (Broom 1998, 70). According to Broom (1998, 72), "transgenesis can result in better welfare, in no change from the average unmodified animals, or in poorer welfare."

In reviewing the question of whether it is morally acceptable to use animals for the benefit of human beings and whether it is morally acceptable to modify animals through the direct manipulation of their genetic material, we raise the double ethical dilemma around the genetic engineering of animals. I will now turn my attention to the concept of inevitable ethical choices.

3 INEVITABLE ETHICAL CHOICES

Moral neutrality does not exist in proposed laws on animal biotechnology. No matter what system of regulation is put into place, the regulatory framework will reflect a particular stance on the double ethical dilemma raised by the genetic engineering of animals. Either explicitly or implicitly, it will reflect both a conception of the relationship between humans and animals, as well as a moral position with respect to the acceptability of genetically modifying animals.

I will try to illustrate my point by using the relevant standards that apply to the protection of animals used for xenotransplantation in Canada. The examples presented below support a characterization of animal biotechnology law as inevitably providing answers to the double ethical dilemma raised by the genetic engineering of animals.

3.1 *The Acceptability of Animal Use*

In Canada, apart from a proposed Canadian standard, which was developed in 1999 by a sub-committee of experts following a National Forum (Therapeutic Products Program [TPP] 1999), there is no specific regulatory framework that applies to xenotransplantation, *i.e.,* the transplantation into humans of organs, tissues, or cells derived from transgenic animals. That being the case, one must refer to the standards that are most likely to find application in the circumstances. As xenotransplantation is still experimental in nature, we will direct our attention to the standards governing animal experimentation.

There is no federal statute that regulates the use of animals for experimental or other scientific purposes.[2] Since 1968, however, there has been a national control system based on peer review. This system is managed by the Canadian Council on Animal Care (CCAC), which originally developed it. The system is based on two main components: animal care committees – which are the keystone of the system – and assessment visits.

Each institution that uses animals for research, teaching, or testing and that is affiliated with the control system established by the CCAC must have an active operating animal care committee that reports directly to senior managers in the institution. This committee is responsible for ensuring that the procedures

governing the care and use of the animals comply with the guiding principles issued by the CCAC. In particular, the animal care committee is responsible for assessing animal use protocols. Indeed, under the CCAC system, no research, teaching, or testing project or program involving the use of animals may be undertaken unless it has been previously approved by the animal care committee of the institution in which the project or program is to be conducted. To obtain the animal care committee's approval, a protocol must meet the requirements laid down by the CCAC in its policy statements and guidelines. Scientific reasons must be given for any departure from these guiding principles.

According to CCAC guidelines, the use of animals in research, teaching and testing is acceptable only if it promises to contribute to "the understanding of environmental principles or issues or fundamental biological principles, or to the development of knowledge that can reasonably be expected to benefit humans, animals, or the environment" (CCAC 1996, 1).

Although the principle stated appears to be rather restrictive, it imposes no limit on the use of animals in research, teaching and testing. The principle stated does not prevent any potential uses of animals for experimental or other scientific purposes; instead, it expresses the position that animal experimentation is acceptable. Nevertheless, in accordance with the anthropocentric doctrine, it guarantees that proposed animal uses will not be gratuitous, as it requires that they be based on scientific need.

CCAC guidelines also provide that "animals should be used only if the researcher's best efforts to find an alternative have failed" (CCAC 1996, 1). In addition, "[t]hose using animals should employ the most humane methods on the smallest number of appropriate animals required to obtain valid information" (CCAC 1996, 1). These last two principles summarize the '3R' principle (Replacement, Refinement, Reduction) laid down in 1959 by the English scientists W. M. S. Russell and R. L. Burch in a work entitled *The Principles of Humane Experimental Technique*. As explained by Donald Boisvert (1996, 80–82), former director general of the CCAC:

> Replacement is the substitution of conscious, living, higher animals with insentient material…. The substitution of one species of animals for another that is lower on the phylogenetic scale is accepted by many as a form of replacement…. Refinement is any decrease in the incidence or severity of inhumane procedures applied to those animals, which still have to be used…. Reduction is the decrease in numbers of animals used to obtain information of given amount and precision.

These three elements underlie the standards governing the treatment of animals in experiments that have been adopted in a large number of Western countries (Létourneau 1994). In conformity with the anthropocentric doctrine, their

combined effect is to provide experimental animals with humane treatment (Létourneau and Leroux 1994, 315–23).

Similarly, when it sets out the conditions under which clinical trials on xenotransplantation may proceed in Canada, the *Proposed Canadian Standard for Xenotransplantation* (TPP 1999) suggests adherence to an anthropocentric conception of animals as being in the service of humans. This conclusion follows from a number of elements. First, the proposed *Standard* expressly refers to CCAC guiding principles, thereby importing within its scope the position on human-animal relations that finds expression through the CCAC Guidelines. As stated in the document, "[a]ll animal facilities associated with xenotransplantation programs must be full participants in the Canadian Council on Animal Care (CCAC) programs and must adhere to all CCAC policies and guidelines" (TPP 1999, 10).

Second, the proposed *Standard* requires that xenotransplantation source animals be cared for and used in a humane manner (TPP 1999, 10). Finally, since the use of primates as a source of organs, cells, or tissues for transplantation into humans is rejected – on the basis of the small body size of the animals, the risk of zoonotic (*i.e.,* animal to human) disease transmission, and concerns that higher primates may become endangered – scientists have turned to the use of genetically modified pigs. Regarding the use of pigs as source animals, the following comment is made:

> While the pig is an animal of sufficient intelligence and sociability to make welfare considerations paramount, there is no evidence that it shares capacities with human beings to the extent that primates do. As such, the adverse effects suffered by the pigs used to supply organs for xenotransplantation would not outweigh the potential benefits to human beings. It is also difficult to see how, in a society in which the breeding of pigs for food and clothing is accepted, their use for life-saving medical procedures such as xenotransplantation could be unacceptable (TPP 1999, 8).

These remarks clearly reflect an anthropocentric viewpoint. First, humans' superiority to primates and pigs – and hence to animals in general – is affirmed. Second, society's blanket acceptance of pigs' use is mentioned approvingly. And, third, welfare considerations are pointed out as the unique proper object of ethical concern.

In addition to relating to animal *use*, the proposed *Standard* also applies to a form of animal use that is made possible through the application of transgenesis, and, hence, takes a stance on the issue of the acceptability of animal *modification*.

The purpose of the proposed *Standard* is to *regulate* xenotransplantation. As stated in its preamble:

> This Canadian Standard for Xenotransplantation addresses the safety of viable animal organs and tissues for human transplantation purposes. This standard is intended to provide performance requirements to prevent disease transmission and to assure optimum clinical performance of viable transplanted organs, tissues, and cells from animal sources. This Standard includes all aspects of care and humane treatment of the potential and actual animals, and the safety of recipients, personnel and others who may be exposed or affected by the transplant of animal tissue (TPP 1999, i).

Yet, to *regulate* xenotransplantation is not the same as to *prohibit* it. To regulate an activity, a practice, or a procedure is to accept its performance, even if solely in accordance with the conditions stated. To regulate xenotransplantation, therefore, is to accept that the procedure will be performed. And since the transplantation into humans of organs, tissues and cells derived from animals relies on the use of transgenic pigs, to accept xenotransplantation is also to sanction the transfer of genetic information between humans and pigs. Implicitly expressed in the proposed *Standard*, therefore, is the moral position that the genetic engineering of pigs is acceptable for therapeutic purposes.

This conclusion is reinforced by reference in the proposed *Standard* to CCAC *Guidelines on Transgenic Animals* (CCAC 1997): "all proposals for creation or use of transgenic animals must follow CCAC *Guidelines on Transgenic Animals*" (TPP 1999, 8).

The *Guidelines* further reflect the judgment that it is morally acceptable to modify animals through the direct manipulation of their genetic material, whatever that manipulation may involve. Such a conclusion conforms to the terms of reference of the CCAC, which are to *monitor* the care and use of animals used in research, teaching, and testing, rather than to *challenge* such use.

This summary analysis of the standards that apply to the protection of animals used for xenotransplantation in Canada, provisions relating to animal biotechnology, are not morally neutral.

4 FACING THE CHALLENGE

The work of these ethics advisory committees provides an appropriate arena for the study of the obstacles to policy-making posed by the inevitability of ethical choices in the context of a plurality of viewpoints, for these committees constitute an excellent vehicle for mediating the tension in play. Indeed, despite the plurality of viewpoints in society, ethics advisory bodies do take positions and form recommendations. How do they frame and legitimize their advice?

In the following pages, the approach advocated in the *Report of the Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals* (MAFF 1995) will be discussed.

The purpose of the *Report* is to address the ethical concerns that arise in relation to the application to animals of a family of techniques regulating their reproduction (MAFF 1995, 6). These techniques include artificial insemination, but also cloning and genetic modification (MAFF 1995, 6).

From a philosophical point of view, one commendable aspect of the *Report* is the following:

> The *Report* challenges the tendency to assess the new technologies solely in terms of questions of risk and benefit, and contends that this tendency uncritically privileges a particular philosophical position. Instead, it proposes a policy and system of moral evaluation, which allows and requires questions of a different sort (Banner 1999, 205).

Another original aspect of the *Report* is the approach taken by the Committee in framing its advice:

> We have not thought it appropriate or necessary to begin by arguing directly with either of these widely differing views, but have approached our task by considering the adequacy of the general principles which seem to underlie the present regulations governing the treatment of animals, to see whether they can properly be applied to the problems before us (MAFF 1995, 8).

Such an approach is of considerable interest, for it circumvents one of the most significant impediments to direct argumentation, *i.e.,* the unavailability of a single, universally accepted method or clear set of priorities for settling ethical disagreements (Nagel 1979, 128–41; Rachels 1998). Another positive aspect of the approach adopted by the Committee is that it provides a framework for decision-making that appears to be both transparent and non-arbitrary. This is far from being a negligible advantage when legitimacy issues are at stake. Still, the approach taken has some weaknesses, which I will now review.

4.1 *Spelling out the Moral Implications behind a Given Law*

As understood by the Committee, animal protection regulations in Great Britain "are based on and express the broad principle that use of animals, for any purpose, agricultural or otherwise, is acceptable, provided the use is humane" (MAFF 1995, 8). This principle, as mentioned in the *Report*, "…represents the culmination of a long tradition of moral reflection, as well as expressing the views of most members of society, that the use of animals is, morally speaking, neither

absolutely impermissible, nor a matter about which one should be indifferent." (MAFF 1995, 8)

The *Report* states three further principles, that the Committee based its recommendations on (MAFF 1995, 8):

a Harms of a certain degree and kind ought, under no circumstances, to be inflicted on an animal.

b Any harm to an animal, even if not absolutely impermissible, nonetheless requires justification and must be outweighed by the good, which is realistically sought in so treating it.

c Any harm that is justified by the second principle ought, however, to be minimized as far as is reasonably possible.

In the Committee's view,

> the first principle provides the rationale for the prohibition of numerous nontherapeutic operations on farm animals – tongue amputation in calves, tail docking in cattle and tooth grinding in sheep, for example." "The second principle is implicit in the *Animals* (*Scientific Procedures*) *Act 1986* . . . and ensures that animals are used in experimental work only where the end result of the experiment can reasonably be expected to be commensurate with the harm suffered by the animals (MAFF 1995, 8–9).

As for the third principle, "[it] is implicit in a large number of codes which, while accepting that certain sorts of procedures involving harm to animals are, in general, acceptable, nonetheless seek to ensure that the harms caused are minimized by good practice" (MAFF 1995, 8–9).

However, the characteristic elements of animal protection law in Great Britain do not wholly support the principles enunciated above. Acknowledging that animal protection law in Great Britain rests on the premise that it is morally acceptable to use animals as means to human ends, principle (a) still cannot be found to reflect the present state of the law. In order to do this, its application would have to be universal and comparable cases would have to be treated in similar ways. However, unlike the nontherapeutic operations mentioned by the Committee, beak-trimming in laying hens and broiler chickens, disbudding in calves and dehorning in cattle, castration in calves and sheep, tail-docking in sheep and pigs, and tooth-clipping in pigs remain lawful procedures. Moreover, whereas the historical backdrop of current limits on animal use in Great Britain reveals that the mutilations prohibited were either not known to be practiced or not commonly performed in Great Britain (Létourneau 2000, 61–66), the mutilations permitted serve the interests of human beings in their use of animals for the production of food, skin, fur, or other products (Létourneau

2000, 69–83). These latter acts are essential to sustain many systems throughout intensive farming. Thus, if to prohibit a number of mutilations on farm animals may seem at first sight to reflect the moral principle that "certain harms caused to animals should have no place in farming practice" (MAFF 1995, 8), careful consideration suggests that human interest – *not* animal interest – operates as the key element in the regulation of the use of animals for agricultural purposes. Human interest, as a matter of fact, permeates all sets of standards of treatment of animals in Great Britain (Létourneau 2000, 67–90). That being the case, principle (c) above, whose wording "as far as is reasonably possible" is vague and imprecise, would be much more explicit if it were modified as follows: "Any harm ought to be minimized if this serves the interests of humans in the efficient and profitable use of animals." In addition, any reference to principle (b) within principle (c) should be eliminated. Principle (b) should actually be removed altogether, for it is based on an erroneous interpretation of section 5 (4) of the *Animals* (*Scientific Procedures*) *Act 1986*. This provision requires the Secretary of State, in determining whether and on what terms to grant an animal experimentation project license, to weigh the likely adverse effects on the animals concerned against the benefit likely to accrue as a result of the program of work to be specified in the license. However, the 1986 Act entails no balancing of "the good which is realistically sought" against the degree of harm likely to be caused to animals. In determining whether and on what terms to grant project licenses, Home Office inspectors assess the potential benefits of proposed programs of work, and examine envisaged costs in terms of animal suffering. However, benefits are not contrasted with costs in order to make sure that they are proportionate or that the former outweigh the latter. Having ascertained, on the one hand, that the science is good, and, on the other hand, that animal suffering is minimized, inspectors must recommend the granting of project licenses (Létourneau 2000, 133–39). In any event, if principle (b) were well-founded, then the broad principle put forward in the *Report* as underlying animal protection law in Great Britain would have to be changed, in order to include an exception regarding animal experimentation. Indeed, if inspectors had to weigh harm to animals against likely benefits, and recommend the granting of project licenses only when the benefits likely to accrue from proposed programs of work are proportionate or outweigh the amount of suffering imposed on animals, this would mean that, within the framework of the *Animals* (*Scientific Procedures*) *Act 1986*, the use of animals for experimental or other scientific purposes would actually be called into question. In such a case, it could not be said that animal protection law in Great Britain is based on the premise that the use of animals "for any purpose, agricultural or otherwise, is acceptable, provided the use is humane." Were principle (b) well-founded, moral acceptability in the case of the use of animals for experimental or other scientific purposes would be determined on a case-by-case basis, rather than based on an overall moral assumption.

For these reasons, it is thus impossible to endorse the principles put forward by the Committee. These principles do not faithfully reflect animal protection law in Great Britain. On the one hand, principles (a) and (b) are patently erroneous. On the other hand, principle (c) is vague and imprecise; it fails to emphasize the determinative role that the interests of humans play in the standards ascribed to the treatment of animals.

At this point, it is useful to take note of Honoré's warning that "it may be a delicate matter to spell out the moral implications which lie behind a given law" (Honoré 1993, 16). If a committee is going to inform its consideration of issues and base its advice on the moral principles underlying existing legislation, then, at the very least, those principles should be accurately identified.

What is more, special care must be taken not to attribute new meaning to the principles. For example, in the *Report*, the Committee does not consider the word 'harm' "to refer only to harm of which the animal is conscious, or even simply to physical harm" (MAFF 1995, 9). The Committee contends "that animals can be harmed or wronged in other ways than simply by physical mistreatment" (MAFF 1995, 9). For instance, in the Committee's view, "[a]n animal can be harmed … by treatment which is degrading" (MAFF 1995, 9).

Such a definition of 'harm,' however, is supported neither by an analysis of case law (Létourneau 2000, 24–30), nor by the socio-historical account of the development of animal protection legislation (Létourneau 2003, 1048–50). The thrust of current regulations governing the use of animals is to protect animals from unnecessary suffering, in recognition strictly of their capacity to feel pain. The effect of extending 'harm' to situations where an animal "may be neither conscious of any wrong being done to it, nor the object of physical mistreatment" (MAFF 1995, 9) is thus significant. For the Committee, in effect, adds a new criterion, that of respect of an "animal's natural characteristics and form" (MAFF 1995, 15–16).

This is clearly unacceptable because, failing to justify the new interpretation of 'harm' in the actual context of the system of regulation contemplated, the Committee hid behind the legitimacy conferred by a reference to principles already embedded in law in order to attribute new meaning to the principles stated. However, such a way to proceed is not without dangers. Not only does it lead the way to abuse, but most of all it threatens to reduce to shreds the whole point of developing regulatory framework policies based on the general principles underlying current systems of regulation. For it allows considerations that are foreign to these principles to be introduced through the back door, hence defeating the objective of transparency and non-arbitrariness of the approach. This explains the importance of adequately identifying the moral implications of a given law and of not extending their import over what their interpretation may properly justify.

4.2 *Existing Legislation as a Mirror of Social Attitudes*

It is widely held that public opinion constitutes a genuine source of legitimacy for policy decision-making.

In the *Report*, the Committee does not express a rationale for its choice of approach. However, one reason for proposing to use the principles that underlie existing legislation as a framework for policy-making might be to make recommendations that conform to public opinion, widespread attitudes, and/or majority viewpoints.

According to philosopher Bernard Rollin (1995, 161–62), present law provides "an excellent indicator of where social thought stands on animal well-being, and what society will and won't accept in the present and future."

Yet, if one's goal is to benefit from the apparent legitimacy that conformity with majority viewpoints usually seems to confer, then why not proceed directly from the results of opinion polls, attitude surveys, or other public consultation exercises? Furthermore, is the law not often accused of lagging behind social developments and progress? In any event, one should not be so naïve as to think that existing legislation always mirrors "where social thought stands." This would be to forget the contribution of pressure groups to the law-making process.

As political theorist Robert Garner explains with respect to animal protection legislation in Great Britain, "British pressure groups who seek significant legislative change must gain access to the national level of decision-making" (Garner 1993, 191). To do so, however, they must have what Garner calls "insider status." "This insider status … is largely dependent upon a group being perceived by government as moderate and respectable" (Garner 1993, 208). Garner maintains that, in today's climate, this perception does not extend to those animal protection groups that make the 'radical' demands warranted by granting animals a higher moral status (Garner 1993, 208–09). Rather, groups with insider status include pressure groups representing animal users, in addition to animal protection groups that do not make such demands because they consider that animals should take a subordinate, albeit important, position (Garner 1993, 48–49, 208).

Existing legislation, therefore, is not always the proper indicator of social attitudes described by Rollin. The law-making process is influenced by numerous factors, including the actions of pressure groups. Hence, the approach adopted by the Committee cannot be defended on the ground that it will confer legitimacy to the ethical choices expressed, the latter conforming to the widespread social attitudes mirrored in current animal protection legislation.

4.3 *A Perpetual State of Status Quo*

Attempts to develop new regulatory framework by employing the moral principles expressed through present legislation are fraught with other difficulties.

One problem is that, if new systems of regulation are based on the principles underlying current regulatory frameworks – which themselves are based on the principles underlying pre-existing regulatory frameworks – are we not, as a result, caught up in a perpetual state of status quo, culturally, socially and morally speaking?

In proposing its framework for evaluation, the Committee intended to provide a basis for the examination and reform of the current pattern of regulation of the use of animals (Banner 1999, 205). It intended to initiate a departure from the actual state of affairs.

There is some value in holding such a view. For instance, in Great Britain, since the adoption of the first anti-cruelty statute in 1822, the number of laws and regulations aimed at protecting animals has grown considerably. However, mere number does not tell the whole story, for, most importantly, it is the scope of animal protection law that has been broadened by successive legislative amendments, abrogation, and replacements. Increased numbers of protected animals and types of targeted human activities, as well as the steady tightening-up of existing provisions have all contributed to this widening. Concurrent legal obligations have also become more detailed, and mechanisms of control have been either toughened or supplemented with new ones.

These successive reforms all fell within the ideological scope provided by the anthropocentric doctrine (Létourneau 2000, 167–74). Nevertheless, they have had the effect of promoting animal welfare. Hence, even within the confines of one and the same ideological framework, there can be room for improvement.

Yet, one should not fool oneself as to the moral significance of the reforms. For instance, as is the case elsewhere in the Western world, in Great Britain the struggle to achieve a higher moral status for animals through legislative change continues. As Richard D. Ryder (1989, 5) asserts in his book *Animal Revolution*, this struggle "is not a sideshow; [instead,] it is one of the main arenas of moral and psychological change in the world today." However, to bring about a higher moral status for animals, groups must pursue legal reforms which will either take the position that animals matter morally, or incrementally lead to an acknowledgement that animals are worthy of moral consideration in their own right. Supporting or calling for reforms that conform to the anthropocentric doctrine is never going to lead to a gradual increase in the recognition that animals matter morally, for, to work within the bounds of anthropocentrism implies that one condones this position, and, therefore, that one reinforces its legitimacy as an acceptable conception of the relationship between humans and animals (Francione 1996).

In sum, although the general principles that underlie present legislation may be used successfully as an instrument of reform, these reforms will reflect the same moral implications as the principles. Therefore, when changes sought involve a concomitant change in moral implications, use of present law as the basis of new

law will not lead to the desired end result. Thus, the development of regulatory framework policies on the basis of the moral principles underlying current systems of regulation will leave us caught up in a perpetual state of status quo.

As a means of meeting the challenge of policy-making in pluralistic, democratic societies, the *Report* offers an alternative to arguing directly with the widely differing views on the genetic engineering of animals. While more thought is definitely required on this matter, our analysis reveals a number of weaknesses with the approach taken. These include: the high degree of difficulty in accurately identifying the moral principles underlying existing legislation and the risk of attributing new meaning to these principles, the inadequacy of existing legal frameworks as an indicator of 'society's views,' and the limitations of the proposed approach as an instrument for change and reform.

Still, without proper justification, regulatory frameworks run the risk of being perceived as the contestable product of the balance of power, rather than as an explicit societal choice. What is worse, they risk being perceived as the outcome of economic interests, government self-interest, or arbitrariness. The task of ethics advisory bodies is a weighty one that involves testing for integrity, transparency, and legitimacy in the development of regulatory framework policies.

5 CONCLUSIONS

In this chapter, I have examined the development of regulatory frameworks in the field of animal biotechnology from the perspective of their embeddedness in ethical issues. These issues are twofold: first is the question of whether it is morally acceptable to use animals for the benefit of human beings; second is the question of whether it is morally acceptable to modify animals for such purposes through the direct manipulation of their genetic material.

The genetic engineering of animals is a source of controversy, giving rise to a multiplicity of viewpoints with regard to the aforementioned issues. From a policy-making perspective, the problem is that each proposed and/or adopted regulatory framework will reflect a particular stance on the double ethical dilemma raised by the genetic engineering of animals. Given that all laws may be subjected to moral approval, proposed and/or adopted regulatory frameworks are likely to receive such criticism, and, as a result, to be contested and considered in need of reform.

As mediators between the plurality of viewpoints represented in society, on the one hand, and the inevitable ethical choices reflected in the regulatory frameworks, on the other, ethics advisory bodies take on considerable importance. The work of one such body – the Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals – was examined. The results of this analysis were mixed. The practice of using present law as the basis of new law raises a number of issues that prompt us to reflect on ways to improve the process of formulating regulatory framework policies.

In any event, notwithstanding the fact that some degree of moral approval remains inescapable, one cannot stress enough the importance of the work of ethics advisory bodies in giving legitimacy to the regulatory frameworks that apply to animal genetic engineering. These committees also play a significant role in enhancing public confidence in the systems of regulation. As part of the political entity that is the State, their task is thus significant in the arbitration of the moral conflicts raised by animal biotechnology and the maintenance of social peace.

Notes

1 My understanding of Regan's theory of animal rights leads me to believe that the theory has no implication for the debate on the moral acceptability of modifying animals through the direct manipulation of their genetic material. The central idea of Regan's theory is that animals have the right not to be used as means to human ends. This core proposition, however, says nothing about whether humans may genetically modify animals. That being said, it is true that arguments on the issue of "animal modification" may use a vocabulary that is reminiscent of animal rights theory. For instance, one might argue that one of the key objections to the genetic engineering of animals lies in the intrinsic value of wild species (naturally evolved life-forms), which such genetic engineering undermines (see Thompson 1997, 12–20). However, respect of the intrinsic value of animal species is not the same as respect of the intrinsic value of individual animals. The former shares closer links with environmental ethics than with animal ethics.

2 Under the Constitution Act, 1867 (U.K.), 30 & 31 Vict., c.3), the federal government does not have jurisdiction to legislate with respect to experiments involving animals.

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12 Second Thoughts on Biobanks: The Icelandic Experience[1]

Gardar Árnason

1 INTRODUCTION

IF ONE HAS ONLY A FEW NEWSPAPER and magazine headlines about the Icelandic Health Sector Database, one might be under the impression that Iceland is a nation of clones, and that these clones have now sold their genes.[2] Of course, this is not quite the case. First, there is no credible scientific evidence for the claim that the Icelandic population is more genetically homogeneous than any other population.[3] And, second, there is no national genetic code for sale. Even the plans for a Health Sector Database (HSD), that gave rise to these headlines, have still not materialized; the Icelandic Health Sector Database does not exist, and perhaps never will.

In this chapter, I will briefly describe the plans for the HSD and how they came about. Then I will discuss the debates that ensued in Iceland, focusing on two ethical issues: privacy and consent. Finally, I will offer a few remarks about what I think can be learned from the case of the Icelandic database.

2 THE ICELANDIC DATABASE

There is a serious ambiguity underlying the discussions about the HSD. The legislation passed in 1998 to allow its construction describes it as a database of health information, which *may* be linked to databases containing genetic and genealogical data (Íslensk erfdagreining 1999). However, it was clear from the outset that deCODE genetics Inc. (the company that initiated the plans for the database and that was subsequently licensed to construct it) intended the three databases to be fully integrated into a single research database (Gulcher and Stefánsson 1998). deCODE called this the Genotypes, Genealogy, Phenotypes

and Resource Use (GGPR) database (*e.g.,* deCODE genetics Inc. 1998). Outside of deCODE's company literature, this name never caught on. In a few instances, the debates and news stories about the 'Icelandic Database' refer to this larger GGPR database, but often they relate only to the first of the three sub-databases, namely the Health Sector Database itself. In Iceland, too, the debates were primarily focused on the HSD. This was unfortunate, as it was never meant to be operated in isolation, *i.e.,* without linking it to the genetic and genealogical data.

The GGPR database was to be created and operated by the newly-created biotechnology company deCODE genetics Inc., which is incorporated in Delaware, U.S.A. According to deCODE, the combination of the three databases would create "a totally informative population with which to search for drug targets and to model both disease and host-drug interactions" (Gulcher and Stefánsson 1998, 526). At the time, Icelandic laws and regulations did not allow for the sort of database envisioned by deCODE. Therefore, specific legislation was required to make its construction possible. In December 1998, the Icelandic Parliament passed a bill, allowing an unspecified commercial company to establish the Health Sector Database and to collect data from Icelandic medical records (Icelandic Parliament 1998). In January 2002, deCODE genetics Inc. was granted exclusive rights to establish the database and sell access to it for a period of twelve years.

The main purposes of the database are to provide both statistical data for research in human genomics and genetic epidemiology, and information for Icelandic authorities about resource use in the health care system. In the words of the HSD act, the purpose of the database is to increase "knowledge in order to improve health and health services." A further goal is a thorough geneticization of medicine and public health; according to deCODE representatives, the "ultimate goal of the database [is] to usher in an era of preventive health care and individual-based disease management practices based on human genetics" (Gulcher and Stefánsson 1998, 526).

The Health Sector Database will contain information taken from medical records in Iceland. Regular staff at medical institutions will transfer data from medical records to medical information software, designed specifically for the purpose of processing the data and transferring them to the database. Once the health sector database has been constructed, it will be possible to query it for "statistical information on health, disease and treatment" (Íslensk erfdagreining 1999), but it will yield no information about single individuals or groups of fewer than ten individuals.

As mentioned above, the Health Sector Database – if it will ever be constructed at all – will be linked to, or merged with, two other databases: one containing genealogical data for every Icelander alive and – going back several centuries – a great number of those deceased; and another database containing genetic information. The genealogical database has been created and deCODE is already

using it for research. The company calls it "The Book of Icelanders." It is based on public information and does not require obtaining consent of any kind for using personal data. The genetic database already contains genetic data from approximately 80,000 Icelanders, or about 28% of the population. The data were acquired through scientific research conducted by deCODE, with the required written consent from bio-sample donors.

deCODE claims that cross-referencing medical data with genealogical and genetic data will enable researchers to quickly find the most likely locations for genotypes linked with such phenotypic issues as disease symptoms and efficacy of drugs or treatment. For instance, it will be possible to feed the database with encrypted names of individuals suffering from a disease and have it map out clusters of related individuals in a number of pedigrees of varying sizes. A researcher could then pick a pedigree and compare genotypes of healthy and sick individuals from that pedigree, assuming that the genetic factor in the disease is common to all the diseased individuals. If the diseased individuals would have a higher frequency of certain genetic differences than the healthy ones, these genetic differences may be a causal factor in the disease. This would greatly speed up the process of locating genes that are a factor in disease. Genes would not only be linked to diseases, but also to drug efficacy and side effects, making it possible (at least in theory) to tailor-make drug treatments according to the genetic profile of the individual patient.

3 THE DEBATES

The Health Sector Database bill was first circulated in the Icelandic Parliament on 6 April 1998. An attempt to rush the bill through parliament failed, primarily because of the immense debate in society and the serious criticism from individuals and from government and non-governmental organizations. Over the next year and a half, more than seven hundred newspaper articles appeared about the database, and there were over four hundred radio and TV programs on the subject (Stefánsson 2000, 31). The debate in Iceland peaked as the Database Bill was passed by parliament on 17 December 1998 (Icelandic Parliament 1998).

The Database was not only debated in Iceland; articles – many of them very critical – appeared in scientific journals and magazines such as *Nature, Nature Genetics, Nature Biotechnology, The British Journal of Medicine* and *Scientific American*, as well as in the *New Yorker*, the *New York Times*, the *Washington Post*, the *Star Tribune*, and the internet news web sites of ABC, CNN and Wired.

3.1 *Privacy: A Technical Problem with a Technical Solution?*

When the Health Sector Database act was in preparation, the problem of privacy was seen primarily as a technical problem that required technical solutions. This was exploited to no end by deCODE; the company limited the discussion of ethical issues to the problem of privacy of medical information and it proposed

complex technical solutions to the problem. By keeping the public discussion occupied with these technicalities, the company and HSD proponents managed to all but completely evade the actual ethical issues.

The first draft of the HSD bill did not have any consent requirements at all, nor did it have any option of opting out. The privacy issue was to be solved by complex encryption methods and the involvement of various monitoring committees and agencies. Due to the general outrage that followed, the bill was amended by introducing presumed consent and the possibility of opting out of the database. To justify applying the principle of presumed consent, privacy was to be ensured by technical means. This included making all personal data anonymous or, more accurately stated, *non-personally identifiable*.

The definition of 'personally identifiable' turned out to be a complicated matter. In the Act on a Health Sector Database, 'personally identifiable' is defined according to Article 2 of a European Union directive entitled "Directive 95/46/EC of the European Parliament and of the Council of October 24 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data":

> '[P]ersonal data' shall mean any information relating to an identified or identifiable natural person ('data subject'); *an identifiable person is one who can be identified, directly or indirectly*, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity (European Parliament 1995; emphasis added).

A draft of the database act, which Kári Stefánsson faxed to the Ministry of Health on 14 July 1997, contained a different definition, based on *Recommendation No. R (97) 5*, of the European Council's Committee of Ministers on the Protection of Medical Data (1997):[4]

> [T]he expression 'personal data' covers any information relating to an identified or identifiable individual. An individual shall not be regarded as 'identifiable' if identification requires an unreasonable amount of time and manpower.

The second definition was used for early drafts of the bill, but at some point it was replaced by the one mentioned earlier. During the controversy over the Health Sector Database bill, deCODE insisted on the second definition. That was perhaps not surprising, since the technologies did not disconnect personal identification from data, but only coded it. According to the Directive, such data are personally identifiable and, hence, not anonymous. According to the *Recommendation*, such data may be non-personally identifiable.

deCODE was to guarantee the security of health data by using complex encryption technologies. The data would be encrypted when transferred from a health care institution to the Identity Encryption Service, which would then again encrypt personal identifiers and send the data on to the company, which would encrypt the data once again. One of the three steps in this encryption procedure is supposed to be one-way, making it in principle impossible to trace the data back to the individual patient.

As the Data Protection Authority pointed out, there are three major problems with regard to the proposed encryption procedure:

1 No encryption system is 100% secure.
2 As Iceland is a small country, information can easily be personally identifiable in indirect ways, even if it contains only a few facts about the patient, and even if these facts are not directly personally identifiable.
3 An encryption system is never more secure than the people who operate it; and, the more valuable the database, the more likely it is that someone will attempt to gain illegal access to it.

A fourth problem is that, in fact, the encryption methods are not one-way. Moreover, they *could* not be either, since if they were, it would be impossible both to link health data to genetic and genealogical data, and to add information about a patient at a later time. A decoding key is required to link information concerning one and the same individual when it is derived from different sources or has been entered at different times.

The issue of consent – and other ethical as well as policy issues – disappeared in the confusion of what counts as personally identifiable data and the technicalities of encryption methods. One lesson to be learned from the Icelandic experience is that the issue of privacy of health data cannot be solved by technological means alone; data security is important, but encryption methods cannot replace confidentiality and trust.

3.2 *Informed Consent and the Role of Institutions*

Informed consent is not required when transferring medical information to the health database. Instead, data collection, processing and storage are based on the principle of 'presumed consent,' *i.e.,* individuals have the choice of opting out by signing a non-consent form issued by the Directorate of Health; this will prevent any information about that individual from inclusion in the database. deCODE argued that once information was entered in the database, it would not be possible to erase it, primarily because it would make it difficult to repeat or replicate studies if data that had been used in the studies could be erased.[5] Parents can sign non-consent forms to keep information about their children out of the database. Yet, many of those most vulnerable of adults, who are not able to access or understand the information, or who do not tend to

paperwork – because of mental illness, drug addiction, etc. – will, as a matter of course, have their medical information entered in the database. Furthermore, there are no provisions for preventing medical information about the dead from ending up in the database.[6]

Linking health data to genetic and genealogical data results in data that are highly sensitive, and it may be impossible to make this information fully anonymous. In any case, since the health data entering the Health Sector Database are personally identifiable, one could argue that informed consent should be required, for instance on the basis of the *Nuremberg Code* (1949), the *Helsinki Declaration* of the World Medical Association (2000) or the *Charter of Fundamental Human Rights* of the European Union (2000).

In the *Nuremberg Code*, the first principle of permissible medical experiments declares that "[t]he voluntary consent of the human subject is absolutely essential" (Nuremberg Code 1949, 1).

The *Helsinki Declaration* of the World Medical Association opens with the words:

> The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. *Medical research involving human subjects includes research on identifiable human material or identifiable data* (World Medical Association 2000, Part A, Article 1; emphasis added).

It is clear that the proposed database research counts as medical research involving human subjects, and not merely as epidemiological research with anonymous data. Furthermore, Article 22 of Part B, on "Basic principles for all medical research," asserts:

> In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely given informed consent, preferably in writing.

The *Charter of Fundamental Rights* of the European Union (2000) states in Chapter 1, "Dignity," article 3, "Right to the integrity of the person":

1 Everyone has the right to respect for his or her physical and mental integrity.

2 In the fields of medicine and biology, the following must be respected in particular: – the free and informed consent of the person concerned, according to the procedures laid down by law.

The *Nuremberg Code* and the *Helsinki Declaration* are generally considered the most important ethical guidelines for medical research. Although Iceland is not part of the European Union, Iceland is a member of the European Economic Area (EEA) and it can be expected to respect the *Charter of Fundamental Rights*. In the case of the Icelandic Database – and in the case of much population genetics research – these guidelines may be difficult or impossible to follow. Proponents of the Icelandic Database claimed that it would be impossible to get informed consent from everyone, although this was a matter of debate. There are two issues that are more serious than the practicalities of getting informed consent from a great number of people. Both these issues have to do with the 'informed' part of informed consent. First, in the case of the Icelandic database in particular, and of genetic databases in general, it is not possible to inform the patient of what exactly will be studied, what the possible risks or benefits may be, nor for how long his/her data will be used for research. These things are not known by anyone. Second, much medical research, and especially research in population genetics, is so complex that one cannot expect even the average adult patient to be able to understand what it is about or what the potential risks and benefits may be. And even if he or she could be informed, it might require unreasonable time and effort.

There are three potential solutions to this problem:

1 Carrying out unethical medical research.

2 Abstaining from research for which informed consent cannot be given.

3 Scaling down the demand for informed consent.

While the first option is clearly not feasible, we should at least consider the second one. The third option may be the best, but it comes with the condition that trustworthy institutions be established that can take some of the weight off individual informed consent.

4 Conclusions: Lessons Learned from the Icelandic Experience

Scaling down the demand for informed consent (the third option above) is, in fact, what was attempted in Iceland. In my opinion, it has been a complete failure. This does not mean that this option is impossible in principle; rather, it means that Iceland failed to establish or to maintain trustworthy institutions.

This lack of trustworthiness is evident at different levels in the institutional framework. The upper level is that of making laws, regulations and policy. Some have claimed that there was democratic, community consent in Iceland for the HSD act and the establishment of the Database (see Árnason and Árnason 2004 for a discussion of these claims). Yet, the Legislature and the Ministry of Health did not demonstrate that they were trustworthy and credible institutions during the development of the HSD legislation, as they cooperated very closely with the company that was expected to be given the license to construct the database; the legislation was not only initiated, but also, at least in part, written, by the company (Jóhannesson 1999). This sort of involvement by corporate interests in drafting the legislation does not make the legislative process and bodies credible.

The lower level of the institutional framework has to do with the creation and operation of the HSD database. The four most important institutions involved are the Monitoring Committee of the Health Sector Database, the Interdisciplinary Ethics Committee, the Data Protection Authority, and the National Bioethics Committee. The first two are specifically concerned with the HSD database, but the other two work on a national level.

The Data Protection Authority consists of five members, all appointed by the Minister of Justice, while the Monitoring Committee of the HSD and the Interdisciplinary Ethics Committee consist of three members each, who are appointed by the Minister of Health. The National Bioethics Committee consists of five people, also appointed by the Minister of Health. Initially, the members of the National Bioethics Committee were nominated by independent institutions, such as the University of Iceland and the main hospitals. In 1999, however, all members of the National Bioethics Committee were dismissed. A new regulation on medical research allowed the Minister of Health to appoint new members now nominated by Ministers and the Directorate of Health. It is of no consequence that no bioethicist has been appointed to the National Bioethics Committee since the change of regulation, or that the present Managing Director is a former deCODE employee. It does not matter either that the current members of the Committee are very knowledgeable about research ethics, or that the Chair of the Committee has been critical of the HSD plans. What really undermines the trustworthiness of the Committee is the sudden movement of power over nominations from independent institutions to the executive branch of the government at a time when the operating license for the HSD was being prepared and deCODE was in a dispute with the National Bioethics Committee, demanding that one of its members resign from the Committee. With the exception of the Data Protection Authority, nominations for these institutions are made by Ministers and the Directorate of Health. Our 'trustworthy' institutions are now almost entirely under the control of the executive branch of the government, which has made the interests of deCODE its own interests.

The fact that the Icelandic institutions involved in the creation and operation of the genetic databases are not completely trustworthy does not mean that, in principle, it is impossible to establish trustworthy institutions. Of course, such institutions cannot serve as a substitute for the consent requirement, but they might allow us to scale down the 'informed' part of informed consent. In a sense, these institutions would replace the need for a fully informed consent by a form of explicit, written consent, based on the subject being informed, to the extent to which that is realistically possible.

Yet, even here we have to be very careful. Despite the fact that there are conceptual as well as practical problems with informed consent, it is still an essential principle in research ethics. The *Nuremberg Code* (1949) requires fully informed consent, and we would need very sound reasons to disregard that guideline, even if in practical applications this requirement is hard to implement. We have to ask ourselves whether we would want to scale down the consent requirement, because all kinds of medical research are becoming more complex. Or does research in population genetics and public health specifically require the scaling down of informed consent, because of its importance and perceived benefits? Especially when considered in an historical perspective, it would be extremely insensitive to disregard the *Nuremberg Code* on account of the importance of genetics, given its eugenic history. As a general rule, we should be very suspicious when vague promises of improved public health and progress in science are called upon to justify the relaxation of ethical principles.

Notes

1 This chapter draws on my research within the project "The Genetic Revolution in Iceland," supported by the Icelandic Research Council RANNÍS, and within the ELSAGEN project (Ethical, Legal and Social Aspects of Human Genetic Databases: A European Comparison), financed between 2002 and 2004 by the European Commission's 5th Framework Programme, Quality of Life (contract number QLG6-CT-2001-00062). However, the information provided is the sole responsibility of the author and does not represent the opinions of the aforementioned. I thank Vilhjálmur Árnason and Ólöf Yrr Atladóttir for thoughtful comments.

2 See *e.g.*, Crosby (1999): "Iceland: The selling of a nation's genetic code," Kahn (1999): "Attention shoppers: Special today–Iceland's DNA," Mawer (1999): "Iceland, the nation of clones" and Schwartz (1999): "Iceland to make its genetic code a commodity."

3 See Abbott (2003), Árnason, Sigurgíslason, and Benedikz (2000), Árnason (2003); and, for DECODE's evidence for Icelandic homogeneity, see Gulcher and Stefánsson (1998); Gulcher, Helgason, and Stefánsson (2000).

4 This recommendation was adopted by the Committee of Ministers on February 13 1997 at the 584th meeting of the Ministers' Deputies.

5 However, recently, DECODE signed an agreement with the Icelandic Medical Association, that data could be erased from the database (Icelandic Medical Association 2001). It is not clear to what extent DECODE is in fact bound by this agreement.

6 This situation has changed after the Icelandic Supreme Court ruled on 12 November 2003, that the Directorate of Health must honour a young woman's request that health information about her deceased father will not be entered in the HSD.

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Part 6

Reflections Beyond the Here & Now

13 In Search of Nanoscale Economics: Intellectual Property & Nano-Mercantilism in the Pre-Assembler & Assembler Stages of Nanotechnology

Michael D. Mehta
& Linda Goldenberg

1 INTRODUCTION

IMAGINE A WORLD WHERE OBJECTS can be built without human intervention. In this future world, very small machines called 'assemblers' can position, in precise ways, nanoscale constructs that could theoretically be made from any raw material (*e.g.,* carbon, silicon) (Drexler 1992a, 1992b, 1994, 1995, 1999), and could be based on blueprints that are patentable, and transportable through high speed networks like the Internet. Or, imagine a world where 'nanobots' patrol the human body, cleaning arteries, destroying cancer and viruses, and repairing cells. This world may seem like something from the realm of science fiction, and be an example of what Mehta (2003) calls "nano-hype," but it is steadily becoming a reality, due to advances in nanoscience. Since the early days of imagining the possibilities of molecular manufacturing, nanotechnology has become a serious, focused area of research, and different visions of its future direction sparked lively debates (see for example the Drexler-Smalley debate [Drexler and Smalley 2003] on the feasibility of molecular manufacturing). To understand such a world requires that we speculate on the likely transformations that nanotechnology could put in motion for economics, intellectual property rights, and international trade. The (U.S.) National Science Foundation makes the following predictions:

> Nanotechnology will fundamentally transform science, technology, and society. In 10 to 20 years, a significant proportion of industrial production, healthcare practice, and environmental management will be changed by the new technology. Economic growth,

> personal opportunities, sustainable development, and environmental preservation will be affected. To take full advantage of the new technology, the entire scientific and technology community must involve all participants, including the general public; creatively envision the future; set broad goals; and work together to expedite societal benefits (National Science Foundation 2001, 19).

A prominent area of research is nanobiotechnology, the convergence of the living and the engineered. Cornell University's NBTC (Nanobiotechnology Center) sees nanobiotechnology as:

> …a new form of biotechnology formed by the union of nanostructure fabrication and biotechnology. We are exploiting nanofabrication to perform individual molecule analyses in biological systems, to study cellular response to structured interfaces and to interrogate dynamic life processes at reduced dimensions. Our research has advanced the ability to structure materials and pattern surface chemistry at subcellular and molecular dimensions, and these continue to be fundamental technologies on which the research of the NBTC is based. It is our vision that nanobiotechnology will be the genesis of substantial new insights into how biological systems function, and conversely, nanobiotechnology will lead to the design of entirely new classes of micro- and nanofabricated devices and machines (NBTC *n.d.*).

Nanobiotechnology research has extensive application in high priority areas of health and the life sciences, for example in cancer therapy, stem cell research, genetic screening, toxin identification, and personalized medicine.

2 WHAT IS NANOTECHNOLOGY?

Before examining the various impacts of nanotechnology on society, we first explore the nature of this new technology. Discoveries in nanoscience and advances in nanotechnology are revolutionizing science and industry, and will likely make advances in biotechnology pale by comparison. These fields are expected to enable scientists to create organic and inorganic matter on an atom-by-atom or molecule-by-molecule basis. The application of nanoscience has the potential to transform medicine, biotechnology, agriculture, manufacturing, materials science, aerospace, information technology, and telecommunications, to name just a few examples (Drexler 1987). Nanotechnology promises breakthroughs that will revolutionize disease detection and treatment, environmental protection, the production and storage of energy, and the way we build complex structures (NNI *n.d.*). According to Canada's National Research Council (NRC), "the economic and social impact of nanotechnology may be profound: discoveries

and applications of nanotechnology could lead to a new industrial revolution in the coming century, and to commercial markets as large as Can $1.5 trillion per year within 10–15 years" (NRC 2005).

In the United States, the National Nanotechnology Initiative (NNI) was established in 2000 to examine ways to create the knowledge base needed to fully exploit technological innovations arising from nanoscience. The U.S. government allocated U.S. $423 million for this purpose during the fiscal year 2001, and it has steadily increased funding, with U.S. $849 million allocated in 2004. Headed by the National Science Foundation (NSF), the NNI has invested in more than six hundred projects and involves 2,500 faculty and university students (NNI 2004). Several other countries around the world have also started to make similar kinds of investments.[1] Since nanotechnology is a powerful, transformative technology, it is critical to understand – and, ideally, shape – it before it becomes too difficult to manage.

Nanotechnology is an umbrella term for a wide range of technologies. Nanotechnology comes from discoveries in nanoscience. It is important to stress that nanoscience is not just another step toward miniaturization. It represents a convergence of quantum physics, molecular biology, computer science, chemistry, and engineering. Innovations arising from nanoscience are likely to be commercialized as greater control over the placement of atoms or molecules is achieved. Although nanotechnology is in its infancy, the principles behind nanoscience are gradually becoming more universally understood and accepted.

Nanoscience represents a revolution in the construction of devices with atomic precision (Crandall 1996). One nanometer is one billionth of a meter or approximately ten atoms of hydrogen in length. Through a comprehensive study of the behaviour of matter at the nanoscale, scientists are exploring ways to gain greater control over matter. Just as computers analyze and distribute data in binary format (0,1), nanotechnology involves constructing new materials (both organic and inorganic) by treating atoms and molecules as building blocks. In essence, nanoscience is about the creation and manipulation of information. For example, a perfect crystal has very little informational content, since its structure can be described concisely with a short string of bits to list the co-ordinates of silicon atoms to form a unit, and some more bits to indicate how the pattern can be repeated to form the crystal. Like with biotechnology, nanoscience is the product of advanced information processing and management. The potential applications of nanotechnology are staggering (see table 13.1).

Although many of these applications are probably a decade or more away from being realized (if ever), several products on the market currently contain ingredients or components derived from nanoscale processes. For example, high-end clear sunscreens often contain a nano-crystalline substance known as titanium dioxide. In fact, the cosmetics industry (*e.g.,* L'Oreal Cosmetics) is investing heavily in nanotechnology and is securing a large number of patents (Oger 2002). In other areas, nanotechnology is stimulating significant advances

Table 13.1
A Sample of Applications Expected to Emerge from Advances in Nanoscience

Environmental	• Remediation of contaminated soil and water. • Reduction of the use of raw materials through improvements in manufacturing. • Re-building of the stratospheric ozone layer with the assistance of so-called 'nanobots' (also known as assemblers).
Medical	• Improvement of diagnostic procedures. • Development of techniques in nanosurgery. • Repair of defective DNA. • Improvement of the delivery of drugs.
Electronic	• Improvement of storage of data. • Development of molecular circuit boards. • Development of molecular computers.
Materials	• Increase of the strength of industrially valuable fibres. • Replication of valuable products (*e.g.,* food, diamonds). • Improvement of the quality and reliability of metals and plastics. • Manufacture of 'smart' materials.

in surveillance technology and may lead to what Mehta (2002a) calls "nano-panopticism," *i.e.,* a form of surveillance by the state and other actors where individuals are observed and tracked in their daily lives through technical means. By facilitating the miniaturization of remote camera technology, it is possible to place undetectable video cameras, microphones and transmitters anywhere one wishes. For example, researchers from Hiroshima University and Nippon Hoso Kyokai (NHK) have discovered that silicon nano-crystal film is photoconductive (TIFAC *n.d.*). Once greater control over the size of crystal grains is achieved, it should be possible to use such films in devices for making highly sensitive, compact video cameras. In addition to reducing the size of surveillance equipment and improving sensitivity, nanotechnology is increasing computing power and storage capacity of electronic devices. Research on the insertion of nano-manufactured molecules, known as fullerenes, into carbon nanotubes (another kind of nano-manufactured molecules) shows how nano-sized wires can be exploited for their conductive and semi-conductive properties (Ajayan *et al.* 1999). Other approaches include the work of scientists at the University of Saskatchewan (2002), who recently secured a patent on a

molecular wire with the discovery of M-DNA (metal-containing DNA). Metal ions from zinc, cobalt or nickel are inserted into DNA to create semi-conductors about two nanometers thick. Lastly, companies like NanoMagnetics (*n.d.*) are developing new magnetic materials that may soon replace the magnetic film technology currently used in hard disk drives. By increasing storage density and decreasing granularity, terabyte drives may soon be available for PCs and hand-held devices.[2] There are several other applications of nano-products such as industrial coatings and lubricants. In short, all of these applications exist at the pre-assembler stage of this technology.

Most of these nano-products involve expensive and energy intensive production methods. It is likely that the economic impacts of pre-assembler stage nanotechnology will be similar in scale to those seen with the advances in biotechnology. It is also very likely that a significant degree of convergence between nanotechnology and biotechnology will occur during this pre-assembler stage. We now turn our attention to challenges to intellectual property rights posed by nanotechnology.

3 INTELLECTUAL PROPERTY & NANOTECHNOLOGY: THE PATENT LANDSCAPE GOES GLOBAL

Nanotechnology is emerging in an extremely complex international property system, which is currently under structural and conceptual development at the global level. Intellectual property – creative works of the mind – can no longer be thought of as a local, regional or even national phenomenon (Wegner and Maebius 2002). Intellectual property is developing into a strategic industrial tool, and into a political 'power tool' for social, cultural and economic development. A proper understanding of the transformative relationship between nanotechnology and intellectual property requires broadening the horizon to include, both, the major underlying social forces that are in play, and the unique characteristics of nanotechnology research and development.

4 WHY IS NANOTECHNOLOGY UNIQUE?

One of the unique characteristics of nanotechnology research and development is the fragmentation of what is loosely termed 'nanotechnology' into a vast array of segments, subject to control through intellectual property mechanisms. Among other things, research has been separated from development, and knowledge from product. With knowledge itself becoming a product, tools have been separated from both product and knowledge, and in themselves constitute intellectual property. Each of these components has value in and of itself, and is a site for control through intellectual property mechanisms. The fragmentation of the various components falling under the general term 'nanotechnology' have disrupted the conceptual and control frameworks of intellectual property to a magnitude similar to the disruption caused by biotechnology and information and communication technologies.

With nanotechnology, research and development have fragmented into numerous components, while the conditions of production for generating intellectual property are increasingly collaborative in nature, and involve a variety of configurations and partnerships with industry, government and universities. Complex ownership relationships have evolved alongside the evolution of a rich research and development environment, and these are increasingly occurring at the global level.

5 SIGNIFICANT TRENDS IN INTELLECTUAL PROPERTY

Nanotechnology is not emerging in a vacuum, but rather onto a complex, dynamic global stage of intellectual property ownership and rights. At the global level, there are three significant trends in intellectual property that are directly relevant for nanotechnology. These are: (1) the trend towards a global or international intellectual property system; (2) the changing role of intellectual property, from a field of claims, to a suite of strategic industrial tools; and (3) the role of intellectual property as a political power tool for social, cultural and economic development, which is closely tied to international trade policies. Patents are the most relevant forms of intellectual property associated with nanotechnology, and will therefore be the focus of our discussion in this section.

5.1 *Towards a Global Intellectual Property System*

Intellectual property is emerging in a global system, embodied in the World Intellectual Property Organization (WIPO *n.d.*a), an international organization that became a specialized agency of the United Nations in 1974. WIPO's mandate is to administer intellectual property matters recognized by its 180 United Nations member states, which represents over 90% of the world's countries (for a list of countries (see WIPO *n.d.*d). It is committed to providing a stable worldwide environment for intellectual property, and by so doing it 'oils the wheels of international trade.' WIPO and the World Trade Organization (WTO) entered into an agreement that came into force on 1 January 1995, entitled the *Agreement on Trade-Related Aspects of Intellectual Property* (TRIPS), which contains provisions concerning copyright and related rights, patents, trademarks, geographical indications, industrial designs, and layout designs of integrated circuits (WTO *n.d.*).

WIPO's magnitude, international connections and broad mandate to administer intellectual property matters at the global level result in a complex organization, requiring considerable time and resources to organize. It is currently in the midst of massive structural, procedural, and conceptual development as it moves towards its stated mandate. At this time, WIPO is in an organizational mode focused on 'harmonization.' In pursuit of harmonization, WIPO is involved in simplifying and standardizing processes involved in an international intellectual property system. Some of these tasks are extraordinarily challenging, as illustrated by the complexity of the emerging international patent system.

The creation of an international patent system involves confronting and harmonizing national laws, legal and regulatory frameworks, processing systems, as well as enforcements and sanctions, and incorporating existing national systems into the new system. Adding to this complexity are different languages and interpretations, as well as social and cultural diversity. WIPO is using a 'treaty' strategy to accomplish these goals in a fair and equitable fashion, and intends to simplify and standardize application and enforcement procedures, and the associated processes of search, interpretation, and registration.

Currently, 180 countries are member states in WIPO, and approximately 65% of those are also part of the Patent Cooperation Treaty (PCT) (WIPO *n.d.*e), the magnitude of this task is staggering. An applicant filing one patent can simultaneously seek protection in all or any of these countries. This is efficient in concept, but has the effect of exponentially increasing the number of applications and corresponding processes, thereby increasing complexity and presenting a need for a technological solution.

Advancements in nanotechnology may play a transformative role in managing the complexity in the intellectual property system. Two specific examples will illustrate the possibilities. One way nanotechnology might simplify existing procedures is through managing the classification process. At present, the system for patent classification is the "International Patent Classification" (IPC), a hierarchical system described in the *Introductory Manual to the International Patent Classification* (IPC) (WIPO *n.d.*c) and the *Introduction to the IPC on the Internet* (WIPO *n.d.*b), comprising eight sections, 120 classes, 628 subclasses and approximately 69,000 groups (main groups and subgroups), with each subdivision indicated by a title and a symbol. This classification process is currently under revision. In June 2003, WIPO's IPC Revision Working Group issued *Guidelines on the Rearrangement of the Main Groups According to the Standardized Sequence*. The United States had previously been invited to prepare detailed guidelines on the rearrangement of main groups, and these were approved (WIPO 2003). The new classification scheme is a standardized sequence arrangement, based on the relative complexity or degree of specialization of the invention; it operates according to a 'top-down' sequence in the following order: (1) methods of using products; (2) products; (3) processes for making products; (4) apparatuses used to make products; (5) materials from which products are made. Significantly, three of the eight examples of classification presented in the *Guidelines* involve classifying nanotechnology, so nanotechnology is clearly playing a role in transforming the reclassification scheme itself.

Another potential role for nanotechnology transformation lies in managing the workload involved in this evolving large and complex system. In an address to the Conference on the International Patent System organized by the World Intellectual Property Organization in Geneva on 27 March 2002, Bruce A. Lehman, the president of the International Intellectual Property Institute (IIPI) in Washington, D.C., stated:

> The global patent system is currently in a state of crisis. This crisis is a result of the following factors: the increasing complexity of inventions, the explosion of patent and non-patent prior art; the expansion of patentable subject matter; the globalization of the patent system; the cost of multinational filing; the disproportionately low level of patent filings from nationals of developing compared with developed countries, and the accelerating number of applications in many patent offices (Lehman 2002).

The 'crisis of workload' is echoed by WIPO itself (WIPO *n.d.*e), as well as the very real problem of the lack of sufficient expertise available to make the sophisticated distinctions required in this complex environment. As a new and emergent science, nanotechnology will require individuals with specialized training and education. In the absence of this expertise, there is a risk of applying concepts such as 'substantial equivalence' as an overarching principle, which could mask fundamental and significant differences (Mehta 2004). For instance, nanotechnology research clearly shows that chemical, mechanical, optical, and electrical properties are different in the quantum realm and this will present both risks and opportunities that are unknown at this time.

Nanotechnology is emerging in an already evolving and transforming global arena, and it will contribute to this complexity, and perhaps provide options for managing it as well. In this sense, it is a transformative influence shaping the patent landscape.

5.2 *From a Field of Claims to a Suite of Strategic Industrial Tools*

Within the context of the current global intellectual property system, the role of patents is undergoing a fundamental change: from a traditional claim-staking exercise to that of a strategic industrial tool (see *e.g.,* Rivette and Kline 2000; Sankaran 2000; Wegner and Maebuis 2002; Parloff 2003). Wegner and Maebuis (2002) compare the major characteristics of the classic 'offensive patent' strategy of the pharmaceutical industry – where an invention requires protection during lengthy and costly testing and trials – with 'cumulative patents' of the microelectronics and telecommunications industries, where any advance in the field requires access to a bundle of prior patents. Some of these strategies include 'defensive patenting' to avoid domination by another's patent (for example, through strategies such as 'land mines'), or a 'patent tax' levy on an industry through a 'patent web' that is interwoven through an area of technology, thereby compelling third parties to take a nonexclusive license.

Another defensive patenting strategy is 'patent flooding,' which involves filing many patent applications around another's core technology, claiming minor, incremental changes. Creating a 'web of patents' to cover an entire technological area has the effect of ultimately lifting everyone out of the patent system and into a licensing and cross-licensing system. By extension, this creates assets and

portfolio additions to corporations through new revenue streams, as well as an increased ability to exert influence through strategic alliances and manoeuvres. The WIPO publication *Intellectual Property: A Power Tool for Economic Growth* by Kamil Idris (2003), Director General of WIPO, presents numerous anecdotal reports that support using intellectual property as a valuable part of business management planning and strategy.

Industries will use nanotechnology patents in a variety of strategic ways, depending on the characteristics and requirements of the industry. In highly vertical industries, such as the pharmaceutical industry, a traditional 'offensive' approach directed at protecting discrete applications is most probable. In contrast, the most likely strategy for optical, telecommunications and computing industries is a 'defensive' approach, directed at incremental changes to prior patents.

This raises an important issue that warrants attention on several levels, specifically of increased concentration of corporate power. This applies in particular to the pharmaceutical industry, where nanotechnology will play a significant transformative role in drug discovery, as well as to clinical and non-clinical applications in diagnostics and intervention, through advancements such as microfluidics and nanofluidics, the study and control of liquids at a very small scale (Pilarski *et al.* 2004). There is no reason to assume that large corporations will see a competitive advantage in participating in, both, the public and global patent systems. This gives rise to an increasing possibility that a large amount of research and development will remain in the private domain of trade secrets and proprietary information, and, hence, beyond regulatory scrutiny. As a result, regulation and accountability for risks remain largely out of sight as well.

5.3 *Towards a Suite of Political 'Power' Tools*

WIPO elevates the concept of intellectual property – including patents, as a strategic *industrial* tool – to that of a *political* 'power tool,' to be used not only for economic development, but for social and cultural development as well. This role is an integral part of WIPO's *Vision and Strategic Direction*:

> Hand in hand with technological development, intellectual property has become a global issue, because of its increasing relevance to key and critical policy fields such as food security, health, labour, trade, culture and heritage, environment, investment, and scientific and technological transformation; particularly as we move into the knowledge-based economy, in which a nation's well-being will depend more and more on its access to, and use of, the intellectual property system to generate wealth and social good (WIPO 1999, 2).

Intellectual property is becoming politicized, is undergoing a process akin to commodification, and is increasingly linked with international trade strategies. Power, influence, and all their ancillary forms will continue to be shifted from

the political to the economic sphere, through government actions and policies, including international trade policies. A significant development related to international trade – and, by extension, intellectual property – is the proposed development of the *Free Trade Area of the Americas* (FTAA *n.d.*), which focuses on uniting the economies of the Western Hemisphere into a single free-trade zone. This initiative formally began in 1994, and at the 2001 Summit of the Americas in Quebec City, the leaders of thirty-four nations in the Western Hemisphere signed a declaration pledging support for completing negotiations of a FTAA no later than January 2005. The FTAA will be the world's largest free-trade area, representing 800 million people. Intellectual property will have substantial global market value, and a considerable amount of it will be tied up in nanotechnology patents.

Several important issues arise with this reconceptualized role of intellectual property: two related ones are the increased concentration of corporate power in the global environment, and moral issues associated with patents. With respect to the former, once corporate or industry players form alliances and are lifted out of the patent system and into a licensing and cross-licensing system, they gain collective strength in defining the developmental trajectory of nanotechnology. Moral issues associated with patents arise when intellectual property is seen as an instrument of economic, social and cultural development – a political power tool – which challenges the 'rights' framework upon which the concept of intellectual property was initially founded. Taken together, and within the context of underdeveloped or marginalized countries or people, several questions need to be addressed, such as, Who has the right to this? The notion of public good is called into play, particularly as it relates to developing countries, but also as it relates to developed countries. Why, for example, should developing countries be denied the benefits of any technology – that may contribute positively to health, welfare, quality of life, and the environment – through patent restriction? Conversely, why should a country be subject to the values and ideologies of another country in order to benefit? These are not new questions, but they will take on increased significance as nanotechnology uses and applications develop, and as they create invariably a nano-divide (Mehta 2002b).

6 WHAT DOES ALL THIS HAVE TO DO WITH NANOTECHNOLOGY?

Global level connections are expanding in all directions and at many different levels, and it is in this dynamic environment that nanotechnology is emerging. Nanotechnology will not just be a technology or a product, but, rather, a valuable tool with tremendous power. In terms of nanotechnology itself, a major transformative potential lies in the contribution it will make in terms of information and communication technologies, including database capacity and supercomputing capabilities, which will facilitate and increase activities such as data-mining and statistical comparisons. In this sense, nanotechnology

will contribute to the transformation currently underway in developing the global intellectual property system. In so doing, it will no doubt contribute to the complexity of the system itself through increased patent applications for software (and perhaps even algorithms), hardware devices and uses, and a need for skilled and knowledgeable individuals to manage intellectual property in a global context.

These challenges to intellectual property rights regimes – and, hence, to the international trade practices with which they are associated – will continue throughout the pre-assembler stage of this technology. However, a breakthrough in the development of assembler technology could cause dramatic changes. We now turn our attention to the assembler stage of nanotechnology and discuss how this stage could reverse current trends toward economic globalization and trade liberalization while potentially ushering in a new mercantilist period in history.

7 THE ASSEMBLER STAGE

For many in the investment community, nanotechnology is a lightning rod for both criticism and promise. Having been hurt, first, by the rapid growth and collapse of the so-called 'dot.com' sector, and, currently, by problems facing the agricultural biotechnology sector, investors have become wary of claims that sound like nano-hype. A significant obstacle faced by scientists – that reverberates throughout the investment community – is the scaling up of nanoscale processes and products to the macro-level. There is no doubt that the development and production of nanoscale powders, coatings and crystals are lucrative and stimulate a race for new patents. Yet, the true breakthrough will occur when nanoscientists can encourage directed self-assembly at the nanoscale, and when universal assemblers are developed. Directed self-assembly may involve developing processes where molecules mimic biology by taking ideas from nature (known as biomimetics), by constructing nanostructures based on properties like the folding of proteins, and by manipulating nucleic acid structures and using cellular fuels like adenosine triphosphate (ATP) to power hybrid organic-inorganic motors and pumps (Soong *et al.* 2000). The search for a universal assembler, on the other hand, involves developing a mechanism for positioning atoms and molecules in pre-defined ways, by mechanical processes. Texas-based corporation Zyvex has developed a crude prototype of a nano assembler that picks up and places atoms, using a modified atomic force microscope (McKay 2000). For Eric Drexler (1987), a universal assembler could be a positioning device with different tools and tips that place, mill, add reactants, and allow for the assembly of nanoscale components into larger structures. Following the laws of nature, the universal assembler should be able to build almost any object (including other assemblers). If, and when, this breakthrough in universal assembler technology occurs, nanotechnology will usher in a new kind of industrial revolution where existing manufacturing processes will be

replaced, the concept of human labour reconsidered, and the current basis of the economy and global trade transformed. Could these changes give rise to a new form of mercantilism?

8 WHAT IS MERCANTILISM?

Mercantilism was a form of economic nationalism that was primarily concerned with questions of competition and the role that governments could play in protecting local merchants, in generating employment opportunities in manufacturing, and in promoting a more secure state (Ekelund and Tollison 1997). Tariffs and other protectionist policies were used to create a positive trade balance (*e.g.,* a surplus); they facilitated the accumulation of precious metals (especially bullion), and supported the expansion of military power and shipping. Mercantilist policies helped forge new alliances between the state and the growing merchant classes. In Europe, the mercantile system protected and encouraged the growth of merchants like the British East India Company, and was ultimately a driver of colonialism (Aldrich 1996).

The origins of mercantilism, as a system of economic and political practice, are a subject of debate. It is generally assumed that mercantilism began in Rome to ensure that profits from the expansion of the Roman Empire could be maximized, by creating a system for trading goods that helped build a wealthy and powerful state (Horrocks 1925). By the 700s, a few centuries after the collapse of the Roman Empire, mercantilism played only a minor role in Europe, as in many European countries culture and economy tended to be matters of national – if not local or regional – rather than international scope (Hooker 1996). However, at the same time, mercantilism flourished in Arabic cultures and spread rapidly through North Africa, Spain and Asia. In the 1300s, European interest in mercantilism was reignited, and a system of trade was established that would eventually evolve into what we now call capitalism. Most contemporary writers on mercantilism focus their attention on Europe during the Sixteenth through Eighteenth Centuries. This period in history is punctuated by bloody religious wars that required large standing armies and additional resources, to support a newly emerging form of civil government. To pay for these wars and other politically motivated reforms, roads and canals were built, guilds were systematically weakened, and venture capitalists were rewarded by the state. By stimulating commerce and extraterritorial trade, the state was able to increase taxes, support manufacturing by importing raw materials at low cost, while exporting finished goods at a premium, and to add bullion to the monarch's treasury. Although no definition of mercantilism is entirely satisfactory, it is important to emphasize that mercantilist thinking was heavily influenced by a desire to achieve economic unity and political control, and that it usually contained a blend of the following elements (see table 13.2).

Table 13.2
Elements of Mercantilism

Characteristic	*Explanation*
Economic self-sufficiency (autarky):	• A political economy dominated by empiricism, issues of competition, and protection by the state. • Economic activities should be subordinated to state interests. • Frequent state intervention in the economy.
Favourable balance of trade and protection against foreign competition:	• Exports outweigh imports. • High tariffs on imported manufactured items and low tariffs on imported raw material. • A trade surplus was desirable. • Assumption that economic relations were 'zero sum' ('my win is your loss').
Bullionism:	• Belief that the economic health of a nation could be measured by stocks of precious metals.
Colonialism and captive markets:	• Colonies were ideal places to secure raw materials and to sell manufactured goods.
Shipping:	• Shipping–and military–infrastructure were key.
Social agenda:	• Used to achieve economic unity and political control (often in the interest of merchants and producers).

It is widely recognized that the end of the mercantile period coincided with debates stimulated by scholars like Adam Smith. Smith's ([1776] 1982) *The Wealth of Nations* helped to put an end to mercantilism by demonstrating its incompatibility with economic liberalism, by questioning the role of the state in directing – rather than simply setting – the national economic agenda, and by pointing out that specialization in production allowed for more efficient economies of scale. The mercantilist doctrine also supported monopolies and strong protectionist measures that were increasingly becoming a hindrance to trade (Engels 1844). Mercantilism was eventually replaced with capitalism in many parts of the world. Periodically, mercantilist thinking – especially when it comes to protectionism – has been revived, in what is called neo-mercantilism. Nevertheless, the dominant economic system is still that of capitalism, with its emphasis on the accumulation of the means of production (*e.g.,* raw materials, labour and land) instead of bullion, on efficiency and the division of labour, with its teleological (*e.g.,* forwardly-directed) stance, and its focus on the individual and the Enlightenment ideal of progress. However, the dominant position of capitalism might change, once advances in nanotechnology make possible the use of universal assemblers.

9 How can nanotechnology stimulate a new era of mercantilism?

A return to mercantilist policies by states that have access to assembler technology is likely to develop slowly. In the first phase of this transition, devices that can perform molecular self-assembly in a directed fashion will have minimal impacts on the foundations of capitalism, as they are currently understood. Devices that mimic biological processes, and help us bridge the so-called dry-wet (*e.g.,* mechanical-biological) interface, will probably magnify existing practices of specialization of labour, deepen international trade and the rush to harmonize intellectual property rights, and create new convergences within the life science and computer industries. In other words, this would be 'business as usual' for capitalism in an era of economic globalization. However, there are a number of reasons why the development of universal assembler technology may foster mercantilism, namely:

9.1 *Assembler-Era Nanotechnology Changes the Significance of Organized Matter*

In theory, universal assemblers decouple manufacturing from traditional raw material markets. As the current global processed-food market demonstrates, interchangeability of inputs and flexibility of formulation has improved efficiency and profitability. In a nano-based economy, universal assemblers can use almost any atomic or molecular building block to create manufactured goods. Instead of relying upon the importation of steel for manufacturing automobiles, countries like Japan could use assembler technology to 'grow' automobiles from other materials that may be lower in cost, or available from domestic sources. An economy based on these principles will require a large number of individuals trained in software development and testing, advanced information and communication infrastructures for processing, storing and transporting blueprints, and an environment for intellectual property rights where patents are granted for reverse engineering a wide range of products. The creative minds amongst us may imagine museums, like New York's Metropolitan Museum, becoming the malls of the future; one day, consumers interested in purchasing works of art may be able to custom-order a nano-fabrication of a scanned artefact!

9.2 *Assemblers Distort International Trade by Capitalizing on Differential Levels of Access to Nanotechnology*

As is the case with mercantilism, trade between nano-'have' and nano-'have-not' countries will involve the shipment of cheap raw materials from the supplying country, and of higher-priced nano-manufactured products back. The impacts on labour, and on the global distribution of wealth, are areas requiring much more research. This kind of trade relationship echoes the colonial arrangement of the mercantilist period, and may fuel louder calls for measures to ensure economic self-sufficiency. Besides, given the heightened concerns about national security in

countries like the United States in a post-9/11 world, and the staggering potential of nanotechnology in military applications, the exchange of knowledge about how to construct a universal assembler will be a closely guarded secret.

9.3 *Assembler-Era Nanotechnology Will Create a New Kind of Bullionism*

A central doctrine of mercantilism was that bullion could be stockpiled, by creating the necessary economic and social conditions for promoting a positive trade balance. This 'zero sum' logic was based on a belief that resources were finite. With respect to this issue, it has to be pointed out that a nano-based economy is filled with several internal contradictions. On one level, the use of universal assemblers means that scarcity of raw materials becomes an obsolete concept. Two of the most common elements on Earth – carbon and silicon – can probably be used to produce a wide variety of manufactured products. On another level, access to universal assembler technology, and to the blueprints used for coordinating the construction of objects, is likely to be restricted. In the assembler era of nanotechnology, the new bullion will consist of the assemblers themselves and the intellectual property for objects that they can build. In this instance, mechanisms for ensuring a positive trade balance (*e.g.,* protectionist measures like tariffs), coupled with differential levels of access to this technology, may help stimulate a new era of mercantilism.

10 CONCLUSIONS

In this chapter, we have attempted to answer some rather difficult questions: How can advances in nanotechnology affect intellectual property rights, global trade, and the foundations of capitalism in a globalizing era? To examine these questions, we made a general distinction between the pre-assembler and assembler era. In the pre-assembler era, the biggest challenges are likely to be intellectual property and international trade issues. Some of these international trade issues will involve – as was the case with biotechnology – a range of regulatory and non-regulatory concerns (such as how and when to apply the precautionary principle), the appropriate application of substantial equivalence, and consumer driven concerns on labelling of nano-derived products (see Mehta 2004).

Our analysis of assembler era nanotechnology distinguished between directed self-assembly (based on biomimetics and other processes) and the development of a universal assembler. This section of our chapter, although highly speculative, is cautionary in tone. Since nanotechnology has the potential to transform so many facets of our existence, it is crucial to consider both the benefits and the risks of this suite of technologies. The traditional ways of examining risks and benefits has been to treat technologies in an application-specific fashion, and to focus attention on environmental and human health risks as well as on economic benefits. Rarely are there opportunities to explore other kinds of risks, like the potential threat posed by new technologies to entire economies.

In conclusion, nanotechnology is more than a way of moving around atoms and molecules. In profound ways, it challenges our understanding of matter and offers ever-increasing levels of control over the physical world. As Einsiedel and Goldenberg (2004) point out, the advent of nanotechnology requires also that we consider how best to craft social tools and mechanisms (*e.g.,* new forms of public consultation) for dealing with the innovations that flow from this suite of technologies. As such, we challenge academic communities (like those that focus on biotechnology) to explore our nano future in critical ways.

Notes

1 For example, in 2001 the Canadian government, through the National Research Council, gave the University of Alberta $120 million to create the National Institute for Nanotechnology (NRC 2001).

2 "NanoMagnetics grows tiny magnetic grains within hollow protein spheres called 'apoferritin,' which are 10,000 times smaller than the diameter of human hair. These particles are limited in size by the inner cavity of the spheres, producing highly uniform grains. The protein can also be used for the production of alternative materials, including other metals or semiconductors. Importantly, these particles are produced in parallel using mild and inexpensive chemical techniques" (NanoMagnetics *n.d.*).

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14 Inhuman, Superhuman, or Posthuman? Images of Genetic Futures

Jon Turney

Science is my territory, but science fiction is the landscape of my dreams.
—Freeman Dyson, IMAGINED WORLDS

1 INTRODUCTION

FREEMAN DYSON (1998) EMPHASIZES the way the imagination operates in a realm defined by both facts and fiction, and this is the territory I want to explore in relation to genetics. If we want to understand how genetics and its technological potential are seen in our culture, then opinion surveys, focus groups and media analyses all provide part of the answer; but they can be enriched by a historical view of key texts and images (Turney 1998). These can give clues to the larger visions that may underlie immediate attitudes, or even policy positions. This is not the place for a full historical survey, so I will offer some snapshots, examples of the kind of resources on offer for building visions of genetic futures. Obviously, this will be highly selective, but I expect that most, if not quite all, of the texts I am going to quote will be familiar to many. And that recognition, of course, is part of the evidence for their continuing importance. I will start just over a century ago, and finish with some very recent contributions, so the reader may get some sense of continuity and change, at least.

First, let me consider whether there is any general framework that might help approach these images. One would be the basic historians' tactic of dividing the century into periods, and describing what kind of contribution was typical of each period, or what seemed to preoccupy people most. José van Dyck (1998) and Celeste Condit (1999) have both done this for images of genetics in general, using rather different approaches and kinds of data. Yet, I think images of the genetic future of humans invite a different approach. One relatively simple classification might be to consider optimism and pessimism, but this is hard to apply, because it begs the question of what a particular writer is being optimistic or

pessimistic *about*. How should we place, say, Francis Fukuyama's (2002) warning of the dangers of genetic manipulation in *Our Posthuman Future*? Is he an optimist, because he argues that human nature should be stabilized in order to continue enjoying the benefits of the best political system we have yet come up with, *i.e.,* liberal democracy overseeing a free market? Or is he a pessimist, because he thinks this is as good as it gets? My answer would be the latter, but others might disagree.

This difficulty draws attention to the fact that speculation about the future incorporates a whole range of assumptions, of which ideas about the genetic make-up of the human species are only a part. When we consider what may happen in years to come, on short or long time scales, we may foresee change in the conditions of life, with humans themselves unchanged. The idea that humans themselves would change is a relatively recent addition to stories about the future. It is, of course, connected with an idea that predates the rise of genetics. When we speak of genetic futures, we are talking, in essence, about evolution. I am going to claim that this is true throughout the last century. Granted, the formal links between genetics and Darwinian theory were not forged until the synthesis period of the 1930s. Yet, if we substitute 'germ-plasm' for 'genes,' I think few would want to argue against the idea that human inheritance and evolution were linked in thought before then. Just think of all those eugenic tracts that exhort readers to look after the future of the race by guarding the germ plasm.

So, it is important to note that the rise of evolutionary thought in the nineteenth century introduced another dimension of historical change into Western imagination. The Enlightenment and the scientific and industrial revolutions had already installed the idea that the future would be different from the past. Usually, of course, this was embodied in a progressive vision. For Enlightenment thinkers, the best that we could hope for in earthly life was no longer a return to some Arcadian past, but a future of man-made perfection.

At first, this was restricted to social, technological, and political change: improve the conditions of life, and humans will change, while staying essentially the same. Yet, with evolution came the thought that *biological* change was also possible; humans themselves might be different in the future. And, although the story of evolution was almost always figured as an upward progression – and still is, as Michael Ruse (1996) has shown in great detail – the images of future humankind have always included the possibility of regression or degeneration. Later, as we will see, this becomes more complex, as what counts as progress comes into dispute.

Yet, although the concept of evolution invites a focus on the biological domain, the term has also come to be used in other realms where change over time may occur. Take cultural evolution, for example. Darwinian schemes for culture seem implausible to me. Whatever the units of selection might be, once you take into account the facts that their variation is non-random, that they are not passed on

Table 14.1
Evolutionary Domains and Dynamics

Evolutionary Dynamics	*Evolutionary Domains*		
	Technological	*Social*	*Biological*
Stasis:			
Indefinite (infinite?) advance:			
Advance, followed by stasis:			
Advance toward catastrophe/collapse:			
Indefinite (total?) regress:			
Regress, followed by stasis:			

independently, and that the selection is most often intentional and directed, it simply seems too much of a stretch to work up a scheme for quasi-Darwinian change. Yet, I do think that, in a more general sense, it is meaningful to speak of cultural evolution.

Here, though, I want to distinguish between evolution in three realms: biological, social, and technological. I am using the term 'social,' rather than 'cultural,' because it seems more sensible to bracket off technology if you avoid the use of the term 'culture.' Although these three categories may be closely bound together, in my opinion they are analytically separable. In other words, in order to assess a particular writer's position on future *biological* evolution, it helps to consider what he or she argues or assumes about the other two dimensions of evolution as well. Sometimes this is obvious, as it is technology that is going to change the course of human biological development; however, in other cases it is less so. Still, I think it gives us a way into some simple classifications. By examining how much change is being proposed, in which of these three realms it is thought to occur, and which of the dimensions (if any) is believed to be the force driving the others, some useful distinctions begin to emerge.

This suggests that, as we are dealing with change through time, the dynamics of the situation are also important. At the extremes, change in any one of the three realms could lead to regression or to endless improvement, with stasis somewhere in the middle. Then there are more complex cases conceivable, in which improvement precedes regression – or even complete catastrophe – or is followed by stasis at a 'higher' level. Thus, the following dynamics can be distinguished: stasis; indefinite (infinite?) advance; advance, followed by stasis; advance towards catastrophe or collapse; indefinite (total?) regress; and regress, followed by stasis.[1] If these evolutionary dynamics are combined with the evolutionary domains discussed above, a two-dimensional array of possibilities emerges (see table 14.1). Aspects of different visions of the future may then be compared by placing them in the appropriate cells in this table.

My first exhibit is an image of degenerate humans. H.G. Wells, who learnt his insights into the workings of evolution from Thomas Huxley, gave us two great Darwinian fables. One was *The Island of Doctor Moreau*, published in 1896 (Wells 2000b). A year earlier, he published *The Time Machine* (Wells 2000a), with its unforgettable vision of those distant descendants of the Victorian class system, the feeble-minded Eloi and the sinister, subterranean Morlocks. Here is the time-traveller's first glimpse of the latter:

> [A] queer little ape-like figure, its head held down in a peculiar manner, running across the sunlit space behind me … 'My impression of it is, of course, imperfect; but I know it was a dull white, and [it] had strange large greyish-red eyes; also that there was flaxen hair on its head and down its back. But, as I say, it went too fast for me to see distinctly. I cannot even say whether it ran on all fours, or only with its forearms held very low (Wells 2000a, web ed., chap. 5, pars. 31–32).

This is clearly an image of degeneration, reinforced by the subsequent revelation that the Morlocks use Eloi for food. And both are victims of, first, the success of their technology, and, then, of its failure. The driving force here is the influence of technical and social evolution on natural selection. Not surprisingly for a pre-Mendelian story, there is no actual genetic technology involved. As the returned time-traveler proposes:

> [T]he Upper-world man had drifted towards his feeble prettiness, and the Under-world to mere mechanical industry. But that perfect state had lacked one thing even for mechanical perfection – absolute permanency. Apparently, as time went on, the feeding of the Under-world, however it was effected, had become disjointed. Mother Necessity, who had been staved off for a few thousand years, came back again, and she began below. The Under-world being in contact with machinery, which, however perfect, still needs some little thought outside habit, had probably retained perforce rather more initiative, if less of every other human character, than the Upper. And when other meat failed them, they turned to what old habit had hitherto forbidden (Wells 2000a, web ed., chap. 10, par. 4).

Hence, the changes in *The Time Machine* are simply the result of continuing selection under changed conditions. Here, obviously, we enter the discourse of eugenics, which spans the pre-genetic and genetic eras. It is not long before eugenics is beefed up by artificial aids, though still as an aid to selection, rather

than through actual engineering of new variants. In J.B.S. Haldane's famous *Daedalus* of 1924, for example, ectogenesis – test-tube baby technology in our idiom – is used as a technical fix, *i.e.,* as a way of forestalling degeneration.

> The small proportion of men and women who are selected as ancestors for the next generation are so undoubtedly superior to the average, that the advance in each generation in any single respect – from the increased output of first-class music, to the decreased convictions for theft – is very startling. Had it not been for ectogenesis, there can be little doubt that civilization would have collapsed within a measurable time, owing to the greater fertility of the less desirable members of the population (Haldane 1924, web ed.).

Haldane was an important voice in the 1920s and 1930s, and he brings us to a group of writers, most, but not all, Englishmen, who, together, forged many of the images we still draw on when we think about genetic futures. In many ways, they set the terms of our current debates.

The work from this period that is best known today is Aldous Huxley's *Brave New World* of 1932. Reference to table 14.1 makes it clear that Huxley's is not so much a vision of human evolution, as of evolution come to an end. True, the suite of technologies Huxley's fictional society deploys has brought about great change, but that change is over. In fact, the rulers' attitude to technological innovation is closer to that of Imperial China than to the capitalist culture Huxley was satirizing. As the chief technocrat, Mustapha Mond puts it:

> We have our stability to think of. We don't want change. Every change is a menace to stability. That's another reason why we're so chary of applying new inventions. Every new discovery in pure science is potentially subversive; even science must sometimes be treated as a possible enemy. Yes, even science (Huxley 1950, 94).

The key to stability, he emphasizes, is Bokanovsky's process, ensuring a reliable supply of compliant gammas and deltas to do the (unnecessary) menial work. Despite its reputation as a depiction of unfettered technological application of biological knowledge, this vision of the genetic future is one of stasis.

I will return to that point later, but let me now move on to a more expansive future. The Marxist crystallographer and technological visionary J.D. Bernal's *The World, The Flesh and the Devil* of 1929 is an extraordinary text, and one that later writers, like Freeman Dyson, often return to. Bernal offers a vision of a humankind that is completely transformed, but not through genetics, which – in his view – will ultimately frustrate such ambition. Instead, his future humans turn to electro-mechanical enhancement, and fashion a kind of super-cyborg.

As he put it:

> The new man must appear to those who have not contemplated him before as a strange, monstrous and inhuman creature, but he is only the logical outcome of the type of humanity that exists at present…. Although it is possible that man has far to go, before his inherent physiological and psychological make-up becomes the limiting factor to his development, this must happen sooner or later, and it is then that the mechanized man will begin to show a definite advantage. Normal man is an evolutionary dead end; mechanical man, apparently a break in organic evolution, is actually more in the true tradition of a further evolution (Bernal 1929, web ed., sec. 3, par. 8).

Bernal gave us both the first instance of future man as a kind of brain in a vat, as well as a stark reminder that more than one kind of evolution was now possible, and that there might turn out to be crucial trade-offs between them.

Olaf Stapledon took up all these possibilities and more in his equally remarkable novel, *Last and First Men*, published in 1930. This, along with his later *Star Maker* (Stapledon 2004), is perhaps the grandest evolutionary narrative of all, and an enduring influence on much subsequent science fiction.

If one wants a catalogue of possibilities for human evolution, then *Last and First Men* is a good place to start. Stapledon relates the history of a succession of species descended from humans, the First Men. The first new departure comes about through traditional evolutionary processes.

> It was some ten million years after the Patagonian disaster that the first elements of a new human species appeared, in an epidemic of biological variations, many of which were extremely valuable. Upon this raw material the new and stimulating environment worked for some hundred thousand years until at last there appeared the Second Men (Stapledon 1995, 113).

Yet, these second men subsequently reconstruct themselves, in different ways at different times, through a dizzyingly long narrative, spanning some two billion years. They begin with genetic alteration, move to electro-mechanical maintenance of giant brains, and then refashion themselves again as embodied beings, as this recovers essential elements of their humanity that had been lost. Stapledon's book, in fact, ends up sketching just about every possibility implied by the table of realms of evolution and the trajectories they may follow. In some ways, there is little to add after this sweeping narrative, although *Last and First Men* is confined to the Solar System, and *Star Maker* opens out the canvas to include other stars and galaxies.

More earthbound writers, on the other hand, continued to develop ideas of directed improvement of the human species. So, we find the pioneer geneticist and lifelong eugenicist Hermann Müller arguing for the long perspective just a few years later in his would-be prophetic tract *Out of the Night*.

> In time to come, the best thought of the race will necessarily be focussed on the problems of evolution – not of the evolution gone by, but of the evolution still to come – and of the working out of genetic methods, eugenic ideals, yes, on the invention of new characteristics, organs, and biological systems that will work out to further the interests, the happiness, the glory of the god-like beings whose meager foreshadowing we present ailing creatures are (Müller 1936, 46).

Out of the Night was a piece of non-fictional speculation, but Müller's perspective was also well represented in subsequent science fiction. In fact, his own discovery of the late 1920s, that X-rays could induce mutations, found its way into the pages of the new pulp science-fiction magazines impressively quickly.

So, even from these few examples one can see that it was in this period that a range of possibilities for thinking about genetic futures were first laid down. Subsequent discussion draws on, and develops, these possibilities, but does not really add any new ones. Later in the twentieth century, of course, genetic futures are discussed more often, and more urgently, not with the urgency that once accompanied the eugenics debate, but with a strong realization that deliberate change, not selection, might now be possible. In the post-DNA era, the possibilities of engineered genetic change largely dominated the picture of future, technologically assisted human evolution. Genetic engineering (a crucial term) was simply easier to imagine than the other kinds of engineering, which Bernal, for example, emphasized. The very recent discussions of cyborgization, robotics, and nanotechnology (McKibben 2003; Mehta and Goldenberg, Chapter 13, this volume) may be changing that again, but here I will limit myself to genetic change.

In the mid-1960s, a number of books explored the potential consequences of a newly identified "Biological Revolution." In *The Biological Time Bomb*, for instance, Gordon Rattray Taylor (1968) declared that: "To judge from what the scientists themselves are saying, the most serious of all the human problems created by biological research is constituted by man's imminent power to interfere in the processes of heredity, to alter the genetic structure of his own species" (Taylor 1968, 76).

Thirty years later, that perception is still current, but there are now three distinct positions on genetic engineering. One is simply to take it for granted, as an inevitable outcome of the kind of biology we now wish to develop. A memorable recent example here is British biologist Adrian Woolfson's (2000)

popular book *Life without Genes*. Woolfson is mainly interested in elucidating the thinking behind his approach to organisms, which sees them as physical realizations of samples from some universe of all possible organisms, which exists in an abstract design space whose rules are almost within our grasp. One result, which is only mentioned incidentally in the book, is what I will call the *'taken for granted'* view of genetic engineering. He puts it like this:

> When we have charted the genetic landscapes that have been explored by natural evolutionary processes and are in a position to fully appreciate the nature of the mechanisms responsible for generating and modifying living things, life will enter a new realm of history. It will no longer lie in the exclusive and capricious historical domain of chance and natural selection. It will instead be possible to design and construct new living things using ahistorical processes, in much the same way that we currently design and construct motorcars, traffic lights, helicopters, and vacuum cleaners (Woolfson 2000, xiii).

This rather arresting idea is included almost incidentally in Woolfson's exposition, which thus sidesteps whole swathes of discussion about the implications of redesigning life, and especially human life. Yet, in an increasing number of books, this is the main topic. The authors of those books tend to take one of two other positions.

One of these positions is represented by Francis Fukuyama's (2002) *Our Posthuman Future*, which has already been mentioned. I will call this the *'keep humans human'* position. It rests on an essentialist notion of human nature, to which what he thinks of as the best of all possible political systems – liberal democracy – is optimally adapted. As he sees it:

> Human nature is the sum of the behaviour and characteristics that are typical of the human species, arising from genetic, rather than environmental, factors…. Every member of the human species possesses a genetic endowment that allows him or her to become a whole human being, an endowment that distinguishes a human in essence from other types of creatures (Fukuyama 2002, 130).

This is how we are, says Fukuyama, and this is how we should stay. It is the only sound basis for defending human rights, and any deviation from the human essence would compromise those rights. Hence, any application of gene technologies to humans should be strongly resisted as jeopardizing the human future.

It is interesting to note that Fukuyama – in common with other critics of new biological technologies like Leon Kass – frames his entire discussion with

images from *Brave New World* (Fukuyama 2002; *cf.* Kass 1972; Kass and Wilson 1998). This is ironic as both his own vision of the future and Huxley's dystopia are visions of stasis, in the biological, social, and political domains. The difference does not reside in the dynamics of the situation, but, rather, in where we come to rest: Fukuyama wants us to stop now, while Huxley depicts a measure of development of biological technology applied to humans first. Yet, it still seems odd to use a depiction of stasis as a warning of the need to maintain the evolutionary status quo, as it seems clear that social and political stability in Fukuyama's future is likely to come at the price of stasis in technological and biological evolution as well.

The main contrasting position is exemplified by Gregory Stock (2002). This author makes an especially interesting comparison with Fukuyama, because both are middle-aged, middle-class, male North American intellectuals. Both accept similar premises about future technological potential, and both have a notion of an essential human nature. It is just that Stock – as a representative of the third, or *'let's get to it'* position – believes that it is our nature to experiment. Thus, in his book, *Redesigning Humans: Choosing Our Children's Genes*, he suggests that "[t]o turn away from germ-line selection and modification without even exploring them would be to deny our essential nature and perhaps our destiny" (Stock 2002, 170).

After chapters of relatively sober exposition and argument, that sudden appearance of the concept of 'destiny' is striking, as Stock is gripped by the grand evolutionary narrative. Like others – Lee Silver (1998), for example – his inspiration comes not from Huxley, but, instead, from the likes of Bernal, Müller and Stapledon. As he goes on to say: "The project of humanity's self-evolution is the ultimate embodiment of our science and ourselves as a cosmic instrument in our ongoing emergence."

3 CONCLUSIONS

So, what can we learn from all this? Most of the time, most of us are nowadays caught up in debating the details of specific technologies, in the practical details of policy debates, and legislative and regulatory regimes. Yet, there is another debate, on a grander scale, which goes on alongside these discussions; and which has been going on for some time. It is conducted in a range of voices, from novels to philosophical reflections, and new contributions continue to appear which could be analyzed in similar terms to those I have set out above (Atwood 2003; Habermas 2003). This matters, because it makes a difference where people's allegiances in that larger debate lie, whether they acknowledge them or not. It makes a difference whether you believe, in the end, that humans ought to be left to make the best of life pretty much as they are now, or whether they should now take their evolution into their own hands, to realize their cosmic destiny.

What about my own allegiances here? I am not generally drawn to their kind of zeal, but, as I am currently watching both my parents' lives disintegrate

through nothing more than extreme old age, I can not help admiring the sheer chutzpah of groups like the Extropians, whose founder Max More puts their position like this:

> Mother Nature, truly we are grateful for what you have made us. No doubt you did the best you could. However, with all due respect, we must say that in many ways you have done a poor job with the human constitution… (More 1999, web ed.).

However, in the end I do not want to come down strongly on either side. I do believe it will be helpful in our ongoing discussion to distinguish more systematically between biological, technological and social evolution, as well as between stasis and change, and to recognize that that yields a larger range of possibilities. Those, in turn, invite further thought. On these grounds, I certainly do not think there is a great hurry to start modifying people.

Finally, we should remember that – although it is hard to use this analytically – optimistic and pessimistic temperaments do make a real difference to positions in this debate. Here, my sympathies lie with the British novelist Fay Weldon. In her 1990s story about biotechnology, *The Cloning of Joanna May*, she has one character put what I think is both a characteristic late twentieth century view, and that author's own: "The future shouldn't alarm us; how could it possibly be worse than what has gone before?" (Weldon 1993).

That sounds like a pessimistic view, but, on closer inspection, it can also be read as an optimistic one. Genetic alteration is one way things may eventually get better, Weldon suggests, but do not expect it to be pain-free.

Notes

1 Regress, followed by recovery is a final logical possibility, but I am not going to offer any examples of that here.

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Part 7

Conclusions

15 The Future of Genomics

Peter W. B. Phillips
& Edna Einsiedel

1 INTRODUCTION

IN THIS CONCLUDING CHAPTER, we have set out to accomplish two objectives. The first is to integrate the ideas presented so far into a single framework and to identify where our deliberations point to in terms of future research. The second is to observe on the state of the debate and to raise a few thought-provoking questions for researchers in the area of genomics and society. Thus, we will try to identify the sets of messages that we have seen in the chapters of this book, and then draw those observations back into the research on the social context of genomics that we are undertaking individually or collectively.

2 THE CHALLENGE

We start from the perspective that the reason we took part in the conference that is the basis of this book is that a group of people – from a variety of backgrounds, and with a variety of motives – has put together a capital pool and declared that there is scientific research that is being carried out under the rubric of genomics that is intended to provide significant societal benefit. As researchers with interests in the ethical, environmental, economic, legal and social aspects of genomics, we have focused our discussions on the challenges and impacts of the commercialization of any technologies and products that may result from that research. The cases examined here – whether it is on the issues around transgenic canola, the challenges posed by gene banks, animal biotechnology, or the financing, hyping or patenting of biotechnology applications – all serve to illustrate that the innovation process is less a straightforward trajectory than a series of fits and starts, of muddling through, of decision-making under conditions of uncertainty, and even of iterative loops of social and institutional learning.

Do we have the appropriate institutions to manage the potential scientific transformations of genomics research? What norms, sets of structures, and instruments do we have to mobilize investments and decisions that will generate individual and social benefits? What sorts of socially desirable outcomes should we aim for and who participates in defining such outcomes? Each of the participants in the conference and the contributors to this book has examined his or her little piece of the puzzle, in an attempt to determine what ideal arrangements and practices might look like or whether these are working effectively.

3 FRAMING THE DEBATE

One way of framing the debate over genomics research is to pose the question in these terms: How is genomics knowledge produced, applied, regulated, commercialized, protected, and disseminated? Who uses the fruits of such knowledge, how and why? Who enjoys its benefits or bears the risks; and how are decisions about all these processes made?

First, there are a range of issues related to the knowledge production component of genomics programs, more specifically, concerns about how the research ought to be structured in order to optimize the results of the research dollars invested. While no author in this book has questioned this investment, some contributors have disagreed with the directions this research investment has taken (*e.g.,* decrying the shift from investment in agricultural research as a public good to a predominantly private investment). Others have questions about how we are setting up these research enterprises (*e.g.,* setting up research repositories such as gene banks which do not provide sufficient protections to donor participants), what types of norms ought to govern how the research is carried out (*e.g.,* the types of welfare considerations for animal or human subjects), and whether there may be alternative, and more appropriate means to organize them (*e.g.,* exploring hybrid models of innovation that might combine features of purely public and purely private structures). Are these even the appropriate research questions to ask? And, if so, within what type of funding framework should these questions be explored?

Second, there is a *gestation* phase, where inventions become tested for potential commercialization, and when these get protected, regulated and scaled up for production. Ultimately, this is where society makes its judgements through the regulatory and intellectual property systems, and where industry makes educated guesses about consumer acceptance and the size of the potential market. As our second chapter, from an anthropological perspective has suggested, diseases – and, we might add, consumers' gustatory interests – have been framed as 'market opportunities,' but whether or how well these opportunities convert into market successes is part market acumen, part institutional savvy, and even part crapshoot. Much of the preceding discussion has – quite rightly – been focused on this stage in the process. Our contributors have deliberated on whether we are asking appropriate questions about what kinds of risks might or might

not be generated from the technology and how these ought to be mitigated, or whether the (increasingly private) mechanisms that are currently being used to commercialize the resulting technologies are optimal. Even in this gestation phase, we are finding that publics and stakeholders are increasingly inserting themselves in how the technology is being developed. In the case of stem cell research, stakeholders have pushed for specific research conditions (*e.g.,* the type of cells and tissues that are 'appropriate' for carrying out this research) and specific policy options. Ultimately, there is a more fundamental question about whether our incursions into genomics research may be radically changing the way we see ourselves as individuals in society at large.

Third, we have made a few cursory forays into investigating how genomics research might generate consumer and market value through *adaptation* and *adoption*. While there is a lot of evidence on consumer perceptions and decision-making, the environment for commercial genetically modified (GM) food products on grocery shelves is a shifting one and needs to be further tracked once transgenic products which claim to have benefits for consumers are in the marketplace. Another aspect to perceived value is the perception of the efficacy of the regulatory system underpinning these products. How trustworthy is the stamp of approval for these products in terms of their safety and their impacts on the environment? More generally, while claims might be made about the scale and distribution of benefits from GM food crops, we have only limited insight into how genomics could generate and reallocate value. Ultimately, the challenge is to determine the technical relevance and the commercial potential, including the social viability, of any new technology, which is – in the last instance – dependent on public attitudes and acceptance.

Fourth, we addressed the conceptual challenges of accounting for *the knowledge-stock effects*, but found it difficult to grasp the scope and challenge of managing this aspect of genomics investments. For one reason, we have yet to fully determine the adoption impacts. For example, while there is evidence presented here about how publics make value judgments about genetics or GM food, this picture is a snapshot which can change down the road as more products with different attributes come on stream, as new evidence is presented about environmental or health consequences, or as more institutional learning occurs about better management approaches. Another reason is the paucity of research in this area, at least in the organizational domain. Knowledge stocks, or the accumulated knowledge within an organization (read 'firm,' 'regulatory institution,' or entire industry) may have implications for that organization's future behaviour. For example, what are the strategic implications of knowledge accumulation in a Research and Development race? What organizational learning occurs and how does this influence an organization's behaviour in the context of public controversy?

Our discussions about these four interrelated stages of knowledge development and use came together when we struggled with the challenge of how

individuals and society actually do – and ideally should – calculate the value of the generated output and the mechanisms we can use to make decisions on the implicit and explicit trade-offs involved in such significant societal investments. The discussions highlight the fact that there are a number of legitimate and, in some instances, potentially conflicting models for valuing inventions. Private companies, on the one hand, use conventional accounting models and, hence, tend to solely take into consideration their private investments and the marginal and total returns they earn from their activities. Economists, on the other hand, tend to use a relatively well-established neo-classical economic model that identifies the social optimum, based on the equivalence of marginal costs and marginal benefits. That model also identifies the scale and distribution of economic (both monetized and non-monetary) benefits and costs. However, neither of these models provides the full picture, as neither the corporate nor the economic approaches generally measure the total research costs (*e.g.,* by both investors and public agencies), account for full gestation costs (*e.g.,* costs incurred by regulators for reviewing products), or account for any knowledge-stocking effects. Indeed, in contrast to economic factors, which can be identified and to which 'value' can be assigned in a relatively straightforward way, social, ethical, and political factors are often less amenable to the quantitative tools of economics, emphasizing the need to broaden our methodological toolkits.

Again, we emphasize that, while these stages appear to be clearly sequential, the innovation process – from knowledge production to application and end use – is also frequently iterative. There has clearly been a changing and broadened mix of actors and actor-networks that exercise influence over this process and this influence is being felt in earlier stages of the innovation process, as the discussion on stakeholder input into stem policies has illustrated.

4 THE ISSUES & THE SOCIAL SCIENCE RESEARCH AGENDA

Our discussions brought forward a number of issues that are unresolved and require further research and debate.

At the *research* stage, we have identified two major issues. First, we have to ask ourselves how we should set priorities, whose priorities we should set, who is going to be in charge of establishing these priorities, and who should be at the table, so to speak. A very eloquent argument has been made that the focus on genomics and biotechnology through large-scale initiatives (such as the federal government lead effort that funded Genome Canada) tends to push the agenda away from, or divert attention from, alternative agendas that many in society would like to see pursued. We expect that our various contributors might come up with different sets of priorities and there might be difficulty in reaching unanimity or even consensus. Ultimately, there is an unanswered question about how to set priorities. The chapters on understanding consumer decision-making processes or consulting with communities suggest that, at

the very least, procedures for gaining such understandings of individual and community views are equally important.

Second, there has been a more explicit discussion on how we could – or should – structure projects at the science level. The challenges of constructing or governing genetic banks, or nurturing networks of knowledge and structuring collaborations – all aspects of how we manage knowledge within the research and discovery stage – are important. Much more research needs to be done within this area. As social scientists interested in genomics, we need to get beyond our disciplinary bounds – that push us to examine the extremes of pure public, pure private, or pure collective models – and begin to investigate the hybrid structures that are being constructed in the genomics and life-science research world. There are an almost endless variety of opportunities to study different models, and many of the approaches identified in this volume offer intriguing possibilities.

In addition to understanding structural factors, examining interactions between different actor-networks and investigating relationships between structural arrangements and the behaviours of actor-networks or stakeholder groups need to be explored more fully.

As for the *gestation* stage, we have been addressing some fundamental issues as to whether we have the right set of questions to ask, as we commercialize products. The scientific risk-assessment and private commercialization model is dominating at this point in the innovation system. Nevertheless, there are many fundamental questions about how effective that model is, and whether we have the right institutions to meet social needs. Before we debate institutions, however, we have to address the broader issue of whether we are asking the right sets of questions as we go through the gestation phase. For example, is the scientific approach to risk-assessment sufficient for the new technologies? How are competing concerns (*e.g.,* international trade) to be accommodated – or should they be? Furthermore, are we considering the appropriate allocation of property rights to intellectual property enhancement? And, finally, are we asking the appropriate sets of questions about the social, the cultural, the economic, the political, and the ethical dimensions of the products that are coming onto the market? These are all legitimate questions, which have been examined from different angles. All in all, we have critiqued the system reasonably well; we have examined the systems in Canada, in the United States and in the European Union, and concluded that there is a significant problem out there. If a criticism were to be made of what we have done so far, it is that we have analyzed the problem quite well, but we have yet to connect to the broader social context. Below, we offer some suggestions on how we might do that.

As far as the *adoption* stage is concerned, most of the debate has focused on whether products will generate consumer benefits. On one level, this boils down to the question of trust. Do we have a product (or at least a regulatory and management process that approves that product) that is trusted in the market

place? On another level, an equally important issue is to understand how actor-networks and other stakeholder groups shape institutional structures and behaviours. Products that reach the marketplace are not immutable; neither are institutions and their manifestations (from pronouncements, to guidelines, to legislation). Both are also the subject of 'social shaping forces' and can be responsive to new information. How these changes and responses take place is another rich arena for examination.

Whether it is a technology (*e.g.,* genetic testing), a consumable good (*e.g.,* GM foods or new drugs) or a less tangible benefit (*e.g.,* a better environment or more social justice) that ends up in a consumer's basket or a citizen's agenda, they all need some form of allocation method, or market. We have investigated a number of ways – some very explicitly, some less explicitly – in which markets are created. While we have deliberated on how issues of labelling and identity-preservation can potentially enhance market-making, clearly more research is required to establish in what ways efficient markets can be created and supported. One of the challenges we, as analysts, face is that we tend to use methodologies from citizen-based structures (*e.g.,* citizen polls) to determine how consumers might respond. Yet, it has been demonstrated that people may have multiple perspectives on issues, depending on whether they are asked to respond as citizens or as consumers. As citizens, for example, people may ask for explicit public policies which call for one set of behaviors (*e.g.,* regulating availability and use of diagnostic genetic tests), while, as consumers, they might actually do something else (use a genetic test for a purpose not sanctioned such as sex selection). In the latter instance, certain consumers might resent the fact that strict rules are imposed on them. This may not necessarily reflect an inconsistency in respondents' attitudes; it could also be the result of analytical procedures that implicitly assume a correspondence between citizens' and consumers' attitudes where, in fact, little may exist. The chapter on stem cells demonstrates the different values and interests that underlie the actions of different lay individuals and groups as they push for (or, instead, oppose) particular policy positions. The challenge is being sensitive to these different contexts and taking them into account in our research approaches.

The *adoption* and *knowledge-stocking* phases are what the public and private sector investors are focused on. At one level, everyone is aware that there is a trade-off involved. It is known that there are costs, and attempts are being made to minimize them, while not undercutting the potential benefits. One question that, so far, has not been adequately answered is: How can we generate benefits from genomics research and how can we ensure that these benefits are equitably distributed? Ultimately, many of the challenges facing the research and gestation enterprise have a potential to increase costs, without considering how that might influence the scale or distribution of benefits.

Finally, there is the question of how we can better understand knowledge-stocking and, as a result, offer clues to more optimal policy choices. We touched

on the problem, but not on the strategies that might potentially be employed to solve it. There is a legitimate concern that the methods we have traditionally used to codify our knowledge – such as scientific journals – are becoming less relevant, as more knowledge is being stocked in semi-transparent patents, in fee-for-service proprietary databases and in opaque, limited-access 'communities' of researchers. This rise of the 'neo'-trade secret threatens to exclude many potential users from the knowledge being generated, which could exacerbate the tragedy of the anti-commons. As the chapters on the media illustrate, some of the knowledge stocks reach publics via the media or the Internet, as scientists further shift their dissemination strategies from the traditional modes of distribution. With the millions of dollars of public investment in genomics research so far – and even if there are no directly commercializable products – there is significant potential to generate 'social good' through the knowledge generated, provided we do not lock it up in inaccessible institutions.

5 LESSONS FOR SOCIAL RESEARCH ON GENOMICS

What lessons can we draw from the discussions, as represented in these chapters? We will address four points. On one level, much of what we are talking about theoretically is how we frame the issues. On a practical level, or more fundamentally, how do we manage normative trade-offs? For a businessperson, these areas could be quite small. Traditionally, this entrepreneur would only consider what affects the balance sheet, for example, or what flows through the enterprise. This picture is changing as entrepreneurs are increasingly challenged to consider public reactions beyond their specific markets and to adapt to regulatory stances not to their liking (as the chapter on European policies on agricultural biotechnology aptly demonstrates). The Canadian government, like many other governments, when it acts in a mercantilist way, considers a larger range of factors (as has been demonstrated in most socio-economic studies), but like many countries, much of its analyses remain truncated at the national boundary. This has been slowly changing, with increasing numbers of discussions with our regulatory neighbours south of the border, and with other countries interested in regulatory harmonization. If one thinks in global terms – which is where institutions like the World Bank and the Consultative Group on International Agricultural Research (CGIAR) centres, as well as where academic social scientists often operate – the range of factors considered often becomes quite large, and the relative balance between them changes significantly. Increasingly, the impacts of global institutions such as the World Trade Organization, of global trade, and of transnational activities of stakeholder groups are being reflected in domestic dynamics.

The tenor of the debate changes even more when non-economic – *i.e.,* non-monetarily quantifiable – variables are added, such as social justice and ethics. These are important aspects which are critical in determining value, but we do not have a generally accepted currency or set of standards like the one we have

for evaluating impacts of an economic or financial nature. Some would even question whether there ought to be such universal standards. Social values are, not surprisingly, bound up in cultural contexts. The differences in, and degrees of, controversy associated with policy-making on stem cell research, for example, reflect these differential cultural preferences. A similar challenge lies with institutions that are, for the most part, national or local, posing its own set of considerations when examining the behaviours and impacts of actors. Although we may not be able to agree on what should be included in – or left out of – the analysis, we should make efforts to more explicitly and more carefully acknowledge where we are making assumptions, and where we are drawing the boundaries of our analysis.

The second lesson comes from our discussions about institutions, not simply those brick-and-mortar or legally-structured institutions, but the networks, relationships and norms that are so critical to a knowledge-based innovation system. There are a number of questions that provide further grist for the research mill which beg for attention, including how these different actors interact, what characterizes networks of activity and action around genomics, and how these affect policy-making. Another obvious question is how one can create transparency and accountability – or at least some sense of predictability in areas of uncertainty – in these institutions and networks. These informal institutions span a variety of domains: industry, stakeholder groups, consumers, citizens, and society at large all have local, national, and international aspects. The more articulate and focused we can be about our basic assumptions as to who is managing and for whom, the more we will be able to build bridges, such as between economists and ethicists, and between people in business schools and those in laboratories. Ultimately, we will need to make use of all of the tools available in our interdisciplinary toolkit, in order to understand the chaotic process of technological change.

A third area deserving of careful consideration is the need for a very explicit framing of the *context* for our observations and advice. Gene banks have developed in a wide variety of countries in addition to Iceland, each with its own set of domestic agendas and imperatives, cultural norms, and institutional practices. The biobank challenges in Iceland will, of necessity, be rather different from the biobank experiences in the U.K., Estonia, Sweden, or Singapore. The GM food experience in Europe has been rather different from the Canadian or U.S. experiences and policy responses have also varied accordingly.

And, fourth, what are the *challenges* for those of us in the social science community? First, by observing the world through the genomics lens, we have isolated what we consider the critical economic, commercial, social, legal, and ethical problems, for which we have also tried to seek solutions. In some cases, we have then gone out into the public arena and said, "Here are the solutions, folks." It is important to realize that governments are now faced with governing very complex societies, in an increasingly pluralistic world. While we sometimes

advocate tailored solutions – such as a food and environmental safety system for GM foods – we have to be aware that there is also the risk of increased proliferation of institutions that are very small and narrow in a global sense. We can convince ourselves that genomics is going to change the world, but at the end of the day, when one goes to Ottawa, Washington or Brussels, or to the capital of any of the E.U. member states, the majority of people are not mounting the barricades, except in very discrete individual areas. Hence, we should think carefully about how we frame our advice in the context of the institutional frameworks that already exist. We have talked about changing some basic assumptions about how governments operate, in order to address concerns related to genomics. However, if lawyers are right that hard cases make bad laws, then genomics may be the 'hard case' that will lead to generally inappropriate laws. Ultimately, genomics may not be the best institutional context for changing the world.

Finally, we social scientists need to be reflexive about our work. We are not only observing on – and analyzing – genomics; we are also part of the very experiment that we are investigating. This may prove to be our biggest challenge. Questions were raised about whether we have just created an industry that has generated a large number of interesting reports and opportunities to get together with interesting people and have interesting discussions, but that is totally disconnected from the values and concerns in the wider society. Therefore, we have to be careful that we do not do exactly as we accuse the scientists in the laboratories of doing, that is, isolating ourselves and going beyond the possible.

In facing these challenges, we can only benefit from approaches based on cross-over insights – collaborating with colleagues across the social sciences, with scientists carrying out genomics research, with the policy communities, and other stakeholder communities.

Contributors

WIKTOR ADAMOWICZ is a Canada Research Chair in environmental economics and a professor in the Department of Rural Economy at the University of Alberta. He holds a B.Sc. in agriculture and an M.Sc. in agricultural economics from the University of Alberta and a Ph.D. in agricultural and applied economics from the University of Minnesota. His research is aimed at developing methods that integrate environmental goods and services into economic analysis and at designing policies and institutions that help capture the importance of environmental services in economic decision-making. He works in the field of environmental valuation, which employs economic theory, statistical methods and survey research to identify the value of environmental goods and services that is implied by economic decisions that individuals, companies and governments make. Applications of this research include the incorporation of environmental services into benefit/cost analyses of projects and policies and the assessment of natural resource damage. His research interests also include the incorporation of economic perspectives into sustainable forest management and the development and implementation of economic instruments for environmental protection.

GARDAR ÁRNASON is a research fellow at the Centre for Professional Ethics of the University of Central Lancashire in Preston, U.K. His main research interests centre on ethical, epistemological and other philosophical issues in genetics. He is currently Scientific Coordinator of the Ethical, Legal and Social Aspects of Human Genetic Databases (ELSAGEN) project, funded by the European Union.

TANIA M. BUBELA is an assistant professor in the Department of Marketing, Business Economics, and Law at the University of Alberta. She holds a B.Sc. (Hons.) from the Australian National University and a Ph.D. in biology from the University of Sydney, Australia. She did her post-doctoral studies in the Department of Zoology at the University of Toronto and the Centre for Conservation and Diversity at the Royal Ontario Museum. She held a faculty position at the University of Toronto where she taught genetics and evolutionary biology. Thereafter she studied law at the University of Alberta, where she was also a research assistant at the Health Law Institute. After completing law school, she clerked for the Honourable Louise Arbour at the Supreme Court of Canada. Her research interests include the representation of genetic research in the media and intellectual property in biotechnology.

MICHAEL M. BURGESS is Professor and Canada Research Chair in biomedical ethics at the W. Maurice Young Centre for Applied Ethics, and in the Department of Medical Genetics at the University of British Columbia. His research program is characterized by qualitative and ethics research that identifies and supports responses to issues raised by genetic and genomic knowledge and technology. He is primarily interested in identifying neglected or novel perspectives on issues of culture, genetics and genomics to assure that recommendations and theoretical approaches engage with poorly understood or disenfranchised perspectives. Genome Canada has funded an interdisciplinary team led by Burgess on Genomics, Ethics and Democracy: Consultation, Deliberation and Modeling. The primary objective is to devise and evaluate methods of ethical analysis for the development of public policy in the area of genomics.

TIMOTHY CAULFIELD has been research director of the Health Law Institute at the University of Alberta since 1993. He recently received a Canada Research Chair in health law and policy. He is also Professor in the Faculty of Law and the Faculty of Medicine and Dentistry. His research has focused on two general areas: genetics, ethics and the law; and the legal implications of health care reform in Canada. He has been involved in a variety of interdisciplinary research endeavours and he has published numerous articles and book chapters on health law. He is the recipient of an Alberta Heritage Foundation for Medical Research Health Research Scholarship entitled Regulating the 'Genetic Revolution'; a Genome Canada project on the regulation of genomic technologies, and is he an associated theme leader in the recently created Stem Cell Network (Networks of Centres of Excellence).

CELESTE CONDIT is a research professor in the Department of Speech Communication at the University of Georgia. She has published five books including *The Meanings of the Gene* (University of Wisconsin Press, 1999) and over seventy scholarly articles, chapters and reviews in journals. Her work on

the social impacts of genetics was initiated through training on a University of Georgia Study in a Second Discipline fellowship in genetics. Her subsequent work has been supported by the National Institutes of Health's Ethical, Legal and Social Implications program as well as by the Centers for Disease Control and Prevention. She has been elected a Distinguished Scholar by the National Communication Association.

ROBIN DOWNEY is completing her Ph.D. at the Faculty of Communication and Culture of the University of Calgary and is a research associate with the GE3LS Genome Prairie research project. Her dissertation research centres on the role of social movements in influencing the direction of technological developments. She is using case studies from the agricultural and biomedical sectors, specifically focusing on the impact of NGOs on terminator technology and patient organizations on stem cell research. She is working with Edna Einsiedel's project on controversies and the innovation process, based at the University of Calgary.

EDNA EINSIEDEL is a university professor and a professor of communication studies in the Faculty of Communication and Culture at the University of Calgary. Her research interests lie in the area of biotechnology in the public sphere. Her research has included examinations of media representations of biotechnology, public perceptions, attitudes and social values, and policy responses. She has also investigated public participation in biotechnology decision-making. More generally, she is interested in the role of controversy in technology innovation and social studies of technology design and assessment. Her research is conducted in collaboration with the International Research Group on Biotechnology and the Public, with research teams in Europe, the U.S. and Canada. Her recent studies include: national surveys on public perceptions of biotechnology, longitudinal media representations on biotechnology and on cloning, a study of the consensus conference as a public participation model on GM foods, a study of the citizen jury model of public participation on the issue of xenotransplantation, and an international comparative study of public consultation approaches on xenotransplantation. She was a member of several policy committees and has written a number of biotechnology policy papers for the Canadian government.

USHER FLEISING is an emeritus professor in the Department of Anthropology at the University of Calgary. His research and teaching interests centre on the interface of social and biological systems. Shortly after joining the Faculty of Social Sciences at the University of Calgary, together with three other colleagues he founded HERA Consulting Ltd., a company engaged in the assessment of the impact of large-scale energy projects on local communities. This consulting experience in technology assessment plus an academic interest in biological theory led to a research program on biotechnology and social change. In 1999, he became the principal investigator on a Social Sciences and Humanities

Research Council of Canada sponsored Strategic Research Grant to conduct a multi-sited investigation of the subcultures involved in the discovery, commercialization, and regulation of new pharmaceuticals. He was head of the Department of Anthropology for nine years, and served as president of the Canadian Anthropology Society. He is now chief scientist at SF Marketing in Montreal.

ROSE GERANSAR completed her undergraduate degree at the University of Calgary, majoring in biochemistry, and is pursuing graduate studies in community health. She has been working as a research assistant on the GE3LS Genome Prairie project and has investigated the potential impacts of genetic use restriction technologies on developing countries, controversy surrounding other genetically modified crops, and the implications of stem cell policy. In the past year, she has been a recipient of the Jason Lang Scholarship and a Canadian Stroke Network Studentship. She is currently engaged in scientific research exploring pathways in embryonic stem cell differentiation, and is working with Edna Einsiedel on controversies and the innovation process, based at the University of Calgary.

BÉATRICE GODARD is an associate professor in the Bioethics Program of the Faculty of Medicine at the University of Montreal and a research fellow with the Fonds de la recherche en santé du Québec (FRSQ). On the one hand, her research explores emerging professional responsibilities in human and medical genetics. More specifically, she has (1) examined the possible moral duty of a genetic service provider to recontact and inform any patient if new information comes to light, or if new strategies are developed, when either could be beneficial to the patient's health; and (2) scrutinized issues surrounding the disclosure of genetic information to the biological relatives of a patient in cases where such information could allow those relatives to opt for preventive monitoring, potentially avoiding or delaying onset. On the other hand, she has sought to gain a better understanding of prevailing attitudes and behaviours with regard to genetic research, especially in the framework of public consultations on population genetics databanks used for research purposes. Her research work is funded by the FRSQ, Génome Québec, and the Canadian Institutes of Health Research (CIHR). She is a member of a number of ethics committees, including one at the National Research Council of Canada, one at the CIHR Institute of Genetics Ethics, the Law and Society P&P Committee and the FRSQ Research Ethics Committee.

LINDA GOLDENBERG is a Ph.D. student and senior research associate in the Faculty of Communication and Culture at the University of Calgary. Her areas of expertise include research design and evaluation in a networked environment, advanced networks and complex systems, risk, ethics, and nanotechnology and nanobiotechnology. Her current work focuses on national security, and the

role of sensory and intelligent systems in disaster and emergency preparedness, health care, and intelligence. Her work has included involvement with the United States National Science Foundation, where she participated in a recent workshop on societal implications of nanotechnology with direct contribution to the Panels on National Security and Space Exploration, and public consultation; her model for nanobiotechnology risks and issues will appear in the forthcoming proceedings. She is involved in research ethics, and sits on the University of Calgary Conjoint Faculties Research Ethics Board (CFREB). She also teaches at the University of Calgary, in the areas of risk, ethics, advanced technologies and national security.

WUYANG HU was recently a Ph.D. student in the Department of Rural Economy at the University of Alberta. His research interests are consumer behaviour, food marketing, and non-market valuation methods. He has worked on economic issues surrounding the effect of labelling of genetically modified food on consumers' decisions. On completion of his Ph.D. research, he was Assistant Professor, Resource Economics at the Department of Rural Economy. He is now at the University of Nevada, Reno.

ANNE JULIANE HÜNNEMEYER received a bachelor's and a master of science degree in agricultural economics from the Rheinische Friedrich-Wilhelms-Universität in Bonn, Germany. Her Ph.D. in agricultural economics is from the University of Guelph, Canada. She has been a recipient of the Resources for the Future Joseph L. Fisher Dissertation Fellowship. In 2002, her thesis was awarded an "honourable mention" for best dissertation by the Canadian Agricultural Economics Association. During her assignment as assistant research professor in the Department of Rural Economy at the University of Alberta, Anne researched consumer responses to genetically modified food products in Canada using a computer based discrete-choice model as a preference elicitation tool. The work has been funded through Genome Canada and supervised by Professor Michele Veeman.

LYNE LÉTOURNEAU is a professor in the Department of Animal Sciences at Laval University since 2002. She is also a researcher with the Research Centre on Reproductive Biology, Laval University, since 2000. Her research interests centre on the legal and ethical issues raised by the use of animals and the genetic engineering of life forms. She is currently setting up a virtual reference centre on genetic engineering of animals and plants as part of a GE3LS research project financed by Genome Canada and Genome Quebec. She is also directing a SSHRC research project on the social responsibility of researchers and private corporations involved in genetic engineering. She has published a number of works, including *L'Expérimentation animale: L'homme, l'éthique et la loi*, published by Éditions Thémis in 1994. She holds a doctorate in law from the University of

Aberdeen (2000), as well as a master in law (1993) and a bachelor in law (1988) from the University of Montreal. Since 1998, she has been a member of several expert committees. She was appointed a member of the Canadian Biotechnology Advisory Committee in 2002.

CHARLES MATHER is an assistant professor in the Department of Anthropology at the University of Calgary. He is currently developing a research program in the cross-cultural study of medicines and medical technology. The first stages of the research are examining the place of pharmaceuticals in the local medical systems of Northern Ghana.

MICHAEL D. Mehta is a professor of sociology at the University of Saskatchewan, and chair of the Sociology of Biotechnology Program with the College of Biotechnology. He specializes in risk domains including nanotechnology, biotechnology, blood safety, nuclear reactors, and endocrine modulators. His web site is at *www.policynut.com*

PETER W. B. PHILLIPS is a professor of political studies and an associate member of the faculties of Agricultural Economics and Management and Marketing at the University of Saskatchewan. His research concentrates on issues related to governing transformative technological change, specifically focused on intellectual property rights related to biotechnology, and trade and marketing issues related to GM products. He is director of the University of Saskatchewan College of Biotechnology, a member of the Canadian Biotechnology Advisory Committee and a member of the NAFTA Chapter 13 expert panel on GM corn in Mexico. He is a senior research associate with the Estey Centre for Law and Economics in International Trade, a co-principal investigator for Genome Prairie's Genomics: Ethics, Economics, Environment, Law and Society (GE3LS) project, a collaborator on the Innovation Systems Research Network, a member of the board of the Canadian Agrifood Policy Institute and a member of the editorial boards of AgBioForum and IP Strategy.

FRANK TIMMERMANS holds a B.A. in cultural anthropology and an M.A. in prehistoric archaeology from Leiden University, the Netherlands. His research and teaching interests focus on the anthropology and archaeology of hunting-and-gathering and horticultural societies as well as on human evolution. Currently he is pursuing a Ph.D. degree in archaeology at the University of Calgary. In his dissertation research, he explores the social dynamics of the interactions among regional groups of nomadic hunters in Europe at the end of the last Ice Age. He has also worked as a translator and editor. Currently he is a research assistant in the Faculty of Communication and Culture at the University of Calgary.

HELGE TORGERSEN has a Ph.D. in biology and worked in the field of molecular biology at the University of Vienna. Since 1990, he has been affiliated with the Institute for Technology Assessment of the Austrian Academy of Sciences as a specialist in the social implications of biotechnology. His main areas of expertise and interest are in biotechnology regulation and policy, risk assessment, the role of experts, public perception and participatory technology assessment.

JON TURNEY has recently taken up the position of editorial director at Penguin Press in London. He has a Ph.D. in the history of science from Manchester University and has worked as a science and policy journalist. He was previously a lecturer in science communication in the Department of Science and Technology Studies at University College London, with a particular interest in the life sciences, and in recent popular science writing. He is the author of *Frankenstein's Footsteps: Science, Genetics, and Popular Culture* (1998), a work that traces the development of biological science and how it has been received and understood by the public in the nineteenth and twentieth centuries. His latest book is *Lovelock and Gaia: Signs of Life* (2003).

MICHELE VEEMAN received a bachelor's degree in agricultural science from Massey University, New Zealand, and a Masterate in economics from Adelaide University, Australia. Her Ph.D. in agricultural economics is from the University of California at Berkeley. She is currently professor of agricultural and resource economics in the Department of Rural Economy at the University of Alberta, which she chaired from 1992 to 2002, and is a fellow and a former president of the Canadian Agricultural Economics Society. Her teaching, research and publications focus on agricultural and food product markets, trade and policy. She is a Genome Prairie GE3LS project co-investigator for Commercialization and Society: its Policy and Strategic Implications; her work within this project is directed to assessing the impact of information on risk perceptions and attitudes to genomic technologies.

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crossing over

Technologies of the life sciences offer tremendous possibilities, but also numerous challenges. *Crossing Over* looks at the social and ethical issues around the new biology, particularly genomics and biotechnology. It examines the world of biotechnology from different perspectives, including economics, law, communications, the sciences, and bioethics. The contributors to this volume respond to questions such as: How will we ensure technologies adopted in genomics research are not just economically beneficial but also socially and environmentally sustainable? What is the impact of the media on the development of these technologies? What are the ethical implications? What governance arrangements are appropriate? How are citizens and consumers expected to participate?

Crossing Over's interdisciplinary approach to the analysis of biotechnology in society will ultimately contribute to our overall understanding of this hot-button issue, and will help us make better-informed choices for the future.

EDNA EINSIEDEL is a Professor in the Faculty of Communication and Culture at the University of Calgary. She has been a member of numerous policy committees and written on biotechnology for the Canadian government.

FRANK TIMMERMANS is a research assistant at the University of Calgary, and is earning his PhD in Archaeology.

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