

MICHELA BETTA

## DIAGNOSTIC KNOWLEDGE IN THE GENETIC ECONOMY AND COMMERCE

### 1. ENTREPRENEURIAL SCIENTISTS

On 5 December 2002 the Australian Senate passed the Research Involving Embryos and Prohibition of Human Cloning Bill 2002, which regulates stem cell research. The bill introduces some restrictions with regard to the use of stored frozen embryos, which are not destined to be implanted. The bill states that only frozen embryos created before April 2002 can be used for research purposes, provided that the individuals whom these embryos relate to give their consent. The alternative to this restriction would have been no research at all, and this would have happened if the law had been stopped. The Australian scientists regarded the new law as a compromise that would undoubtedly slow down research, but not entirely stop it.

Here, it is perhaps worth noting that Australia is at the forefront in stem cell research, as one of its most prestigious scientists, the embryologist Alan Trounson and his team in Melbourne, have played a major role in the discovery of embryonic stem cells. That discovery was shared with two other US research groups: one led by the embryologist James Thomson (Wisconsin), and the other led by the embryologist John Gearhart (Baltimore). In terms of biomedical research, Alan Trounson is a strong player. In spite of this, the passage of the mentioned bill risked jeopardizing his reputation and consequently to ridicule the scientific work of many Australian scientists. Attached to that bill package was the allocation of \$43.55 million granted by the Commonwealth Government and by the Victoria Government to Trounson and other Australian scientists working in the biomedical field for the creation of the National Stem Cell Centre. Surprisingly, in spite of being worldwide one of the most productive countries in stem cell research, politicians threatened to stop the research. During the bill debate in August 2002, Trounson spent time at the Australian Federal Parliament educating politicians by providing them with details concerning stem cell research, in an attempt to help them to formulate informed judgement about the scientific work performed in Australia. The ultimate goal was to see the law be endorsed by the majority of the parliamentarians and the allocation of the large public funding

confirmed. To underline the potentialities of the new research, Trounson showed a video taken by two American scientists: John McDonald, Director of the Spinal Cord Injury Unit in Missouri; and Doug Kerr, the director of a research centre for the treatment of transverse myelitis in Baltimore.

The video documented a treatment administered to a mouse affected by transverse myelitis, a virus that puts the immune system into chaos making it attack a wrong target, for example a group of nerves in the spinal cord instead of a virus looming in that area. In the first sequence, the video recorded a mouse affected by that virus that left it paralysed. In the second sequence the video showed the same mouse using its hind legs after a treatment by which embryonic stem cells were injected into its spinal cord. Trounson used the video to reinforce the potentialities of stem cell research. An opponent of the use of embryo research, American scientist David Prentice from Indiana University, contradicted Trounson declaring that the cells used to cure the mouse were not embryonic stem cells, but germ stem cells taken from a 9-week-old aborted embryo. The peculiar scientific meaning of that difference, which was known only to scientists, caused a delay in the parliamentary debate and an unprecedented campaign against Trounson. The scientist was denounced for having shares in a private stem cell company, which was said to gain financial advantages from the passage of the law. The hysteria that followed made some public commentators portray scientists as greedy vampires exclusively interested in their own financial rewards. The law was then finally passed in December 2002 and the grant reconfirmed, which led to the formal establishment of the National Stem Cell Centre, now renamed as the Australian Stem Cell Centre (ASSC). The interesting aspect here lies at the terminological level. Germ stem cells are those cells that will form egg and sperm and have the potential to develop any other type of tissue, and are therefore considered pluripotent cells. Conversely, embryonic stem cells derive from *in vitro* embryos and are not necessarily germ cells. Some commentators and politicians spoke of fraud and private interests that were blinding the scientists. The scientists themselves replied that the mistake was due to the fact that many did not differentiate between the two types of cells. John McDonald, one of the two video authors, commented that when speaking of stem cells "people lump them in the same category all the time; it's a fine line."<sup>1</sup>

This anecdote reveals two conflicting lines. One is related to (scientific) rigour, and the second to the need for scientists to move forward as speedily as possible. It is indeed difficult to believe that a scientist of the calibre of Trounson, well known for his scientific stand, had overlooked such an important detail. Perhaps he thought of it, but then he must have considered it too difficult to explain, or too risky to introduce such a terminological differentiation, as the aborted embryo would have indeed captured the moral fantasy of politicians, and for certainty questioned the ethical stand of the research applied to the paralysed mouse. The other line is related to scientific passion. Undoubtedly, the public saw (and some admired) one of the world's most recognized scientists descending the way to Parliament in order to convince political parties and their lobbies of the necessity to let scientists

do what they have been trying to do since the existence of the scientific method. The severity of some criticism formulated by politicians, journalists, and public commentators, who attacked Trounson on a personal level by alleging economic advantages for the scientist himself, was reminiscent of the Inquisition. Undoubtedly, Trounson did not contribute to an increase of trust towards bioscience. It is the latter aspect that instigates reflection, because those reactions seem to suggest that as soon as scientists get involved with commercial activities, they lose their scientific aura, and therefore their objectivity. This is an issue that is increasingly occupying the minds of some critics, in and outside the academic field, who are worried about an increase in scientific and commercial joint ventures. But does this preoccupation with science collaborating with commerce not derive from an instinctive mistrust towards commerce? Here the question arises of whether the expectations we hold towards science and medicine, namely to avoid any commercial involvement, do not originate from an old notion of medical science.<sup>2</sup>

This book opens with a quotation by the French historian Jean Delameau, who argued that the French Revolution would not have paved the way to modern society without technology and science, which means that politics alone cannot change society. But do science and technology not need an additional component to make knowledge transfer and implementation possible, i.e., to take scientific and technological progress out of the laboratories and make it available to the public? But how open are we towards scientists trying to commercialize their research in order to implement it on a large scale? Why do scientists have to become entrepreneurs? Do they do this just for money or in order to get recognition? Admittedly, the palpable lack of trust towards science in general and bioscience in particular is worldwide. In her 2005 book *Stem Cells: Controversy at the Frontiers of Science*, Australian scientist Elizabeth Finkel points the finger to punitive minds and political circles, which always insist on promoting negative spin when talking about science and scientific endeavours, especially in the “new genetics” and stem cell debate. In her reconstruction of the most salient moments of the emergence of the stem cell field, Finkel remarks: “Scientists were portrayed as amoral and only out to make big bucks.”<sup>3</sup>

Finkel herself is a biochemist and a well-recognized scientific journalist. She worked as a research scientist for many years before becoming a writer. She has won many important prizes for medical journalism in Australia and abroad, and therefore she knows what it means to work as a researcher in a scientific environment. Finkel is perfectly aware of the constraints scientists are subjected to, in terms of financial support and social recognition for their efforts. She is an attentive observer of the Australian scientific culture and of its protagonists, and her interlocutors are the best researchers in the new field called biomedicine. Her work is highly productive, and her passion and partiality for the researchers very seldom escape her objectivity. Therefore, it is always worth trying to understand why such a profound connoisseur of the scientific scene sarcastically reminds us that “there are dragoons of ethicists, lawyers, conscientious scientists and activists who make medical

ethics their livelihood.”<sup>4</sup> She reproaches these people for having overlooked the shift that occurred in the scientific style and collective, not only in Australia but in many other western countries as well, leading scientists “through a cultural revolution that shed them of the bourgeois notions such as ‘knowledge for knowledge’s sake’.”<sup>5</sup> This revolution, she argues, has catapulted them into the open social field. The reasons for this transformation of the scientific ethos are to be found in “the exigencies of the cash-strapped universities”<sup>6</sup> as well as in a new commercial approach of the international venture capital after the collapse of the dotcom economy. But the goodwill of the scientists does not seem to have been counteracted by equally enthusiastic commercial actors. According to Finkel, Australia would have a stronger position on the international level if it had not been for the lack of “business managers” capable of giving “wings to changes” in the global marketplace.<sup>7</sup>

This is also something that Manuel Castells reproached commerce and private companies for, namely their lack of vision and commercial courage.<sup>8</sup> But, as it often happens during cultural shifts, what to some gives reason to condemnation is to others motif of prize and support. This chapter deals with science and scientists as well as medical practitioners and their involvement with commercial partners. The author restrains from taking a stance against or for one position, but opens the chapter to different positions and interpretations of the trends we are currently witnessing. In an exemplary way, she explores the effects of emerging biomedical techniques that make the deposit and conservation of body parts in cell banks, specifically created for this purpose, possible. The umbilical cord blood (UCB) banks represent a successful encounter of two types of minds: the biomedical and the business. Other examples could have been chosen, but this one is interesting because—perhaps substantiating the criticism expressed by Finkel and Castells—it does not represent a big commercial risk. On the other hand, it opens the scene of one of the most intimate moments in private life to commercial actors. In fact, the UCB must be collected at the very moment of a baby delivery. Finally, the collecting and banking technique would not have been possible without testing technologies capable of excluding health risks from collected human genetic material. Genetic testing is therefore a central step in a healthcare practice that is increasingly oriented towards the creation of new forms of investments in health, while aiming, at the same time, at increasing society’s ability to respond to health crises through private and public initiatives based on personal and bodily resources.

## 2. BODILY TERRITORY AND GENETIC TESTING

If genetic testing and screening in the early stages of human life confronts us with ethical dilemmas, questions, new social risks, and fears, all of which make increasingly difficult the formulation of policies that addresses everybody’s interests and ethical expectations, the issues surrounding genetic testing and screening of adolescents and adults do not seem less cogent and

difficult to govern. The discourse that accompanies local policies of genetic testing and screening can be articulated into two categories: the narrative of great promise and the narrative of concern.<sup>9</sup> The first maintains that the new predictive knowledge resulting from such tests is a social good whose distribution will positively change our approach towards our health and body. The second speaks of risks and the impossibility of finding a compromise based on common sense. These two attitudes are simultaneously present in the social landscape, reinforced by a “genohype” narrative that portrays benefits and risks associated with genetic research and genetic engineering. Who disseminates these words? According to a study undertaken by Tania Bubela and Timothy Cauldfield (2004):

Only 15% of the newspaper articles and 5% of the scientific journal articles discussed costs and risks, whereas 97% of the newspaper articles and 98% of the scientific journal articles discussed the likelihood of benefits of research.<sup>10</sup>

The data collected by the two authors, however, seem to reflect the interesting trend whereby “the journalists may not always be the primary source of exaggerated claims.” Moreover, they maintain a cool attitude towards the narrative of promise compared to the scientific divulgators of knowledge, who “may be inadvertent ‘complicit collaborators’ in the subtle hyping of science stories.”<sup>11</sup> MacIntyre (1997) also comes to this conclusion. She argues that some of the most optimistic views about the potential power and benefits of genetic testing and screening are to be found in official reports, and not in the tabloid press as sometimes assumed.<sup>12</sup> The two studies suggest the emergence of two trends: first, the more optimistic reading of scientific research data comes from the scientific community itself; and second, the narrative of benefits and great promise has worldwide attracted more fans than that depicting risks and exaggerated expectations. How is this lack of balance to be interpreted? What are the forces driving this discourse? Before discussing this aspect, which is undoubtedly related to public policy and the regulation of new research, it is necessary to define the perimeter of our investigation through a discussion of the types of currently available tests and their repercussions on people. A methodological remark is necessary at this stage. In the course of this analysis we will be referring to both narratives, sometimes giving precedence to the discourse underlining risks, and sometimes to the enthusiastic discourse of scientific advancements. The uncertainties and potentialities of scientific advancements are such that a clear-cut stance does not as yet seem justified. In the following sections, the writer moves into the privileged position of an observer, trying to maintain as objective a style as possible.

### 3. PROBABILISTIC AND PREDICTIVE TESTS VERSUS A NEW DEFINITION OF ILLNESS

Diseases can be assessed according to a grid of four different categories of genetic tests:

- Disease/illness<sup>13</sup> caused by the defect of a single gene
- Multifactorial disease deriving from a combination of gene defects
- Disease deriving from chromosomal abnormalities
- Mitochondrial abnormalities manifest in the early stage of the DNA

These four categories create the territory on which genetic testing and screening is erected in order to install a new register of illness that will differentiate between predictive and preventive medicine. They are embedded in different testing practices that underline the function and purpose of the testing itself. The tests cover the following areas:

- *Diagnostic testing* (which formulates or reconfirms a diagnosis)
- *Presymptomatic testing* (which ascertains whether a healthy person has been subjected to a possible genetic mutation that will develop into a disease)
- *Predictive testing* targeting genetic susceptibility/predisposition (which detects risk factors that become active through exposure to specific environments or through gene interaction)
- *Testing to detect heterozygotes* (which detects carriers of genetic disease inherited from different factors)
- *DNA fingerprint* (which identifies a person by analysing specific regions of DNA)<sup>14</sup>

Although this register extends to different areas of the DNA and bodily geography, it seems reasonable to argue that diagnostic testing is the overarching technique with which all the others are related. In spite of this, it is not easy to define what a genetic test is. The more comprehensive definition goes back to 1996 when the American National Association of Insurance Commissioners tried to set the principles governing genetic testing and screening. The length of the definition, however, reveals the difficulty inherent in such a definition that, considering the possible advancements in diagnostic knowledge, may very soon become obsolete.

Genetic screening or testing means a laboratory test of a person's genes or chromosomes for abnormalities, defects, or deficiencies, including carrier status, that are linked to physical or mental disorders or impairments, or that indicates a susceptibility to illness, disease, or other disorders, whether physical or mental, which test is a direct test for abnormalities, defects, or deficiencies, and not an indirect manifestation of genetic disorders.<sup>15</sup>

The formulation reiterates the peculiar nature of genetic testing and screening embedded in predictive and personalized medicine. Predictive medicine is probabilistic in so far as it singles out those at risk while they are healthy, but for that very reason is also difficult to quantify. Some powerful commentators have called upon these two aspects to criticize the validity of predictive medicine. A position paper submitted to the Conference of European Churches in October 2003 argues that genetic testing and screening causes a “reversal in the perception of time”—the future that has always been open and undetermined becomes a certainty through genetic

prediction. A psychological consequence could be that people might live in preparation for the worse. “The final outcome, like a metaphorical cancer, invades every space and everything revolves around it.”<sup>16</sup> According to this interpretation, genetic testing and screening seems to introduce a subtle change in the perception of illness: Whereas before genetic testing and screening medical doctors confirmed the presence of a state of illness, now their skills are directed towards the assessment of the “risk of illness.” It is said that this transformation will have major repercussions on the relationship between doctor and patient.

Therefore, the European Churches identify here a shift of actions from beneficence to autonomy. Treating the patient is understood as the relation that installs beneficial effects, while the predicting of an illness presupposes “a looking further into the detail of the diagnosis, rather than just managing the illness or curing it.” This new regime will also have repercussions on the principle that underlines our duty to respect the individual’s autonomy, as this seems to become more important than the principle of beneficence. Furthermore, genetic testing is considered to indirectly target the family members of the persons who undergo the testing, extending diagnostic knowledge to larger social territories. It is likely that the Council of Europe had this in mind when they accorded “hybrid legal protection” or an intermediate status to the families and their members genetically related to the tested person. Such new legal definitions allow for distinguishing family members from third parties and, therefore, to ascertain their rights to know or not to know or to refuse the diagnosis.<sup>17</sup> Finally, here the European Churches see the emergence of a double register: one for those who are potentially sick, and another for those already “living with the reality of illness.” Are the European Churches overestimating the psychological effects of genetic testing and screening? Are they assigning a passive role to people, especially in the way they understand their status as carriers of potential diseases and chronic illness? Is it possible that genetic testing and screening introduces new attitudes towards one’s own physical status, demystifying illness and strengthening other factors?

The Churches themselves acknowledge this possibility by stating that “a person’s moral and spiritual health are decisive components of bodily health.” However, where people gain these strengths from is still an open question. Very often personal resources derive from strategies embedded in local and peripheral knowledge and experience. It seems reasonable to suggest that faith constitutes one of these resources, but faith may be only one option among many. Interestingly, in his 2003 essay “Faith and Knowledge,” the philosopher Jürgen Habermas<sup>18</sup> suggests that in our postsecular societies faith is re-entering the social fields called upon by genetic engineering, revealing how transitional our secularization is. “Even in Europe . . . feelings towards secularisation are still highly ambivalent, as shown by the dispute over genetic engineering.” Habermas reinforces faith as a personal resource to withstand “the depressing current events” caused by the “new genetics.” This turn makes many sceptical of the profound sense of cultural pessimism

that underpins his conclusions. Undeniably, genetic testing and screening introduces new regulatory elements in the strategies of every single person. The social effects of genetic diagnoses on people and their relationships are well encapsulated in the following statement:

One friend says, “well, you aren’t well”, and I think, “well, but I’m not ill”. So, if I’m not well, but I’m not ill, what am I?<sup>19</sup>

Given that genetic testing is predictive, the impossibility of pronouncing a final judgement might make people think of their illnesses in terms of perception of illness rather than physical impediment. Lowton and Gabe (2003) speak of four concepts of health perception used by people affected by cystic fibrosis, an autosomal recessive genetic disease, in the context of their daily activities. According to this grid, “health” is identified as “a normal state,” as “controllable,” as “a distressing state,” and as “a release.”<sup>20</sup> This approach is contrasted with the attitude adopted by people who accept their chronic physical illness as a fate. According to Bury (1991), chronically ill individuals tend to rely on a module that helps them to live with their condition, and follow three trajectories: coping, style, and strategy.<sup>21</sup> This approach is reflected in an attitude that aims at *managing* chronic illness and treatment. Perception and management of illness underline two different personal ethical approaches towards the sick self. A further discussion of these findings would go beyond the scope of the present analysis. This differentiation nonetheless underlines how a clear-cut definition of illness has never existed. People try to identify strategies that allow them to live their lives, however physically limited they might be, according to an idea of health that very often is cultural rather than medical, and very often profoundly rooted in an ethics of the care of the self. For that reason, some of the criticism that has accompanied genetic screening and testing from the very beginning of its emergence seems to be the product of ideological interpretations rather than ethnographic observations. Lowton and Gabe (2003) open up a new narrative line in the discourse of genetic screening and testing by saying:

It is well known that the concepts of “health” and “illness” mean different things to different people and it may be here that difficulties in distinguishing between coping, style, and strategy lie.<sup>22</sup>

The two authors reveal that, although cystic fibrosis is considered a “child-killing disease,” genetic testing has demonstrated that many previously undiagnosed adults appear to have a milder form of it. What are the consequences of genetic testing and screening and the diagnostic knowledge that this technology installs in the social field? Is genetic testing and screening extending the radius of control? Does it represent a threat to social cohesion and personal identity? The European Churches do not of course adopt this position,<sup>23</sup> and in their paper they underline the importance of predictive medicine in terms of policies of prevention. And it is not by chance that they refer to the recommendations of the British Human Genetic Commission that introduces the discourse of “genetic solidarity and altruism,” a sort of genetic



welfare state or common genetic territory on which the health of future society can be erected. The notion of the sharing of genetic information is reinforced by the exhortation to show “respect for the person, which implies observing the principles of respect of the privacy of the individual and the confidentiality of personal genetic information, as well as the principle of free consent and non-discrimination.”<sup>24</sup> In their position paper the European Churches reiterate two principles that they believe should facilitate the regulation of genetic testing and screening. The first underlines the notion that human beings are “equal with regard to risk,” and the second that our “collective ignorance is fundamental to our solidarity.” The fact that predictive medicine can now push forward the limits of knowledge, and thus allow us to see those “who are more at risk than others,” is said to undermine the system of fundamental solidarity.<sup>25</sup> This contention will be further investigated in Section 4.

#### 4. FROM GENETICS TO PROTEOMICS—THE LONG-STANDING COLLABORATION BETWEEN COMMERCE AND LIFE SCIENCE

What do we actually mean when we speak of genetic tests? The International Genetics & In Vitro Fertilization (IVF) Institute, the world’s largest provider of infertility treatment and genetic services, offers a range of tests addressing different problems. These include, testing for immigration purposes, DNA profiling, self-service paternity testing, full paternity testing, contract paternity, and infidelity testing. The latter test involves “an easy-to-use and inexpensive kit to detect semen on clothing or related items,” which costs \$210 per item.<sup>26</sup> This institute and its services embody a new relationship between the cellular and the social level of knowledge, or between the local (the collection of material deriving from cells, genes, eggs, sperms, and proteins) and the global (services that can be marketed and ordered globally). This relationship installs a new bodily and cellular geography that can be best described using the Foucauldian term of biopolitics and the emerging term of diagnostic geopolitics. Biopolitics revolves around the body, its regions, and the new enhancement regimes. Diagnostic geopolitics creates registers and classifications according to an idea of well-being that allows for the creation of new clusters: genetically healthy persons, at-probable-risk persons, at-risk persons, sick persons. Diagnostic geopolitics finds its expression in the bio-banking projects currently undertaken in the United Kingdom, Iceland, Estonia, and Japan which aim at transforming countries into repositories of the genetic information of a country and its people. At this stage, we can maintain that this new relationship between the bodily local and the diagnostic global reveals a redefinition of cultural patterns and social regions in which health professionals, economists, scientists, medical practitioners, genetic counsellors, families, and individuals are renegotiating personal rights and reorganizing their genetic resources and well-being.

#### 4.1 *Profit or Care?*

In his 1999 article, *Genetic testing and therapy: A pathway to progress and/or profit?*, Robert F. Rizzo<sup>27</sup> opens his analysis with the uncompromising statement that “genetic testing and therapy are in the process of becoming enterprises propelled by the profit motive for the creation of an industry of multibillion dollar proportions.” Rizzo’s article targets the US healthcare system that has reached an exasperated level of budgetary management of primary care services. The US-managed health service seems to highlight fundamental contradictions of the healthcare system itself, especially when healthcare has to cope with genetic testing and screening and therapy. We will dwell a little on Rizzo’s analysis embedded in social economics, and try to understand the angle from which he formulates his criticism. A clear sign of the enterprising nature of modern healthcare systems is a technological mentality that seems to penetrate even the thinnest interstices of the doctor–patient relationship. This development appears to be as unstoppable as it is inexplicable, as “it is difficult to sort out what motivates the use of technology in every instance.” One reason is the intended benefit to patients. However, Rizzo refers to a number of studies which suggest that aggressive—highly technological—care and treatment have “often resulted in poor survival rates. . . . This has also been true of neonatal intensive care of infants with minimal brain function.”<sup>28</sup> But the application of technology in medicine seems also to derive from a productive collaboration between physicians, hospitals, research scientists, and medical industrial corporations—all of whom benefit financially from the use of technologies. This network is gaining predominance, especially in the field of biotechnology in which history seems to be “repeating itself in the collaboration of commercial interests and medical research”<sup>29</sup> propelled by the profit motive.

This analysis has been confirmed by successive studies such as that by Australian scientist, Nicolas Rasmussen (2004). Rasmussen has identified a special biotechnology relationship between drug firms and academic biomedicine. His discussion of two cultures “brought together by perceived mutual advantage” seems to confirm Rizzo’s thesis of the profit motive. Interestingly, Rasmussen also speaks of a perception of common interests, which, perhaps not intended in the way they are perceived, for that very reason, cause “deep clashes” in the values of the two cultures<sup>30</sup>: the pharmaceutical industry and the academia. But where does the profit motive come from? According to Rizzo,<sup>31</sup> it arises out of a fundamental transformation of healthcare into a commodity that introduces market practices into the medical profession and its establishments. New biotechnologies such as genetic testing will increase the level of intervention and with it also health costs, causing the healthcare system to reach “a deeper level of crisis than it is now experiencing.” Rizzo exclusively refers to the US healthcare system that is controlled by different forms of managerial strategies such as health maintenance organizations (HMOs), independent practices associations (IPAs), preferred provider organizations (PPOs), point-of-service plans (POSs), and

prepaid group practices (PGPs). The common element of these diversified private regulatory systems is capitation. There are two forms of capitation contracts. In the first, primary care capitation contract physicians work under tight budget guidelines and receive pay for each treated patient, which covers the visit, in-office tests, and other minor procedures. Additional budgetary subforms cover emergency, X-rays, referrals to specialists, admissions to hospital, all of which are paid under “fee-for-service.” This is because specialists themselves, despite also being subject to budget constraints, are paid for each service provided. A second form of capitation contracts for primary care accords high monthly salaries to physicians who are ultimately responsible for referrals to specialists and hospitals. Here Rizzo sees room for negotiations between different interests, as “*capitated* physicians can reap larger profits by staying under budget,” because “capitation provides financial incentives to treat less.”

It is generally believed that the historical shift that led to capitation was caused by the creation of medical savings accounts (MSAs), a sort of self-insurance in which individuals are given the opportunity to use funds deposited into their insurance accounts to shop for the best and most economical care. The social economist Rizzo argues that there is no better example of the pervasive influence of the marketplace mentality in the healthcare system, as the savings accounts turn patients into consumers.<sup>32</sup> But what is the problem with being a consumer instead of a patient? “From a consumer’s perspective, tests, drugs and other medical procedures are much less attractive than clothes, cars, homes, vacations and luxury goods.”<sup>33</sup> The profit motives and the marketplace mentality are turning primary healthcare service into goods that can be bought according to an individual’s budget rather than his/her needs. The changes are pervasive as they install the idea that healthcare as such is an economic good produced by an industry.

#### 4.2 *Biomedicine and Commerce—Merchants of Life?*

It is undeniable that medical science has been attracting the attention of big money since the beginning of the 20<sup>th</sup> century. But what in the early 1900s seemed to constitute largely philanthropic moves into the healthcare system—think of the American Carnegie and Rockefeller foundations—has now turned into corporate interests. It seems that the current corporate interest in healthcare coheres around five targets: (1) discovery and sequencing of genes related to diseases (genome and DNA); (2) identification of biochemical markers; (3) ascertainment of function and role of the proteins (proteomics); (4) provision of genetic testing; and (5) development of (individual) drug therapies (pharmacogenomics). These five strategies take place concurrently and are interrelated to each other. At present, we are in the genomics phase, but the limited geography of the DNA will soon be overcome by the need to extend territory exploration into the proteins and their functions as well as expressions. Indeed, drug therapy will be successful only

after a coherent classification of proteins and the creation of a new taxonomy has taken place. This scientific taxonomy could lead to the installation of different social regimes defined by different understandings of the power of cellular life. At present, we are witnessing financial manoeuvres directed towards large investments of companies into the promising market potential of diagnostic testing on individuals without symptoms. According to some European analysts, proteomics will be the successor of the genomic era, as it “has already supplanted genomics.”<sup>34</sup> These sharp market observers speak of genomics as a first wave and proteomics as the second wave of the bio-era. That such a shift has begun is said to be demonstrated by already existing “powerful technologies that allow data to be stored, analysed, and interpreted.”<sup>35</sup>

From the point of view of targets and effects, proteomics and pharmacogenomics are interrelated, in so far as they refer to the study of genes and proteins in a person’s genome that determine a certain drug reaction. According to Aitken and Metcalfe (chapter 7), the “pharmacogenomic future is one where a person would be screened for a host of gene variants before being prescribed medications.” As the two authors maintain, this emerging rational approach towards prescription of medication “is set to become an integral part of medical practice.” Developments towards “individualized prescribing” seem to confirm a shift from the hospital, as the curative place of the past, to the laboratory, as the place in which disease can be predicted and its treatment tailored to the needs of the individual person, who therefore will turn into a customer rather than a patient. Through this historical shift the laboratory will turn into a privileged medical scene capable of permeating healthcare policies and social life.<sup>36</sup>

Another significant aspect that highlights the changes in bioscience and biotechnology and related applications is the emergence of new commercial actors that are about to replace the chemical companies of the past. Rizzo (1999) believes that free enterprise and the profit motive in healthcare will invigorate inventiveness and risk-taking, and create “new industries in research and applications.”<sup>37</sup> Some commentators speak of “the industrialization”<sup>38</sup> of healthcare, which is understood as a rational system that aims at creating the conditions of predictability, quality control, and an inclusion of cost-benefit reasoning. This would reflect a “rationalized” industry that maximizes the utilization of personnel with minimum expenditure of resources. The healthcare industry is related to biotechnology. According to Bock et al. (2001), one-fifth of the new drugs originating from biotechnology already represent 5% of total pharmaceutical sales. The United States and Japan are dominating the European market, while US firms seem to be an invincible force in terms of innovation and innovative drugs. In 1999 its global market participation reached 40% of the total world market for prescribed drugs. This commercial and economic net is spun by new commercial actors called Amgen, Chiron, Biogen, and Genzym, small firms that are “securing an increasing proportion of the global pharmaceutical market”<sup>39</sup> and perhaps completely replacing acronyms like BASF, Hoechst,

Merck, Roche, Dupond, and Cyba. Genomics is said to have the potential to create completely new industrial clusters and activities, and therefore to replace existing industries.<sup>40</sup> Nicolas Rasmussen, who has written extensively on the moral economy of drug companies from a historical perspective dating back to the 19<sup>th</sup> century, speaks of the pharmaceutical industry as a

powerful presence in academic life science, in the form of both the giant multi-nationals that sell drugs and the smaller “biotech” firms that supply them with some of their new products.<sup>41</sup>

This collaboration goes back to the first decades of the 20<sup>th</sup> century, as accurately underlined by Rizzo (1999) and Rasmussen (2004). However, the two authors differ in their interpretation of the reasons why this collaboration has turned into such an extensive business since the 1920s. Rizzo seems to suggest that scientists pursue profits no matter how compromising this attitude might be for their moral status and their professional standing. In the course of this development, Rizzo contends, physicians have become “more dependent on pharmaceutical companies for the application of research through drug therapy, becoming the bridge for the marketing of the industry’s products with both parties reaping the financial benefits.”<sup>42</sup> Instead, Rasmussen<sup>43</sup> has elaborated on the moral dilemmas that have accompanied the emergence of a new collaboration between the emerging pharmacologic industry and the medical researchers in American society and culture since the 1900s. Rasmussen’s historical reconstruction, while exclusively referring to the American case, can be applied to western countries in general. It was inevitable after World War I that the role of scientists in academia be reorganized, and that they open up their scientific establishments to external forces such as industries.

Rasmussen, however, seems to read these developments in rather pessimistic terms. He underlines that “according to the original ethos prevailing among US preclinical scientists devoted to the research ideal, ethical standards had declined between the 1890s and 1930s.”<sup>44</sup> Rasmussen’s interpretation of the transformations that occurred in the academic environment during the previous century, leading to an extensive collaboration with the industry, seems to be influenced by a purist attitude.

It could be worth investigating the reason for that collaboration. Can it be that a transformation of society, caused by the entrance of the idea of social welfare into political calculations, made it necessary to create the conditions of a more practical collaboration between academia and industry, in order to guarantee a safer production and distribution of drugs? Is this collaboration perhaps foremost due to the emerging mass society and mass consumers? A different reading of the development would therefore place the scientists in a different light—between Rizzo’s voracious scientists and Rasmussen’s utilitarian researchers. At the beginning of the previous century, with the US pharmaceutical field dominated by numerous private medical colleges that produced a glut of physicians with inadequate education, especially in science, modernizing seemed unavoidable.<sup>45</sup>

This modernization was intended to curtail the number of patent medicine makers with a poor academic background, and to impose new marketing practices on drug companies. The notion of the “ethical drug firms” emerged. However, only those firms that labelled active ingredients and marketed through the medical professions earned this title.<sup>46</sup> The necessity of selling more scientific drugs to the public made the ethical drug firms look for more productive collaborations with academic scientists and physicians and, consequently, invest more in research. These collaborations, however, did not always form smoothly. For many scientists at the beginning of the previous century, intellectual reputation was the scientist’s salary. In addition, “academic disrespect for business ran especially high.”<sup>47</sup> Although both cultures perceived the fresh wind of the medical reform, “commercial involvement” of pharmacologists and physiologists was considered “inconsistent with ethical codes,” which were understood as “requiring disinterestedness and full disclosure of scientific findings.” In spite of this resistance, Rasmussen identifies a “blossoming of collaborations between academic life science and ethical pharmaceutical firms” throughout the 1930s. “Materially, what drug firms chiefly wanted from laboratory researchers was access to new scientific drugs that could readily be marketed.”<sup>48</sup>

According to Rasmussen, this collaboration, which must be understood as the pharmaceutical firms assuming control over scientific findings, manifested in three different ways: (1) exclusive access to the practices and knowledge of the academic researchers; (2) exclusive rights to use the name of a compound, made famous by the scientists who discovered it, as a trademark (this strategy led to the discovery of insulin in 1922 as a result of the collaboration between the University of Toronto and the drug firm Lilly); and finally (3) patents taken by individual scientists. Of these three strategies, the patents became the more successful for scientists and their universities, and therefore their preferred form of collaboration between science and commerce/economy. This, however, does not mean that patents were easily introduced as a self-rewarding device. As Rasmussen maintains, patents on medical products were especially controversial among physicians. Indeed, they were forbidden in France and by the American Medical Association, and regarded by many as inconsistent with the Hippocratic oath. To make them morally acceptable a new discourse was introduced in the scientific practices, one that underlined the notion that patents in the name of public protection were morally acceptable, as they could “protect the public from bad medicine.” A scientist working for the University of Toronto wrote in 1922:

I can see no more reason why the man that separates the active constituent of the pancreas should not share financially as much as the man that makes a new wireless telephone.<sup>49</sup>

Rasmussen interprets this statement as a utilitarian argument in favour of “inventing for the general benefit.” The quotation of course unveils the active role played by scientists in shaping the patent culture of the previous century.

This prompts Rasmussen to conclude his impressive article with a note of subtle criticism:

Indeed, patenting trends among academic life scientists in especially competitive fields during the interwar period may not have been entirely due to industrial pressures. Academic scientists seem to have placed exaggerated value on patenting, at least in the view of drug firms, which sometimes would have preferred special access to know-how or exclusive use of trade names.<sup>50</sup>

It seems, therefore, that science rather than commerce has created patents and their successful system. And if scientists preferred them to other forms of reward, there must be a reason beyond simple utilitarianism. Perhaps patents can be understood as a particular surviving strategy pursued by scientists in a historical phase dominated by a cultural shift in the context of which scientists were beginning to lose their privileged position. It might be that the emergence of the mass university and with it different fields of knowledge increased the level of competition.<sup>51</sup> In the 1930s,

few topics were as important to physiologists and biochemists in the period as hormones and vitamins, molecules that appeared to account for many of life's processes. The importance of these substances made discovering and purifying them especially competitive.<sup>52</sup>

It seems therefore that being an entrepreneurial life scientist in the 1930s was a necessity rather than a choice. In the changing economy of the 20<sup>th</sup> century, with its managerial commerce, new cultural codes become installed by practices that would prepare the scientific field of biology and biochemistry for the “new genetics.”

### *4.3 Healthcare Contra Marketplace? Three Contradictions*

Patents still represent the most coherent way of ascertaining research activities and results. According to Bock et al. (2001), between 1985 and 1997 the United States had a sixfold increase of pharmaceutical patents, whereas Japan and the European Union only doubled their number. In 2001 more than 75% of pharmaceutical firms listed on stock markets were US-owned. In 2001 there were already 800 patents on genetic tests in the United States,<sup>53</sup> which will by now be on the market. In spite of these trends, genetic testing, on its own, represents only a small portion of total market and potential market (healthcare benefits) compared to, for example, drugs (pharmacogenomics and proteomics). But if genetic testing and screening is embedded in a larger field, e.g., biopharmacology, its importance seems to be steadily increasing. In addition, the cultural and social effects of genetic testing and screening appear to be irreversible, as it represents the first steps towards a universal redefinition of human nature, well-being, healthcare, and the social and legal policies that will accompany their implementation. In his 1999 article, Rizzo describes the current phase as transitional, but one leading to “universal genetic testing and therapy.”<sup>54</sup> Some medical practitioners and scientists rely on an imminent trend towards the screening of “entire

populations or specific subgroups for genetic information.”<sup>55</sup> Population screening as a public policy was first established by the World Health Organization (WHO), and was erected on three fundamental principles:

1. The identification of individuals who are at risk of specific disorders (the aim here is to develop preventive policies)
2. The identification of subgroups that need medical attention because of those specific disorders (public prevention)
3. Intervention to benefit the tested individual/individuals

This grid covers testing on an individual level and screening as group intervention in the name of public health. But this policy, created to reshape healthcare strategies and intervention on a global level, encounters problems on a local level. These problems might be caused by an intrinsic contradiction of the economic and commercial strategies that have permeated the healthcare system of the world’s largest economy. An understanding of these problems may help others to avoid the same mistakes. It is worth noting, at this stage, that genetic testing and screening and therapy allow a special form of access to the personal data of an individual. The information collected through this intervention is unique, because it is related to the person undergoing a test and consequently also to his/her family or ethnic group. Therefore, it is generally suggested that special care must be taken in order to avoid exploitation of the data in terms of social exclusion from insurance policies, health insurance, and employment.<sup>56</sup> But, because the information resulting from the tests might leave the person in a sort of limbo in terms of risks and real health status, the repercussions of genetic testing and screening also need to be addressed on a psychological level. For that reason Annas et al. (1995) speak of DNA information as “a personal diary” of a highly private nature with the potential to affect all aspects of individual life.<sup>57</sup>

In addition, genetic testing and screening has installed a system in the context of which diagnosis is not always related to treatment, in so far as not all diagnosed diseases can currently be treated. The consequences here are enormous for the counselling field, as demands for more counsellors will emerge in order to deal with the sense of confusion that a diagnosis might create in a person and his/her family. Other difficulties could emerge once parents claim the right to have their offspring genetically tested. How is society to regulate these issues? Can parents demand a genetic test for their children without their children’s consent? Additional problems might be caused by the fact, recognized by scientists as well, that genetic tests are not infallible, that errors can occur on biological, clerical, and/or laboratory levels—the so-called false negatives or false positives that might influence a diagnosis. The commentator, Rizzo, wonders whether our society and its healthcare system are prepared to provide the support and protection to individuals who avail themselves of the tests. “In a society noted for law suits for malpractice and negligence in informing, counselling faces a formidable task.”<sup>58</sup>

Rizzo identifies three fundamental contradictions that the US healthcare system will have to face as soon as genetic testing and therapy become some



of the most basic services of primary care—basic because they are strictly related to pharmacogenomics or personalized medicine and drug therapy. The first contradiction is that managed care will increase the risk of malpractice liability as “under capitation, managed care will be incapable of meeting the demands of genetic testing, diagnosis and counselling, because they demand more contact with patients.”<sup>59</sup> The second contradiction seems to be caused by the “industrialization” of healthcare, which aims to rationalize the sector in economic terms. But it is not clear whether the economic principle of minimal costs and maximum profit can be successfully applied to healthcare. This vision might instead increase “the financial risks of physicians and put them squarely in the business world.”<sup>60</sup> Again the question arises as to whether physicians will be able to offer the care that genetic testing and therapy require. The third contradiction is related to health insurance and the possibility that the insurance industry might refuse to sell life or health insurance to individuals identified as high-risk, or may attempt to charge higher premiums. In October 2000 insurance companies in the United Kingdom gained permission to ask for genetic tests results. This permission was subsequently withdrawn as many observers anticipated that this move would lead to the creation of a “genetic underclass” of people unable to buy health or life insurance. However, some observers suggest that no obligation of disclosure of genetic test results could represent a high risk for the insurance industry itself, because it would undermine the principles and fundamental understanding of the insurance industry. The issue related to the Australian insurance industry and disclosure of genetic information will be explored by Weisbrot and Opeskin (chapter 6).

Another problem, according to Rizzo, is that due to the costs of genetic tests and therapy, a price regulation could make many companies look for more competitive markets, in turn causing an increase in insurance costs. The employers could also decide to discontinue the group plans for their employees. This makes Rizzo conclude that whether health insurance is less regulated or stringently regulated, “the system will be unable to cope with genetic testing and therapy.”<sup>61</sup> Here Rizzo is indicating that health insurance systems need to be controlled in such a way as to positively respond to social rather than commercial and economic imperatives. Does this make sense to the insurance industry? This question will be addressed in Section 5. At this stage, it seems that two fundamental consequences derive from the introduction of genetic testing and screening and therapy into western healthcare systems: the uncertainty surrounding the treatment of diseases diagnosed by genetic tests; and the increasing need for counselling, which will require state intervention in order to govern the social, ethical, and psychological problems related to genetic medicine. This is an extraordinary change in an economic and social order in which we have been witnessing widespread state deregulation since the 1980s. It seems, therefore, that the genetic economic and commercial order resulting from free market ideology has created new conditions for strong state regulation or governmental intervention. The governance of genetic testing and therapy will question the fairness of the marketplace as

the only regulatory dimension. It might follow here that “wherever health-care turns, it has to contend with the marketplace mentality.”<sup>62</sup> Rizzo seems intuitively correct in identifying a clash of cultures between medical health practices and commerce.

## 5. INSURANCE INDUSTRY AND GENETIC TESTING

Since the emergence of issues related to genetic testing, the public debate has been dominated by different attempts to address health insurance and the responsibilities of the insurance industry. This debate has produced the peculiar situation in which consumer activists have promulgated a definition of insurance as “a vehicle to meet community goals,” or in other words as a societal way of reducing social risks. This approach is of course opposed to that of the actuarial profession and private industry, both of which see insurance as “an economic institution opposed to an instrument of social policy.”<sup>63</sup> The ultimate goal of the insurance field is to distribute risks according to a list of classification variables generally known as risk and discrimination. Now some commentators and consumers’ representatives maintain that genetic information cannot be included in that list. The insurance industry, on the other hand, replies that suppressed information regarding genetic questions might create discrimination among the insured and lead to an increase in premiums levels.

When there is suppression of information, as would occur, for example, if insurers were forced by law to ignore genetic information in classification, and if the insurers were forced to charge the same rate to insured persons who are known to have different expected loss costs, then the insurance pricing not only might be viewed as “unfairly discriminatory” to the group of lower-expected-cost persons but also would encourage more hazard and adverse selection against the insurer.<sup>64</sup>

The authors quoted above add that the consequences of suppressed genetic information would be disastrous for the industry, as it might even threaten the solvency of insurers. Other commentators put it more bluntly: “If insurers are forbidden under any circumstances from using genetic information to adjust premiums, then we are on the highway to eliminating insurance.”<sup>65</sup> Undoubtedly, genetic testing represents a challenge for one of the oldest businesses of modern economy and commerce. According to Brockett et al. (1999), the debate on the restriction of accessing genetic information and the resulting indiscriminating distribution of risks among low-risk and high-risk groups result from a flawed understanding of the insurance field. The authors believe that social demands are led by a welfare expectation that aims at transferring wealth from one group to another. “While this may be desirable from a societal perspective, it must be debated whether insurance is the most appropriate mechanism to achieve this wealth transfer.”<sup>66</sup> Brockett has written extensively on the effects that the “new genetics” will have on insurance and workplace relations, and he has also debated the necessity to differentiate between the interests of the industry and

those of the individuals and social policymakers (2001, first published in 1973). "From the perspective of the insurers, who view themselves as financial intermediaries, the ultimate rationale for using . . . genetic-based information for classification purposes is economic."<sup>67</sup> This fact has also been reiterated by Weisbrot and Opeskin (chapter 6), who maintain that the ALRC-AHEC Inquiry into insurance practices and genetic information in Australia has rejected the notion of genetic exceptionalism, through which some would like to justify a revision of insurance practices and more incisive state intervention. Although the two authors understand that claims for more control are influenced by fears that the insurance industry could discriminate against certain prospective individuals threatened by genetic predispositions, they argue that such discrimination is more prone to happen in America than in Australia. They, therefore, reject claims that the insurance industry should not be allowed to ask prospective clients to undergo genetic testing.

The stance taken by consumer groups advocating the prohibition of genetic testing for any type of insurance has been criticized as deriving from the belief that because healthcare is a right, so also must healthcare insurance be. The debate is still open. The US Senate passed Bill S. 1053 in mid-October 2003, the *Genetic Nondiscrimination Act*, which protects the privacy of genetic information and prevents health plans, insurance carriers, and employers from discriminating on the basis of genetic information. The bill is still awaiting action from the US House of Representatives, and many signs suggest that no decision will be taken in the next months. Many observers see the political wait-and-see approach as a welcome delay to the decision-making process regarding genetic testing, genetic information, and insurance industry. Most western countries do not as yet have any clear legislation on genetic testing in place. In the last 15 years, some American states imposed a moratorium on the use of genetic information for insurance purposes, and in 1995 the Netherlands and the United Kingdom followed. The United Kingdom has reviewed a previous decision to accord access in order to avoid the emergence of a two-class regime in the insurance field, but this political strategy does not seem to satisfy the industry. According to Brockett et al.:

The states that disallowed classification in genetic testing issues have raised privacy rights and employees' concerns onto a higher pedestal while invalidating the business concerns of insurance companies.<sup>68</sup>

The authors believe that this trend has blurred the lines between social programmes and insurance companies, with the genetic testing issue transformed into an argument against insurance. Genetic testing and screening and therapy are undoubtedly a challenge for public policies as they reflect an emergence of conflicts deriving not only from a reorganization of the risks allocation system but also from a new understanding of what risks are in the genetic economy and commerce. Interestingly, this debate seems to overlook the fact that genetic testing provides ways of assessing predispositions and susceptibilities, but by no means concrete diseases. If illness is defined

according to genetic information rather than expression of illness, we might all turn out to be somehow high-risk-insured, as the probability of an illness does not say anything about its genetic mutation. Nevertheless, genetic information is becoming a source and a reference not only for medical practitioners, healthcare managers, and the insurance industry but also for new investors and the new economy.

#### 6. THE GENETIC ECONOMY AND COMMERCE—A NEW ORDER

In his 1988 book *Embryo Handel* (Trading Embryos), the Swiss author and academic researcher Samuel Stutz<sup>69</sup> posed the question that many had been thinking about since the creation of the first IVF laboratory embryo in 1977/78. Stutz asked whether the laboratory structure of the new biomedicine would transform embryos into raw material for the medical and pharma industry.<sup>70</sup> Since then, this question has occupied the minds of many biotechnology critics, as the biolaboratory opens up another site in the economic and commercial system in which genetic resources are more easily acquired. Stutz did suggest that a sort of illegal trade was already taking place in the late 1980s, one capable of giving research laboratories what needed for the advancement of their research activities. The author singled out Australia as one of the western countries that most eagerly cultivated a utilitarian approach towards the use of embryos and foetuses for research purposes, turning its scientists into merchants of life. Since then, however, new regulations and genetic laws have been introduced in western societies to make it more difficult to trade genetic resources as raw material, although this does not necessarily mean that the illegal economy, which is the other side of the coin, has been completely defeated. The fears expressed by many critics that the bioscience and biotechnological field will enter new collaborations and alliances with industry and commerce intuitively reflect what has been acknowledged over the years: that genetic material—stem cells, embryos, cells, genes—is profitable raw material. And analyses projected towards the future reinforce this sense of repositioning of the compass in terms of the creation of wealth using genetics and bodily resources. In their 2002 article “Genomics and Social Science,” Harvey et al. propose a series of forecasts that describe the genomic era and the cultural system in which it is embedded. The authors, however, do not engage in a debate about definitions, and admit to using the expression *genomics* in rather general terms, as at the time of writing, it might already be superseded by “proteomics” or “the post-genomics era.”

Proteomics is the science of the gene and protein functions, as they are used in healthcare, agriculture (genetically modified [GM] food), stem cells research, organization and work, and other emerging fields like biomining and bioremediation (environment). Proteomics represents a caesura in so far as “there is a great distance between a nucleic acid sequence and gene expression,” and for that very reason the possibility is given that “the concept of a gene itself will fall.”<sup>71</sup> Undoubtedly, Hil and Hindmarsh (chapter 3)

would argue here that the term gene will fall anyway, and not only because of scientific advancements that make proteins (gene expression) more important than the gene itself. According to the two authors, the connotations attached to genes reveal the political machinations to which that term has been exposed. This would justify speaking of gene as “a fuzzy” term to underline that it lends itself to many uses, especially in criminal law and in disciplinary techniques targeting children. As Hil and Hindmarsh say:

Above all, there is readiness to assert the primacy of biological factors in crime causation, and to assert that “criminality” can be found in constitutional features rather than in socio-economic, cultural and political contexts. On such questionable premises are based futuristic notions of screening for such fuzzy concepts as the “crime gene.”

This controversy reminds us of the precariousness of terms in a changing social and economic order, and of the consequences that that precariousness may have for cultural habits. But what are the consequences of genomics/proteomics for economy and commerce? According to Harvey et al., certain developments seem to indicate that public sector investments in genomics could overtake those going to NASA in the United States. Individual medical profiling, the creation of drugs genomically tailored to individuals, is said to lower the overall costs of drug production and diminish the demand for most drugs. Drugs will also be combined with staple food (nutriceuticals) and create different styles of consumption. A new framework of risk assessment in terms of individual and public risks will boost the insurance industry.<sup>72</sup> Harvey et al. wonder whether the changes that are occurring in industry and global gross domestic product (GDP) through biotechnology will make it necessary to change classic assessment methods. “Do statistics measures need to be modified to cope with changing structures and relationships?” In other words: “How do you calculate the value of genomics-based research and development (R&D), and the economic returns to R&D investments?” or “How is economic and financial risk assessed in relation to genomics-related externalities, such as environmental degradation, public opinion, biodiversity, and human health?”<sup>73</sup>

An investigation of the emergence of a new banking system illustrates the vastness of the changing economy and commerce. Since the emergence of the first (egg and sperm) donor banks in the late 1970s, the cell, zygote, and embryo banks in the 1990s, and now the establishment of human tissue banks, the notion of investment has undergone a fundamental change. Currently there are 400,000 frozen embryos deposited in different US embryo banks. The critic Lori Anderson suggests that this would be enough to create an entire new city.<sup>74</sup> The general impression is that an increasing number of people create term deposits on their genetic material. One of these new forms of investment in genetic resources is the *umbilical cord blood* (UCB), which apparently contains a high number of stem cells and is generally described as “the mother of all blood cells.”<sup>75</sup> The stem cells of the UCB have the potential to turn into different types of blood cells that could be used to regenerate bone marrow after intensive chemotherapy. According to Gesche

(chapter 4) the UCB technology in Australia has led to the creation of the National Cord Blood Network, which includes 11 collection centres. Given that Australia's population scarcely reaches the 20-million mark, this is an impressive network of blood stem cells and DNA, which Gesche compares with other genetic databases that collect genetic samples to create new and "commercially useful cell lines," from which "substantial financial profit" can be expected.

It is worth dwelling on the significance of this new form of banking in terms of a reorganization of commercial and economic activities in the genetic field. To begin with, it seems reasonable to argue that the notion of "the new economy" makes sense not only in informatics but also when referring to the genetic economy and business that is transforming the relations between production, profit, physical enhancement, and body.<sup>76</sup> Authors Rusinko and Sesok-Pizzini (2003) reveal the fundamental relationship between the new economy and its new raw material when they maintain that UCB stem cells are readily available as a by-product of birth, making them less ethically and politically controversial than embryonic stem cells.<sup>77</sup> But why does UCB banking represent a fundamental element of a new economy, rather than just another technology to be added to the list of the biotechnologies that are already shaping and modifying the social space? Rusinko and Sesok-Pizzini argue that UCB is an innovation that is embedded in a technological community framework.<sup>78</sup> This technological community framework is constituted by three chronological and interdependent activities: R&D functions (given by basic research, financing, education, and training); institutional functions (legitimation, regulation, and technology standards); and, finally, proprietary functions (applied R&D, testing, manufacturing, and marketing).

These functions and subfunctions represent a technological community in which central roles are played by corporate interests, social expectations, public governance, grants and financial support, educational establishments and networks of practitioners, proprietary knowledge (patents) and profit, genetic testing for safety reasons, manufacturing of final products, and customer information and selling strategies. The institutional functions are given by the policies that legitimate and govern the members of the technological community. That the UCB banking necessitates such an apparatus in order to move from an innovative stage to applied knowledge and finally proprietary knowledge is due to the special human aspects related to this form of system that collect this "raw material" during the birth or soon after the placenta has been expelled from the female body. It is an emergent economic practice that commodifies a highly intimate part of private social life. The UCB banking represents an economy of the body and, as such, it requires a different way of penetration and regulation of the human territory. In addition to that, specific questions arise concerning ownership, privacy, and transferability and use of the stem cells in the cases in which the UCB derives from an abortion.<sup>79</sup> Who owns the UCB—the child from whom the placenta was taken or the parents? If the UCB is donated to be used on

patients external to the family, additional forms of genetic testing of cells and genetic testing and screening of the donor are necessary to avoid the transmission of genetic diseases. In this case, privacy questions emerge connected with informed consent and safety. If the UCB stem cells derive from aborted fetuses, the ethical issue are said to be less cogent; however, a question of safety arises when spontaneous abortions reveal foetal anomalies that must be coded in the stem cells.<sup>80</sup>

But what do UCB banks do? They collect, analyse, test, and store the cord and its cells for the donor and his/her family for later use in case of disease and invasive operations. Usually, this sort of banking is defined as private UCB banking, because its services are exclusively directed to the donors and their family members, and the potential UCB beneficiaries must pay a fee for the initial storage. According to Rusinko and Sesok-Pizzini (2003), the largest of the commercial UCB banks, Viacord Inc., charges \$1,500 and an annual storage fee for the duration of the storage contract (\$95). But a very large non-profit system has also emerged, called natural family planning (NFP) UCB banking, in which the donors do not have exclusive use of the stored cord. Here the donors and their families have no precedence over other customers. The NFP UCB banks collect a fee (\$15,300) only when the UCB is used for transplant, and the NFP fee is paid by the public sector.<sup>81</sup> When the UCB is used for research purposes, no fee is required.

The most striking aspect of the genetic economy and commerce is that, contrary to what it is generally assumed, many projects and technologies related to the “new genetics” are publicly funded. Interestingly, the private sector is increasingly capitalizing on (perhaps exploiting) the knowledge provided by “government-funded research and on the expertise of researchers in academic institutions, many of which are publicly funded.”<sup>82</sup> The first research activities on the use of stem cells deriving from UCB started in the United States in the 1980s and were primarily federally funded and directed to NFP UCB laboratories and banks. According to Rusinko and Sesok-Pizzini, the National Heart, Lung, and Blood Institute of the National Institute of Health (NIH) has invested millions of dollars to support a network of research, transplant centres, and UCB banks in the United States. The first privately funded UCB bank appeared in the 1990s “due to the profit potential in UCB collection and storage for individuals and families.”<sup>83</sup> In the mean time numerous UCB banks have been created such as the London Cord Blood Banks (LCBB) which belong to the National Blood Service, the latter of which has invested £4 million in this public service in recent years. There are also private UK Cord Blood Banks, a business venture of the US New England Cord Blood Bank Inc. Other banks are an emanation of transplant or blood centres, like the New York Blood Center, the Eurocord (a cooperative of clinical trials groups), and the Placental Blood Program.

The private UCB banks store stem cells for family use, while the NFP UCB banks do so for public use. However, studies seem to confirm that transplants from relative to relative have a higher success rate than donor transplants. These results have prompted the creation of a Cord Blood Registry in the

United States (2001) storing cord blood stem cells for family members. These cells “might allow a patient to obtain a new blood and immune system as healthy as that possessed at birth in case of need, and other family members might also receive the same protection.”<sup>84</sup> It seems that, through the technological transformations that are currently taking place, family ties, and perhaps family in general, emerge as invigorated and stronger (in genetic-economic terms) and more disciplined (in biopolitical terms) than ever. Finally as Rusinko and Sesok-Pizzini confirm, there are already patents related to UCB in the United States, Europe, and Japan.<sup>85</sup> The “new genetics” and genetic economy and commerce reveal a very interesting network of actors that goes beyond the social clusters of the past. It seems that the medical and scientific profession has irrevocably entered into new forms of alliances and commercial fields in order to respond to demands coming from both personal and public interests. This shift perhaps also results from a second repositioning of the scientific and medical profession. If in the past medicine was regarded as a high-standard profession, and the medical professionals as a sort of priest-caste that pronounced their sentences in terms of hope or lack of hope, they now seem able to narrate a different story that takes the individuals away from the realm of fate and into that of action. The narrative of prediction is reminiscent of the ancient practice of foretelling dangers in order to prepare individuals for the challenges looming in the future.

This new way of approaching risks might lead to a different attitude towards the self, a sort of care of the self that is embedded in a different knowledge culture in which the private and the public are intrinsically connected to each other. But who are the guardians of this knowledge? The Australians, Otlowski and Williamson (2003), argue that “doctors must be the gatekeepers of the new genetic knowledge.”<sup>86</sup> As explained by Weisbrot (chapter 5), there seems to be a need to give medical doctors and practitioners decision power in matters related to the disclosure of, or denied access to, genetic information. This is what emerged from the recommendations that the Australian Law Reform Commission and Australian Health and Ethics Committee (ALRC-AHEC) have formulated in the final report resulting from their inquiry into the protection of human genetic information in Australia. It seems, therefore, that through genetics doctors reposition themselves in the social sphere as mediators between the interests of the individual and those of the family, groups, society, as well as economy and commerce. Considering the myriad of new actors operating in the genetic economy, it seems reasonable to cultivate a privileged relationship with the physicians, who have been the most trustworthy allies of women, children, and human beings for many centuries.

But now the question arises of whether they can be trusted to the extent of being considered the owners of genetic knowledge. Perhaps here lies the most challenging task for public policy, policymaking, and politics, for the governance of the new genetics will succeed only when we come to a shared definition of who is the morally legitimate owner of genetic knowledge. And at this stage everything seems to point to the ethical self.



As argued in the preceding chapter, new laws and policies regulating individual choices and personal rights must be formulated in order to create the conditions of shared principles capable of facing the challenges of new genetic science and technologies. As a consequence, a new political system must arise from the historical transformation that we are witnessing, one that expresses a social policies framework in which the ethical self and its social, cultural, and economic activities are embedded.

What the social policies framework in the genetic society will look like is still an open question, as no definitive decisions have been made in terms of governance of biotechnologies and proprietary knowledge emerging from the “new genetics.” Some commentators, e.g., Gottweis (1998), exhort policymakers to consider the necessity to develop conditions of reinvigorating old institutions and creating new institutional bodies capable of ensuring a high degree of tolerance of, and respect for, the variety of socially available policy narratives and interpretations of realities in the field of social policies. Gottweis understands this multiplicity of different positions as an expression of the postmodern condition of our culture characterized by an “irreducible pluralism.” The postmodern style of policymaking could be guaranteed through the creation of “public spaces” within the confines of institutional politics and policies that allow for the “articulation of alternative readings of genetic engineering.” This approach would institutionalize what Gottweis calls “the micropolitics of boundary drawing” between politics, the economy, and science.<sup>87</sup>

But, as Fisher (2003) suggests, a changed way of understanding policymaking and, consequently, policy analysis necessitates a different political framework removed from “technocratic policy analysis.” The author privileges a post-empirical approach to policymaking oriented towards “an understanding of the discursive struggle to create and control systems of shared social meanings.” At this stage, Fisher argues: “If politics does not fit into the methodological scheme, then politics is the problem.”<sup>88</sup>

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## NOTES

- <sup>1</sup> Finkel, E. 2005. *Stem Cells: Controversy at the Frontiers of Science*. Sydney: ABC Books, 101.
- <sup>2</sup> Betta, M. and Clulow, V. 2005. Healthcare management—training and education in the genomic era. *Journal of Health and Human Services Administration* 27 (1): 465–500.
- <sup>3</sup> Finkel, *ibid.*, 259.
- <sup>4</sup> *Ibid.*
- <sup>5</sup> *Ibid.*, 134.
- <sup>6</sup> *Ibid.*
- <sup>7</sup> *Ibid.*
- <sup>8</sup> Castells, M. 2001. *The Internet Galaxy: Reflection on the Internet, Business, and Society*. Oxford: Oxford University Press, 22. “The Internet did not originate in the business world. It was too daring a technology, too expensive a project, and too risky an initiative to be assumed by profit-oriented organizations.”

- <sup>9</sup> MacIntyre, S. 1997. Social and psychological issues associated with the new genetics. *Philosophical Transactions of the Royal Society of London* 352: 1095–1101.
- <sup>10</sup> Bubela, T. M. and Caulfield T. A. 2004. Do the print media “hype” genetic research? A comparison of newspaper stories and peer-reviewed research papers. *Canadian Medical Association Journal* 170 (9): 1399–1400. The authors investigated 26 newspapers from four countries or 627 newspaper articles reporting on 111 papers published in 24 scientific and medical journals.
- <sup>11</sup> *Ibid.*, 1404.
- <sup>12</sup> MacIntyre, *ibid.*, 1095.
- <sup>13</sup> For the purpose of this chapter I will use the terms illness and disease interchangeably without specifying their semantics or differences originating from local/peripheral knowledge.
- <sup>14</sup> For more details on available tests see Genetics & IVF Institute at <<http://www.givf.com>>.
- <sup>15</sup> American Council of Life Insurance, 1996. The need for genetic information insurance. Statement of the American Council of Life Insurance presented to the National Association of Insurance Commissioners Genetic Testing. Working Group of the Life Insurance (A) Committee on 3 June 1996. White paper. Washington, D.C. Quoted in Brockett, P. L., MacMinn, R., and Carter, M. 1999. Genetic testing, insurance economics, and societal responsibility. *North American Actuarial Journal* 3 (1): 1–20, 3.
- <sup>16</sup> Author unknown. 2003. Genetic testing and predictive medicine. Conference of European Churches. Commission for Church and Society. Working Group on Bioethics, 1–13, available at <<http://www.cec-kek.org/English/BioethicGeneticTesting.pdf>>. Cited 7 July 2004. The following quotations refer to this article.
- <sup>17</sup> *Ibid.*, 6.
- <sup>18</sup> Habermas, J. 2003. *The Future of Human Nature*. London: Polity Press in association with Blackwell. [*Die Zukunft der menschlichen Natur. Auf dem Weg zu einer liberalen Eugenik?* Frankfurt: Suhrkamp, 2001.] Interestingly, the English version contains a postscript, and the essay on faith, which are missing in the original German version, in which Habermas seems to argue that in the genetic era philosophy is moving towards religion. A controversial move indeed. I refer here to pp. 102–103.
- <sup>19</sup> Lowton, K. and Gabe, J. 2003. Life on a slippery slope: perceptions of health with cystic fibrosis. *Sociology of Health & Illness* 25 (4): 289–319, 298.
- <sup>20</sup> *Ibid.*, 296.
- <sup>21</sup> Bury, M. 1991. The sociology of chronic illness: a review of research and prospects. *Sociology of Health & Illness* 13 (4): 451–468. Quoted in Lowton and Gabe, *ibid.*, 291.
- <sup>22</sup> *Ibid.*, 315.
- <sup>23</sup> Catholic and Protestant Churches have never absolutely condemned technological and scientific research—of course after Copernicus and Galileo. In the debate concerning IVF, genetic research, and cloning, the Churches have maintained an open position that reveals their will to avoid the mistakes of the past. Even the abortion debate has demonstrated how stratified and sophisticated their argumentation is, which should not be confused with the sectarian fighting among some of its members. For a detailed analysis of the official documents and position taken by the Churches in the genetic debate, see Betta, M. 1995. *Embryonenforschung und Familie. Zur Politik der Reproduktion in Grossbritannien, Italien, and der Bundesrepublik Deutschland*. Frankfurt, Paris, New York: Peter Lang Verlag, especially 147–163.
- <sup>24</sup> Author unknown, *ibid.*, note 6, p. 10, available at <<http://www.cec-kek.org/English/BioethicGeneticTesting.pdf>>.
- <sup>25</sup> *Ibid.*, 12.
- <sup>26</sup> See Genetics & IVF Institute at <<http://www.givf.com>>. The institute’s main offices and laboratories are in Fairfax, Virginia. The services offered include egg donors, the world’s largest group of sperm banks, and one of America’s most active pre-implantation genetics testing centres. Cited 14 September 2004.
- <sup>27</sup> Rizzo, F. R. 1999. Genetic testing and therapy: a pathway to progress and/or profit? *International Journal of Social Economics* 26 (1/2/3): 109–133, 109.
- <sup>28</sup> *Ibid.*, 113.
- <sup>29</sup> *Ibid.*, 112.

- <sup>30</sup> Rasmussen, N. 2004. The moral economy of the drug company–medical scientists collaboration in Interwar America. *Social Studies of Science* 34 (2): 161–185, 162.
- <sup>31</sup> In the following paragraph I will refer to Rizzo’s analysis on pp. 113–118.
- <sup>32</sup> For a philosophical analysis of the transformation of patients into consumers through the emergence of the biotechnological laboratory, see Betta and Clulow, *ibid.*
- <sup>33</sup> *Ibid.*, 129.
- <sup>34</sup> Bock, A.-K., Ibarreta, D., Lheureux, K., Libeau, M., and Nilsagård, H. 2001. Data is destiny: health care and human genomics. *Foresight* 3 (4): 377–388, 378.
- <sup>35</sup> *Ibid.*, 378.
- <sup>36</sup> Betta and Clulow, *ibid.*
- <sup>37</sup> Rizzo, *ibid.*, 109, 117–188.
- <sup>38</sup> Kleinke, J. D. 1997. The industrialization of health care. *Journal of the American Medical Association* 278: 1456–1457. Quoted in Rizzo, *ibid.*, 117–118.
- <sup>39</sup> Bock, *ibid.*, 381–382.
- <sup>40</sup> Harvey, M., McMeekin, A., and Miles, I. 2002. Genomics and social science: issues and priorities. *Foresight* 4 (40): 13–28.
- <sup>41</sup> Rasmussen, *ibid.*, 161.
- <sup>42</sup> Rizzo, *ibid.*, 112–113.
- <sup>43</sup> Rasmussen, *ibid.*, 164.
- <sup>44</sup> *Ibid.*, 178.
- <sup>45</sup> For the following reconstruction of the modernization of American medicine towards “scientific medicine” I will draw on Rasmussen’s historical analysis on pp. 163–174.
- <sup>46</sup> A trend that we are currently witnessing with the increasing attempts to discipline the biomedical laboratories and new genetic firms by requesting them to label genetically modified food or the exact ingredients of genetic drugs. The debate that originated out of GM food labelling and genetic drugs labelling, and which is currently taking place in all Western societies, confirms that we are in the middle of a dramatic reorganization of the pharmaceutical and healthcare system, as well as of the production systems of primary goods (food/agriculture) and distributive justice.
- <sup>47</sup> Rasmussen, *ibid.*, 166.
- <sup>48</sup> *Ibid.*, 168.
- <sup>49</sup> *Ibid.*, 172.
- <sup>50</sup> *Ibid.*, 177.
- <sup>51</sup> Perhaps current grants and grant applications can be classified in the same way, namely as a means by which scientists, especially social scientists, collaborate with governments or bureaucracies, such as the European Union which is still a supranational state, in order to secure much needed money for their academic activities, and to take part in the governance process. For governments grants are a form of scientific cooptation that does not evoke the same negative feelings as political cooptation of intellectuals and scientists. The effects, however, might be the same.
- <sup>52</sup> Rasmussen, *ibid.*, 179.
- <sup>53</sup> Bock et al., *ibid.*, 384.
- <sup>54</sup> Rizzo, *ibid.*, 117.
- <sup>55</sup> Khoury, M. J., McCabe, L., Edward, R. B., and McCabe, M. D. 2003. Population screening in the age of genomic medicine. *The New England Journal of Medicine* 348 (1): 50–58, 50.
- <sup>56</sup> The effects of genetic testing in the workplace have been a cause of concern to many observers. In spite of this, no national policies seem to have been created in order to manage this new form of employee–employer relation. The unions, not only in Australia, have failed to produce any coherent policy in the field. The following literature underlines the necessity to anticipate at least some aspects linked with testing employees. MacDonald, C. and Williams-Jones, B. 2002. Ethics and genetics: susceptibility testing in the workplace. *Journal of Business Ethics* 35: 235–241. French, S. 2002. Genetic testing in the workplace: the employer’s coin toss. *Duke Law & Technology Review*, May 9, available at <<http://www.law.duke.edu/journals/dltr/articles/2002dltr0015.html>>. Cited 6 July 2004. Jinks, A. M. and Daniels, R. 1999. Workplace health concerns: a focus group study. *Journal of Management and Medicine* 13 (2): 95–104. Draper, E. 1998. Drug testing in the workplace: the allure of management technologies. *International Journal of Sociology and Social Policy* 18 (5/6): 62–103.

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- <sup>57</sup> Annas, G. J., Glantz, L. H., and Roche, P. A. 1995. *Guidelines for Protecting Privacy Information Stored in Genetic Data Banks*. (The Genetic Privacy Act and Commentary). Boston, MA: Health Law Department, Boston University School of Public Health. Quoted in Rizzo, *ibid.*, 127.
- <sup>58</sup> Rizzo, *ibid.*, 123.
- <sup>59</sup> *Ibid.*, 115.
- <sup>60</sup> *Ibid.*, 118.
- <sup>61</sup> *Ibid.*, 125.
- <sup>62</sup> *Ibid.*, 129.
- <sup>63</sup> Brockett et al., *ibid.*, 9.
- <sup>64</sup> *Ibid.*, 5.
- <sup>65</sup> Fisher, N. L. 2004. Genetic testing and health insurance: can they coexist? *Cleveland Clinical Journal of Medicine* 71 (1): 8–9, 9.
- <sup>66</sup> Brockett et al., *ibid.*, 7.
- <sup>67</sup> Brockett, P. L. and Tankersley E. S. 2001 [1973]. The genetics revolution, economics, ethics, and insurance. Beauchamp T. L. and Bowie N. E. 2001 [1973]. *Ethical Theory and Business*, 6th edn. Englewood Cliffs, NJ: Prentice-Hall, 310–318, 311.
- <sup>68</sup> *Ibid.*, 17.
- <sup>69</sup> Stutz, S. 1988. *Embryo Handel*. Bern: Zytglogge.
- <sup>70</sup> The question of selling human bodily parts is not new, but it is acquiring increasing importance. See on this topic Kolnsberg, H. R. 2003. An economic study: should we sell human organs? *International Journal of Social Economics* 30 (10): 1049–1069. Kolnsberg develops economic scenarios and outcomes related to the selling of human organs particularly focusing on pricing and profitability in relation to donor benefit. In the end, the donors do not seem to benefit at all.
- <sup>71</sup> Harvey et al., *ibid.*, 23.
- <sup>72</sup> *Ibid.*, 23.
- <sup>73</sup> *Ibid.*, 16–17.
- <sup>74</sup> Anderson, L. 2004. Rasche Lösungen, magische Pillen. *Gen-Ethischer Informationsdienst* 165 (August/September): 38–40.
- <sup>75</sup> Rusinko, C. A. and Sesok-Pizzini, D. A. 2003. Using a technological community framework to manage new medical technologies: the case of umbilical cord blood (UCB) banking. *Journal of Health Organization and Management* 17 (96): 399–421.
- <sup>76</sup> Not only human bodies are meant here but also the entire genetic body of nature comprehensive of animals and plants.
- <sup>77</sup> Rusinko and Sesok-Pizzini, *ibid.*, 400.
- <sup>78</sup> The authors draw on the theoretical model of the technological community framework developed by Van de Ven, A. H. 1993. A community perspective on the emergence of innovations. *Journal of Engineering and Technology Management* 10: 23–51.
- <sup>79</sup> Yang, M., Kuo, T. R., and Murphy Jones, R. 2003. The marketing strategies analysis for the umbilical cord blood banking service. *International Journal of Health Care Quality Assurance* 16 (6): 293–299, 294.
- <sup>80</sup> *Ibid.*
- <sup>81</sup> Rusinko and Sesok-Pizzini, *ibid.*, 409.
- <sup>82</sup> Buchanan, A., Brock, D., Daniels, N., and Wikler, D. 2000. *From Chance to Choice: Genetics and Justice*. Cambridge: Cambridge University Press, 4.
- <sup>83</sup> *Ibid.*, 406.
- <sup>84</sup> Yang et al., *ibid.*, 294.
- <sup>85</sup> Rusinko and Sesok-Pizzino, *ibid.*, 406.
- <sup>86</sup> Otlowski, M. and Williamson, R. 2003. Ethical and legal issues and the “new genetics.” *Medical Journal of Australia* 178: 582–585.
- <sup>87</sup> Gottweis, H. 1998. Governing molecules. *The Discursive Politics of Genetic Engineering in Europe and the United States*. Cambridge, MA, and London: MIT Press, 9, 27, 336–338.
- <sup>88</sup> Fisher, F. 2003. *Reframing Public Policy: Discursive Politics and Deliberative Practices*. New York: Oxford University Press, 2–5, 12–13.