Chapter 7
Biotechnology, Ethics, and Society: The Case of Genetic Manipulation

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Biotechnologies are transforming human existence and their potential ever increasing. The discovery of the DNA double helix in 1953 paved the way for genetic medicine and even the possibility to alter the genetic makeup of human beings. Since then, the capacity of the human being to learn about and intervene in their own biological makeup has not ceased to grow: artificial reproduction techniques; cell culture and transplant that allow human tissue and organs to be repaired; developments in nanotechnology applied to healthcare for diagnosing, therapies or rehabilitation; and so on. This power raises both hopes and fears. It can undoubtedly contribute to the well-being of people and human progress, but it can also have undesirable outcomes in the form of known risks, or hidden transformations of human life which have not been decided by anyone.

This chapter attempts to offer an overview of biotechnologies applied to human life, tracing its development since the 1950s to the present day and its close link to society. Accordingly, it is divided into two parts. The first one is concerned with the way in which human biotechnology interacts with society, taking as a starting point some particularly significant events in biotechnology in 2010 and 2011. The second part analyses what could well be the most serious question that biotechnologies pose for human beings: the possibility to completely recreate oneself by these means. Is this the ultimate expression of human emancipation? An incredible dream that can never come true? A plausible option, albeit laden with risks? Or is this something which should not happen under any circumstances?

It is true that the possibility to modify the genetic makeup of a human being has been contemplated and debated since the discovery of DNA, and equally true that this technology is still not available today. But the issue of whether biotechnology

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should be sanctioned or not, has once again become the object of attention in recent years with the advent of posthumanist and transhumanist approaches[1] and new debates concerning "human enhancement."[2] However, my aim here is not to deal with all the ethical issues involved, but to simply express some doubts about the solidity of the arguments posed by those who favour the "enhancement" of human beings by means of germline intervention.

7.1 "Biotechnology 2.0"

During 2010 and 2011 there were four events regarding human biotechnology that epitomise some of the social changes that have taken place in this field in the last decade. This section first begins by explaining each in turn. After this I maintain that, in the light of these events, the links between human biotechnology and society break down, into two clearly defined periods to date: the first begins in the 1950s with the arrival of molecular biology[3] and continues until 2000 with the announcement of the decoding of the human genome; and the second, which I propose be called "Biotechnology 2.0," comprises the beginning of the twenty-first century until now.

7.1.1 Genes, "Test-Tube Babies," "Stem Cells," and Clones

The aforementioned four events in biotechnology I would like to address are as follows:

(a) *The tenth anniversary of human genome sequencing*. On June 26 2000, the President of the United States, Bill Clinton, made a White House announcement concerning the first survey of the human genome. He did so accompanied by Francis Collins, Director of the Human Genome Project, and Craig Venter, President of Celera Genomics. Collins led the international consortium of scientists financed with public money, which had been working on the human genome sequence since 1990. Venter, with private funding and using a different sequencing method, had joined the race to decode the human genome 8 years later. The British Prime Minister, Tony Blair, participated in this ceremonious event by satellite link.

Although that was the most talked about announcement, February 2001 saw the simultaneous publication of the human genome map in the two most important scientific journals in the world, *Nature* and *Science*. Hence, the tenth anniversary of this accomplishment was celebrated both in 2010 as well as 2011. It was also later

[1] For a review of the philosophical foundations and historical antecedents of post-humanism, see Ballesteros (2007), pp. 21–46.

[2] See Bostrom and Savulescu (2010).

[3] See Sánchez Ron (2000), pp. 253–299.

celebrated in 2013, since the complete map of the human genome was not presented until 2003. These anniversaries were the object of attention of both scientific journals,[4] yet they did not arouse any special interest in public opinion. In 2000 exaggerated and persuasive metaphors were resorted to, and had been used for some years, to underline the magnitude of what had been achieved,[5] pointing out the revolutionary nature of this achievement for medicine. Ten years later, genetics has still not revolutionised medicine and enthusiastic claims have been replaced by questions.

It is acknowledged that the vast amount of information available has proved difficult for hospitals to interpret and that, in short, "Still, genomics and related disciplines are more closely aligned with modern science than with modern medicine" (Harold Varmus 2010, p. 2028). It is also recognised that rather than giant strides to bring genomics to the field of medicine, one has to think in terms of a gradual assimilation of genetic information into clinical practice. What is unanimously accepted is that, as genomics is incorporated into medical practice it will become more personalised, since personal genetic markers–the small differences between the genomes of individuals–will be the decisive markers to fine-tune both diagnostics and treatment.

(b) *The "father" of the world's first "test-tube baby"–Nobel Prize for Medicine*. Another event in 2010 was the Nobel Prize of Medicine awarded to the English physiologist, Robert Edwards. According to the official press release by the Nobel Prize organisers he was awarded "for the development of human in vitro fertilization (IVF) therapy. His achievements have made it possible to treat infertility, a medical condition afflicting a large proportion of humanity including more than 10 % of all couples worldwide".[6]

As is well known, the world's first "test-tube baby," Louise Brown, was born in 1978 as the result of in vitro fertilisation techniques used by doctors Edwards and Steptoe. Since then, there have been around 4 million births across the world using this technique. Some of the techniques which have been developed for more effective, comfortable and safer procedures include: intracytoplasmic sperm injection

[4] Both *Nature* and *Science* published editorials and articles by leading scientists to celebrate the anniversary and assess achievements since those dates. The tone used was one of caution, and even reserve, in contrast to the euphoria that surrounded the presentation of the HGP in 2000. See Editorial 2010. This issue included articles by both Francis Collins as well as Craig Venter. In addition, *The New England Journal of Medicine*, the most important medical journal in the world, echoed the anniversary and pondered on the foreseeable development of genetic medicine; Varmus (2010).

[5] Some of a particularly hyperbolic nature, which are now in every-day use are: "the language of life," "the book of life," "the Holy Grail of life," "the language of God," etc. But if we leave aside the religious or theological metaphors, those which reign are of technocratic nature that speak of "programme," "control," "code," "map," etc. For further reading on different types of HGP metaphors and their impact on the citizen health culture, see Davo and Alvarez Dardet (2003).

[6] http://www.nobelprize.org/nobel_prizes/medicine/laureates/2010/press.html (accessed on March 25, 1013).

(ICSI), which replaces the spontaneous penetration of the egg by the sperm; obtaining eggs from the woman's ovary by puncture as opposed to laparoscopy; freezing eggs and ovarian tissue; and preimplantation genetic diagnosis. At present the success rate of these techniques (see de Mouzon et al. 2010) ranges between 20 and 30 %, which some regard as extremely inefficient while the organisers of the Nobel Prize themselves consider this to be a major therapeutic success.

The press release mentioned above highlights the contribution of in vitro fertilisation to solving the problems of so many infertile couples around the world. However, it does not point out the real revolution that followed in its wake: creating human life in the laboratory. Edwards and Steptoe will not go down in history for having put an end to the problem of infertile couples, but rather for having created an alternative reproduction method to that of sexual intercourse between women and men. Infertile couples who undergo assisted reproduction techniques can manage to have a baby, but they are still infertile, and in fact when this infertility is genetic in origin, it is usually passed on to their children. Since 1978, and even though assisted reproduction techniques have helped to bring millions of babies into the world, the problem of infertility has only worsened. Hence, what Edwards and Steptoe achieved was to render human fertility unnecessary in order to have children.

Clearly assisted reproductive technologies (ARTs) have helped circumvent the problem of infertile couples and managed to provide many of them with the child they wanted. But this outcome must be assessed in the general context of some practices that convert procreation into a process which is increasingly subject to human control, and in which many other agents, other than the couple, have become an essential part. Furthermore, this process, as stated earlier, can be used for many ends other than dealing with the problem of infertile couples. For all these reasons, reproduction tends to find itself within the domain of what has been called "wish-fulfilling medicine" (see Buyx 2008; González Quirós and Puerta 2009) and, as a result, a global business (see Spar 2006).

(c) *Geron abandons its clinical trial on, and line of research into, human embryonic stem cells*. In November 2011 the biopharmaceutical company Geron announced its decision to abandon its clinical trial on human embryonic stem cells to combat spinal cord injuries, along with their entire line of research in this field. This did not figure as a news item other than references in the financial sections of the press, however, it was highly symbolic. Geron was, along with Advanced Cell Technology, one of the pioneering companies in research into human embryonic stem cells. Since 1998 it had lobbied for a legal framework in the United States which was more favourable to this research, which had stirred so much debate on ethics there and around the world. Up until the moment Geron announced this decision it was considered to be a strong contender for achieving the first therapies by means of these controversial cells.

A few months after his election in March 2009, President Obama was quick to lift the restrictions governing financing research into human embryonic stem cells.[7] The President understood it was not appropriate to limit scientific research on ideological grounds,[8] and even less so when it concerned a field of knowledge which offered so much promise to put an end to serious illnesses such as Alzheimer's, Parkinson's or diabetes.[9] In the face of this this new scenario, the world pioneering company in embryonic stem cell research wasted no time in requesting authorisation from the Food and Drugs Administration (FDA) to carry out a Phase I clinical trial on people with bone marrow injuries. These experiments received a loan of 25 million dollars from the California Institute for Regenerative Medicine (CIRM), which is mainly sustained by funding from taxes paid by the citizens of California.[10] The trials began in summer 2011 but were abandoned in November of the same year. The reason given by Geron to justify abandoning their line of research into human embryonic stem cells, which had earned them world renown, was based on purely financial grounds. The trial was interrupted along with the entire line of research not because the cellular grafts were dangerous for the trial subjects, but simply because it proved more economically viable for the company to focus its efforts on other lines of research. After this announcement a CIRM press release stated its confidence in the potential of these trials and that perhaps some other company would carry out the project.[11]

(d) *The first triploid embryos are cloned*. In October 2011 the journal *Nature* (Noggle et al. 2011) announced the cloning of triploid human embryos. As opposed to conventional cloning, in which the egg nucleus is substituted for the

[7] The two Bush mandates had maintained the prohibition on public financing of research which used cells obtained from human embryos. The most influential scientific journals were highly critical of this measure, on the basis that science was being driven by ideology; see Nisbet, Brossard, and Kroepsch (2003).

[8] "Next, we are restoring science to its rightful place. On March 9th, I signed an executive memorandum with a clear message: under my administration, the days of science taking a back seat to ideology are over. Our progress as a nation – and our values as a nation – are rooted in free and open inquiry. To undermine scientific integrity is to undermine our democracy. It is contrary to our way of life"; http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-at-the-National-Academy-of-Sciences-Annual-Meeting/ (accessed on January 17 2012).

[9] The front cover of *Time* magazine, on February 8, 2009, was dedicated to stem cells with the following heading: "How the Coming Revolution in Stem Cells Could Save Your Life." In issue number 24, January 2009, *Time* echoed approval of the first clinical trial on human embryonic stem cells with the following heading: "Cautious Optimism for the First Stem-Cell Human Trial," http://www.time.com/time/health/article/0,8599,1873825,00.html (accessed on January 17, 2012).

[10] The California Institute for Regenerative Medicine was set up in 2005 to compensate for the lack of public funds set aside for research into human embryonic stem cells by the Bush administration. To date, the only clinical trial with these cells financed by the CIRM was begun and abandoned by Geron. An in-depth and critical monitoring of the work done at this centre since it was set up can be found at http://californiastemcellreport.blogspot.com/ (January 23, 2013).

[11] "Geron discontinues stem cell program, CIRM optimistic about future of stem cell therapies." CIRM, Press release, November 14 2011; http://www.cirm.ca.gov/PressRelease_2011-11-14 (accessed on January 17, 2012).

nucleus of a somatic cell, here the nucleus of the somatic cell was implanted without removing the egg nucleus. The resulting embryo was developed until the blastocyst phase, and the experiment was performed by a team from the New York Stem Cell Foundation Laboratory team, led by doctors Scott Noggle and Dieter Egli.

This event differs significantly from that which figured Woo Suk Hwang. He published two articles in the journal *Science* in 2004 and 2005 in which he stated he had managed to clone human embryos (see Hwang et al. 2004) and had derived specific stem cell lines for patients based on this technique (see Hwang et al. 2005). There are three main differences between these two experiments:

– The first and obviously fundamental difference is that Dr. Hwang's announcement was a fraud, while the results presented in 2011 by Noggle and Egli do not appear to be so.

– The second lies in the fact that, while Dr. Hwang said he had obtained human embryos by means of oocyte enucleation and subsequent transfer of the nucleus of the somatic cell to the oocyte, the new technique performs the transfer of the nucleus of the somatic cell without prior oocyte enucleation.

– The third, and by no means least important, is the contrast between the opaque information given by Dr. Hwang concerning the way the oocytes had been obtained and the total transparency on this point by the team led by Noggle and Egli. In their article they acknowledge that they used oocytes obtained from paid donors (cf. Bellver Capella 2012).

Once again we find ourselves before a situation, as in the previous cases, in which the money factor plays a decisive role in developing research. In order to obtain oocytes donors have to undergo painful treatment and surgery with possible side effects. Many donors are needed to obtain a sufficient number of oocytes to be able to research into nucleus transfer. The most effective incentive to procure donors is to offer a considerable payment by way of compensation for the entailing discomfort and costs for the donor. Whether this practice should be sanctioned or not has been the subject of lengthy debate. In effect, in October 2011 the Nuffield Council on Bioethics published a report on organ donors, which posed the question and argued in favour of compensation for egg donors for research. Along the lines proposed by the British committee on bioethics, the Human Fertility and Embryology Authority, approved a series of guidelines the same October, which established payment of 750 lb for eggs donated in one menstrual cycle.[12]

[12] See Human Fertility and Embryology Authority (press release), "HFEA Agrees New Policies to Improve Sperm and Egg Donation Services," http://www.hfea.gov.uk/6700.html (accessed on February 1, 2012).

7.1.2 New Relationships Between Biotechnology and Society

With regard to the relationship between human biotechnology and society, there are some general features can be identified in the light of these four events. Although to a certain degree all these features have been present from the beginnings of contemporary biotechnology, they have taken on specific profiles in the first decade of the twenty-first century.

(a) *The consolidation of the network made up of scientific-technological centres, private enterprise, public administration and public opinion*. Scientists, private companies, public administration and public opinion were ever present in the four events mentioned earlier, and so it is clear that science, and particularly biotechnology, is not a matter which concerns scientists alone. Their research projects and technological developments require increasingly heavier financial backing, and this funding either comes from governments and other non-profit making organisations, or from private companies which invest in these projects for profit. In order to attract financing, researchers have to demonstrate the social interest of their projects in the advancement of knowledge and human progress, or potential profitability for the companies which invest in them.

At least since the 1950s, science ceased to be a pursuit which could be carried out simply by guaranteeing scientists academic freedom in their research. All developments in biotechnology have been the result of a hybrid relationship between science, private enterprise, the State and society, which have been studied in depth by science philosophers and sociologists alike. But in recent decades the pressure to gain access to financing has grown exponentially. The financial resources set aside for R+D have multiplied, but even more so the need for financial backing for science and its technological developments. On the one hand, the infrastructures and human resources necessary to carry out increasingly more complex and ambitious projects generate costs which grow exponentially. On the other hand, the search for zero risk and total safety in these projects causes their costs rocket even more, to the degree that they are difficult to sustain. Research group leaders spend most of their energies raising funds, which the continuity and prestige of their groups depend on. The excellence of the research group is not measured by its scientific results alone, but also by its ability to obtain financial resources. As a result, research and technological development inevitably lean more toward obtaining financing than carrying out research projects based on their own merits. Financing a project can be seen as the best guarantee of its scientific interest. But this is not always the case, regardless of whether we are talking about public or private financing.

Public funding is usually assigned in accordance with a public announcement for proposals, which are decided in line with the evaluations obtained by the projects or research group applicants. However, the leaders of these research groups logically exert pressure so that the reviewers are those who they consider the best suited, so that the lines of research they lead are given a higher priority, and so that the

evaluation criteria are the best suited to the projects they present. In the sphere of private financing, including when this is offered through public calls, the main decision-making criteria is usually the short-term profitability of the results of the various research projects or technological developments.

As a result, scientific practice nowadays is determined by the power the leading scientists have over establishing the ground rules (above all when financed from public funds) and by the profitability of the results of the research or technological developments (above all when financed by private enterprise). Consequently the idea of scientific excellence ends up being inverted: it is not what is considered excellent which is financed but rather what receives finance is what is considered excellent.

In this competitive atmosphere to obtain financing one cannot overlook the decisive role played by the media. The media is the main source of information about science for the public and those best placed to guide public preferences when it comes to giving financial support to one or another area of research. The case of research into human embryonic stem cells proves paradigmatic. These cells have still not produced any therapeutic benefits, while adult stem cells have done so since the end of the twentieth century until now. Yet, public opinion is unchanged in that it is cells originating from embryos that are going to be able to regenerate all the damaged tissues in our body. Society's view concerning embryonic stem cells –equally encouraged by scientists, private enterprise and the media– has been decisive in tilting the ethical debate on research into these cells in its favour, passing laws which allow this and assigning huge amounts of money to carry them out (see Nielsen 2008).

(b) *Biotechnologies maximise their "sales" strategies*. I have just pointed out that the economic viability and public opinion backing have become decisive criteria for considering research projects as excellent and, as a result, eligible for financing. Faced with these ground rules biotechnology, like all the science-technology areas in general, has to use the right strategies. One of these, elementary but extremely effective, consists of generating major financial and social expectations. Along these lines, the possibilities of applying certain research results are stressed to the utmost. In contrast, the failure of research results are obscured or massaged, alternatives that could prove more effective are ignored, and the risks and adverse effects are minimised. The research group thus struggles between two forces that are difficult to reconcile: the essential capacity for self-criticism in the advancement of knowledge; and the pressing need to "sell" what you are working on to ensure financing.

This is the case in the four instances mentioned earlier. The Human Genome Project was presented as the definitive step forward towards predictive and personalised medicine. In vitro fertilisation opened the way because it was a solution to a health problem that had become more widespread in recent years and allowed millions of infertile couples to have children. Human embryonic stem cells were presented as the great promise for regenerative medicine and cloning embryos as the ideal technique to deal with the problem of rejection.

However, in the first decade of the twenty-first century it has been proved that these expectations were very often overstated and in some cases fraudulent. When the first draft of the human genome was announced in 2000, Bill Clinton spoke of the beginning of a new era in genetic medicine. Knowledge about the human genome has certainly provided valuable information, but 10 years later it has been acknowledged that genetic medicine is far from being a reality (see Marshall 2011). How many years will be needed to transfer genetic knowledge from the laboratory to the clinic?

There have been noteworthy successes in the case of in vitro fertilisation and, in general, assisted reproduction techniques. However, the impact of these techniques on health and for society has not always been given due attention. There has not been sufficient assessment concerning the degree to which developing these techniques has slowed down research into both preventing and combatting infertility. Neither do we know with any degree of certainty the extent of health problems suffered by children born using ARTs that are associated with these techniques. Lastly, and perhaps most important of all, ART official authorities (specialist journals, scientific bodies, etc.) have lobbied for more flexible regulations, yet in contrast there has been no assessment of the harm done to both women and children (see Annas 2011).

The case of human embryonic stem cells is the quintessential paradigm of misleading expectations.[13] Almost 15 years after they were isolated in the laboratory, and the leading scientific journals in the world baptised this as a scientific landmark opening doors to regenerative medicine,[14] it has not led to a single therapeutic result. There are hardly any clinical trials on this type of cells.[15] The announcement by Geron in 2010, which appeared on the front cover of *Time*, no less, was abandoned a few months after it began. This case highlights an important difference with regard

[13] In November 2007 the Shinya Yamanaka team announced they had obtained human induced pluripotent cells (iPS), cells which have the same potential as embryonic stem cells but which were obtained without having to destroy embryos. It is worth noting that the editorial in the *The New York Times* basically consisted of claiming that embryonic stem cells, were like "the gold standard for measuring how valuable the new cells will be." Editorial, "Behind the Stem Cell Breakthrough," *The New York Times*, December 1 2007; http://www.nytimes.com/2007/12/01/opinion/01sat1.html (accessed on January 23, 2012).

[14] See Vogel (1999). In the article he says: "We salute this work, which raises hopes of dazzling medical applications and also forces scientists to reconsider fundamental ideas about how cells grow up, as 1999s Breakthrough of the Year," p. 2238.

[15] Advanced Cell Technology (ACT) was, along with Geron, one of the pioneering companies in working on embryonic stem cells. In January 2012, 2 months after Geron announced it was abandoning clinical trials using these cells, *The Lancet* published a study on the first positive results of a clinical trial with human embryonic stem cells financed by ACT to treat certain eye injuries. The experiment was carried out by two people. There is a certain degree of doubt surrounding the trial since the sponsor, "has been criticized in the past for overstating results, in part because it has been desperate to raise money to stay in business"; Andrew Pollack (2012) http://mobile.nytimes.com/2012/01/24/business/stem-cell-study-may-show-advance.html (accessed on January 23, 2013).

The clinical trial is presented as "the first description of hESC-derived cells transplanted into human patients"; Schwartz et al. (2012), In: http://download.thelancet.com/flatcontentassets/pdfs/S0140673612600282.pdf (accessed on January 28 2012).

to the Human Genome Project. Although the HGP was presented as road to a new way of practising medicine, it never promised short term cures. In contrast, the proponents of embryonic stem cells were quick to offer a convincing discourse laden with therapeutic promises, which allowed them to gain wide support from public opinion and in particular from associations for serious pathologies such as diabetes, Alzheimer's or Parkinson's, in the face of the ethical objections posed by the use of human embryos.[16]

Finally, there has also been a profound disappointment as regards cloning embryos. After the announcement in 1997 that the sheep Dolly had been cloned it seemed that cloning human embryos was just a matter of time. While efforts focused on the birth of a cloned human generated almost universal apprehension, cloning to provide human embryos to use in research into stem cells received wide support throughout the science community,[17] while public opinion in general was more divided.

At present we find that there are three types of deceptions in the field of cloning. The first is the case of the sadly famous doctors Antinori and Zavos, or the Raelian sect.[18] They announced that they had managed to clone embryos and the first human clone was about to be born. Although they generated certain notoriety at that time around the world, their deception is no more than a naïve attempt since they were never able to prove anything scientifically. The second and certainly the most serious, was the case of Dr. Hwang mentioned earlier, who was able to pull the wool over eyes of the journal *Science* and, with this, the scientific community and world public opinion. The third consisted of presenting human embryonic cloning for scientific ends as something that was ethically innocuous, and radically different from cloning for producing humans.[19]

The only significant progress made in this field until now is that mentioned earlier in 2011. As opposed to the earlier research teams, the authors of this experiment went to great lengths to avoid false expectations and were quick to state that the end purpose behind creating triploid embryos was exclusively for research purposes, not therapeutic. Additionally, they openly acknowledged that the eggs used to clone

[16] For an interesting review of the background and main arguments that have dominated debate on human embryonic stem cells since 1998, see Nielsen (2008).

[17] The editor of *Science* published a passionate report urging the House of Congress not to legislate against cloning humans as, "it would interdict a wide range of experimental procedures that might, in the near future, become both medically useful and morally acceptable"; Kennedy (2001), p. 745.

[18] Although almost forgotten now, when they are remembered, they seem more like vendors at a trade fair than premier league scientists. We must not forget that these people were called by the National Academy of Science in the US to speak at a symposium and their statements were given prime space major newspapers around the world such as the *New York Times*; see Stolberg (2001), http://www.nytimes.com/learning/teachers/featured_articles/20010809thursday.html (accessed on January 18, 2012).

[19] From the pages of *Science* came the call to avoid the term cloning when referring to the nuclear transfer aimed at obtaining embryos for research into stem cells, and only use this term to refer to cloning embryos to be used for giving birth to human clones; see Vogelstein et al. (2002).

embryos came from women donors who were paid.[20] Here we have a style of scientific statement which is radically different from that followed until then in this field, and, in general, in biotechnologies: less pretentious and more transparent.

(c) *Globalisation minimises the role of Law concerning biotechnologies*. One of the social changes in the last 15 years which is having the most impact on biotechnologies concerns the role played by Law in this field. Up until the 1990s Law exercised regulatory control over biotechnologies at two levels. At a national level, each State fixed the limits within which biotechnology could be developed. Hence, between the end of the 1980s and the beginning of the 1990s, many States promoted citizen debates and parliamentary enquiries which later led to passing laws regulating ARTs. This generated a wide range of positions, from the most restrictive to the most permissive, while some countries were either unable or unwilling to pass any laws on this matter. A similar situation came about in the field of genomic research, with the difference that the very same Human Genome Project (HGP), led by the United States, sat up a permanent working group on the ethical, legal and social implications of this research (Ethical, Legal and Social Implications, ELSI working group).

At an international level, it was understood that States could agree on legal regulations that compiled the fundamental principles that should regulate biotechnologies applied to human life and that, in any event, would safeguard the rights of those people affected: human dignity, right to life, right to privacy, right to informed consent, freedom of research, right to the environment, etc. At a world level UNESCO took the initiative in the field of genetics and in 1997 passed the Universal Declaration on the Human Genome and Human Rights. At a regional level, the role played by the Council of Europe is particularly noteworthy via its Steering Committee of Bioethics. The main outcome was sanctioning the European Convention on Human Rights and Biomedicine in 1997 and, to date, four additional protocols: on the Prohibition of Cloning Human Beings (1998), on Transplantation of Organs and Tissues of Human Origin (2002), on Biomedical Research (2005), and on Genetic Testing for Health Purposes (2008).[21] This is the most comprehensive body of international regulations in the area of biotechnology and the most binding for those States which ratify them.[22]

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[20] It should be remembered that in the false cloning announced by Dr. Hwang the information about the way in which the eggs used in his experiments had been obtained was at first conspicuous by its absence, and was only obtained after the investigation undertaken by the Seoul National University, where he worked.

[21] This last one has not yet entered into force.

[22] Regulations with effect at a supranational level to guarantee human dignity and human rights with regard to biomedicine, which is the purpose of the Convention and its additional protocols, have not been generally approved. Many sectors have criticised its efforts: those which put State sovereignty before international regulations; those who consider that in the area of science and technology the legal systems should give primacy to scientific self-regulation; those who consider that the term human dignity is of no use and it makes no sense to set up international regulations to protect it; etc. See Mori and Neri (2001).

But this scenario of relative stability in developing national and international regulations on biotechnology applied to human beings, went up in smoke after the end of the 1990s. Since then on the situation has remained as follows:

– As regards laws at the state level, we are witnessing an accelerated loss of effectiveness to regulate practices in biotechnology influenced by two factors: first, the free movement of people means that scientists can work wherever there are laws and financing suited to their research, and, second, individuals can go to wherever certain services are offered which are prohibited in their own country. One such example in the former case is the United Kingdom, which attracted financing and researchers from other European countries where laws governing research into human embryonic stem cells were more restrictive. An example of the latter case is Spain, which has extremely permissive laws regarding ARTs, and has become a reproduction tourist resort for couples or single women wanting to have children from countries where there are legal restrictions (cf. Pennings 2004, p. 2690; Inhorn and Patrizio 2009).

– International Law is equally weakened. There are two alternatives for States to reach agreement on biotechnology. The first consists of passing a body of principles general enough so that any State could feel comfortable with them. In these cases the countries with the most permissive laws manage to obtain a legal framework at an international level which they have already sanctioned for themselves. The second aspires more in the direction of regulating matters and in such a way as to effectively guarantee human rights and dignity. In this case we find ourselves before wide range of State averse to following this regulation. Somewhere between these two options, both the Council of Europe and UNESCO are trying to walk a third path, which is not limited to ratifying that which is prohibited by the most permissive of the States as a minimum universal ethical threshold, but that neither establishes thresholds that are only going to be backed by a few States. The most recent result of such attempts was the Universal Declaration on Bioethics and Human Rights, which has been criticised from those who consider it to be completely inadequate as well and also from those who consider it to be excessively restrictive or lacking in legal basis (see Levitt and Zwart 2009; Schuklenk 2010).

7.2 A "Brave New World," Enhanced Individuals and a Posthuman Future

Although the organisers of the Nobel Prizes insisted that the Nobel Prize for Medicine was awarded to Dr. Robert Edwards because of his contribution to the problems of millions of infertile couples (patent function), one cannot overlook the far-reaching effects that ARTs applied to human life have had on the power of humans over the future of the human race.

ARTs have made a decisive contribution to considering human embryos as an object of experimentation, and furthermore put thousands of frozen embryos in the hands of researchers that were never going to be implanted in a woman. The concurrence of these two factors facilitated the development of research into isolating human embryonic stem cells in the laboratory.

But ARTs were not only responsible for generating innumerable "spare" embryos and helping to sanction the idea that human embryos could be used for research under certain conditions. They made it equally clear that human reproduction was something which could take place outside intercourse. It could be a process that was subject to quality control in a laboratory. And, in this case, the characteristics of future children no longer needed to be left to random genetics and instead could be chosen by the progenitors. The way this choice is made nowadays consists of discarding those not considered ideal and implanting those which are, by the means mentioned earlier. But it is foreseeable that the time will come when one can not only choose from the embryos available but also that embryos can be created with those genetic characteristics which we consider desirable.

Leon Kass (see Kass 1985, 2002, p. 81) shrewdly points out that the laboratory is the door to Huxley's "brave New World" in which new human lives are manufactured. It is unanimously acknowledged that Huxley's world is a dystopia: the way society is represented is a counter-example of what human society should be. In this world the State takes exclusive charge of reproduction and does so by creating five classes of people with specific abilities to perform different tasks in society. It is a perfected form of the totalitarian eugenics that some wanted to impose in many advanced societies in the first third of the twentieth century. Nowadays there is still interest in eugenics but, according to its proponents, without the nuances which made it abhorrent in the past. It is no longer the State which controls the production of human beings, determines the most desirable genetic characteristics, or sterilises those considered unsuitable for reproduction. The aim of eugenics now is to enhance the reproductive freedom of individuals, which includes being able to choose the genetic characteristics of their progeny. If parents are looking for the best for their children throughout their life, then why not begin by choosing the best genetic characteristics? The question is whether Huxley's "brave new world" is a dystopia only because of its totalitarian context or also because of its eugenic nature. If the latter is the case, the fact that present day eugenics may be liberal and not totalitarian would not prevent the advent of a "brave new world" equally as undesirable as Huxley's, even if not totalitarian (see Agar 2004).

Since the early stages of research into DNA, the scientists most committed to the social dimension of their work discerned a hitherto unheard-of horizon in the history of humankind: for the first time human beings would be able to be the master not only the natural setting in which they live, but also their own biological makeup: "We were at an epochal moment, not only for our society or for *Homo sapiens* but for all of life on earth. For the first time in the long course of evolution, for the first time in all time, a species was coming to understand its origins and its inheritance, and with that knowledge would come the ability to alter its inheritance, to determine its own genetic destiny, as well as that of other living species. Through DNA, biology was moving beyond analysis to synthesis" (Sinsheimer 1994a, p. 135).

But many of them, including Robert L. Sinsheimer–one of the "founding fathers" of recombinant DNA and synthetic biology–,did not limit themselves to stating a new challenge for human kind. In 1966, on the occasion of the 75th anniversary of the California Institute of Technology (CalTech), Sinsheimer stated: "Ours is an age of transition. Alter two billion years, this is the end of the beginning. It would seem clear, to some achingly clear, that the world, the society, and the man of the future will be far different from that we know. Man is becoming free, not only from the external tyrannies and the caprice of toil and famine and disease, but from the very internal constraints of our animal inheritance, our physical frailties, our emotional anachronisms, our intellectual limits. We must hope for the responsibility and the wisdom and the nobility of spirit to match this ultimate freedom".[23] At this conference he mentioned some of the more attractive possibilities for human beings offered by science in general and genetics in particular: choosing sex, prolonging life, enhancing intelligence, controlling emotions, altering genetic makeup and, in short, applying intelligence to evolution.[24] But Sinsheimer does not suffice himself with simply stating these possibilities and also adopts a position. In doing so he makes clear his support for three postulates, shared by scientists and philosophers alike, from which they conceive what a human being is and should do. First, science shows that all in human beings is ultimately caused by matter.[25] Second, biotechnologies can help us to achieve the objective of our freedom more efficiently than through education.[26] Third, the State will have to extend its control over new and more intimate spheres of human life.[27]

[23] Sinsheimer (1966). Years later, at the time when the Asilomar moratorium was adopted in 1975, he expressed himself in the same terms: "As individuals men will have always accept their genetic constraints, but as a species we can transcend our inheritance and mould it to our purpose –if we can trust ourselves with such power. As geneticists we can continue to evolve possibilities and take the long view"; Sinsheimer (1975), p. 151. Although Jeremy Rifkin holds that Sinsheimer evolved towards more critical postures regarding the power of biotechnology, in my understanding he still retained his unfailing faith in the capacity of human beings to guide their own evolution through biotechnology; see Sinsheimer (1994b), pp. 145–146.

[24] See Sinsheimer (1966), p. 10. Although he does not cite this in his book, John Harris follows in the footsteps of Sinsheimer when giving the title to his book on human enhancement *Enhancing Evolution. The Ethical Case for Making Better People*, Princeton University Press, Princeton, 2010.

[25] "Indeed, it may be supposed that even the deepest mystery, the nature of mind and sensation and consciousness, will be understood in the end as a natural consequence of matter in a certain state of organization." Sinsheimer (1966), p. 9.

[26] "Perhaps we would like to alter the uneasy balance of our emotions. Could we be less warlike, more self-confident, more serene? Perhaps. Perhaps we shall finally achieve these long-sought goals with techniques far superior to those with which we have had to make do for many centuries;" Sinsheimer (1966), p. 10. Although not stated explicitly, he allows for thinking that education and social control might be methods that can be replaced by the superiority of biotechnology. This proposal has been taken up again recently with renewed vigour: see Douglas (2008). Opposed to the possibility of improving the moral behaviour of people through biotechnology, but from a more libertarian view in favour of any kind of enhancement of the human race, see Harris (2011).

[27] On the topic of increasing control over choosing the sex of children, Sinsheimer says: "When this prospect is combined with the already pressing problem of the expanding world population, it

Almost half a century later, all of the possibilities discerned by Sinsheimer are now the object of debate and many are interpreted as opportunities to achieve the complete liberation and enhancement of human beings. In the first decade of the twenty-first century, there have been major developments in neurosciences which have revived the conviction that we can radically enhance our intelligence, our emotions and even our moral behaviour through brain interventions. In the same way that in the 1960s, recombinant DNA was seen as the key to the coming of a new era in the evolution of humans, now it is the neurosciences that appear to have usurped this power. And today, as then, there are two opposing paradigms to interpret this new knowledge and resulting power. On the one hand, the messianic-materialist paradigm, for which the beginning and end of all human beings is material and so through manipulating matter human beings can reach their complete liberation. On the other hand, there is the pluralist paradigm, which acknowledges the material bases on which human existence is sustained –whether genetic or neurological– but rejects the postulate that a human being can be reduced to matter alone and, as a result, that the liberation of humankind lies in biotechnological manipulation of whatever kind: genetic, neurological, etc.[28]

But let us return to the possibility of altering the genetic characteristics of human beings. I shall not dwell on all the ethical reasons that have been summoned up in order to oppose them,[29] and that have been unanimously rejected almost unanimously by legal systems all over the world (see Bellver Capella 2004). I shall begin by surmising that there is a perfectly safe technology to configure the genetic makeup of each new human being, and most citizens have expressed their wish to have access to them. Two questions need to be addressed here: why is it licit to resort to this technology?; and, under what conditions should it be performed?

Without attempting to analyse all the answers that have been provided to these questions, I shall focus on the proposals of two of the leading figures who believe that germline interventions are licit (or even our duty to use), namely, the noted bioethicists John Harris and Julian Savulescu. The following analysis which focuses on their proposals attempts to illustrate that, behind apparently plausible and consistent arguments, lie hidden unresolved deficiencies and problems.

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seems ever more clear that in the future world the right to give birth, as is today the right to take life, will have to be controlled to preserve some semblance of balance;" Sinsheimer (1966), p. 10.

[28] Adela Cortina has pointed out the radical difference between recognising the brain science bases of moral conduct, for which the neurosciences are offering priceless information, and claiming that these provide a basis to extract moral obligations, yet another attempt to reduce human beings to their material condition; see Cortina (2011).

[29] Hans Jonas and Leon Kass were the first to raise the alert concerning the risks of this possibility; see Jonas (1974). Kass (1985), pp. 43–80.

7.2.1 Why Germline Intervention Should Not Pose Moral Problems? John Harris's Answer

One of the leading present-day proponents of the right and obligation to use germline intervention to produce children with enhanced genetic qualities is John Harris.[30] His position is based on what was already defended by techno-enthusiasts in the 1970s: from the moment science offers human beings the chance to guide their own biological evolution it is their obligation to do so. Leaving aside the problems of safety and abuses, John Harris holds that germline intervention does not pose any special ethical problems because, like education, it is nothing more than an instrument to enhance our children:

"Now suppose, as is much more likely, we could use genetic engineering, regenerative medicine or drugs, or reproductive technology or nanotechnology to produce healthier, fitter and more intelligent individuals. What should reaction be? Would it be unethical to do so? Would it be ethical not to do so?

Our question is this: if the goal of enhanced intelligence, increased powers and capacities, and better health is something that we may strive to produce through education, including of course the more general health education of the community, why should we not produce these goals, if we can do so safely, through enhancement technologies or procedures?" (Harris 2010, p. 2).

The rhetorical questions posed by Harris prove extremely persuasive. But closer analysis of the reasoning behind these proposals reveals inconsistencies. The answer to Harris's question is: enhancement procedures, and in particular germline intervention, cannot be used to achieve enhanced intelligence, health or one or other capacity for the simple reason that they cannot be achieved by these means.

If they were safe, these techniques would make it possible to either combat certain exclusively genetic defects or make humans people who are different from what they have been until now. In case of the former, germline intervention does not bring happiness, guarantee health nor endow us with enhanced capacities; it simply fulfils a medical end. In the latter case, germline intervention does not bring about happiness, health and enhanced capacities either, and simply creates a human being who is different from those that have existed until now. Who can know what happiness or health is for a human who is different from us? But even if we maintain that this difference is in reality of little consequence, who can guarantee happiness, health or enhanced intelligence or other capabilities by means of manipulating genes?

When germline intervention is taken beyond a strictly therapeutic function, it engenders people who are the product of a designer. In this case human beings neither procreate nor reproduce; they are developing a product. Even if done with the best of intentions, they inevitably break with the essential symmetry between the generations as regards how everyone has been conceived until now (see Habermas 2003). The progenitor's role is replaced by the genetic "designer," who must assume responsibility for the designed product. The characteristics of the product will be

[30] Harris has written two books on these issues. See Harris (1992), and (2010).

unalterable. In the event that the end subject is not satisfied with the design imposed on them, can they take legal action? Under what circumstances? And who can they claim against? The designer, the person carried out the work or the person who took on the responsibility for raising him?

The aim of education is to make people better, in other words, free and happy. This aim can only be pursued by involving the freedom of the person from the very same moment it appears in his development. Without the collaboration of the liberty of the subject there can be no education. There can be training or enhancing, but not education. Therefore, it is a fallacy to invoke education to justify human enhancement.

When germline intervention is used to correct serious genetic defects we are talking about genetic medicine. When germline intervention is used to "enhance" the intelligence, health or aptitudes of future individuals, we are not doing the same we claim with education, but through other means. We are probably doing the opposite of what we do through education. This attempts to put the individual in the best of conditions to exercise her/his freedom. Germline intervention, in turn, consists of imposing on another person those characteristics the designer deems would enhance him/her, over which the subject has had no input nor can ever change. What, if anything, does this have to do with education?

It is true that education includes the development of instrumental capacities (memory, calculation, logical reasoning, etc.), some of which perhaps could end up being enhanced more effectively by germline intervention. But the aim of education is not to develop superlative instrumental capabilities in the individual for their own sake. Quite the contrary, it is only concerned with these to the extent that they are necessary for a flourishing life. While germline intervention imposes enhancements that the subject has not decided for her/himself and cannot be modified, education provides these enhancements as and when the individual wants them. And what is most important, the individual is continually redefining these enhancements.

7.2.2 How Should Germline Intervention Be Regulated. Peter Singer's Answer

The fear of Nazism is a continual reminder of attempts by the State to employ the practice of eugenics, not only in Germany during the time of the nazi movement but also in some other developed countries around the world during the first half of the twentieth century, such as the United States, Canada, Norway and Finland. In all these countries forced sterilisation programmes were approved for those people deemed unsuitable to have children (see Ridley 2006, pp. 286–300). But DNA recombinant techniques opened up an attractive eugenic panorama: select the characteristics we wanted for our children and ruled out forced sterilisations, gave us greater freedom to reproduce and ruled out State intervention, looked for ways to enhance performance of new humans and rather than sanctioning one particular race or nation (see Rifkin 1998, pp. 116 and ff). This new eugenics, labelled liberal

eugenics or laissez fair eugenics (see Fitzpatrick 2001), has been defended by many scientists and philosophers, among them, Peter Singer, who backs his defence with a specific proposal to ensure that it is not counterproductive.

Singer is convinced that "citizens should choose the constitution of their government; government should not choose the constitutions of their citizens" (Singer and Wells 1984, p. 186). Consequently, he flatly rejects the idea that the State should determine the best genetic characteristics and impose germline intervention on its citizens to endow their progeny accordingly. Neither does he consider it correct to simply leave the genetic selection of future generations in the hands of the market because, "it puts too much power in the hands of individuals who might use it irresponsible or even pathologically" (Singer and Wells 1984, p. 186). Singer holds that "the genetic endowment of children should be in the same hands it always have been – the hands of parents." But if the parents wished to, for the first time, to incorporate a genetic characteristic in their children by means of germline interventions, they should require the pertinent authorisation from a public body created for this purpose. "A broadly based government body could be set up to approve or reject particular parents' proposals for genetic engineering. It would consider whether the proposed piece of engineering would, if its practice became widespread, have harmful effects on individuals or society. If no harmful effects could be foreseen, the committee would license the procedure. This would mean that parents who wish to use it were free to do so" (Singer and Wells 1984, p. 188).

Singer's proposal has many valuable points in its favour. For extremely complex and constantly changing areas such as biotechnology, it is much more operative to entrust a professional multidisciplinary and plural body with the power to propose regulations or authorise, or not, certain practices after having studied each case. This has been adopted in certain areas of bioethics; countries such as the United Kingdom or Spain have State bodies authorised to govern practices or experiments in certain areas of biomedicine. The best known example is the Human Fertilization and Embryo Authority (HFEA).

However, if there were a body responsible for authorising germline intervention for future parents, which according to their criteria would not represent a danger either for individuals or society, then would it work? To my way of thinking such a proposal is unviable for several reasons:

– It is impossible for a commission of this nature to come to a broad agreement if it attempts to reflect the various postures adopted on germline intervention in society. To be truly operative its members must share the idea that germline intervention is positive providing it does not lead to abuse. Then it would be able to discuss whether a certain genetic "enhancement" involves a risk or not for the individual or society. But then these commissions would no longer reflect the plurality of views in society: one group would be imposing its particular view of what is good over the others.

– In a globalised world it is impossible for a commission with these characteristics to be effective in real terms if the area in which it operates is not universal. It would be able to prevent the practice of certain types of germline intervention, but it could not prevent the citizens from going to another country where they are autho-

rised, should they so wish. Reproduction tourism, which at present is limited to the search for certain assisted reproduction services when they are prohibited in their own country or prohibitively costly, will extend to germline intervention by necessity.

When the market is global, national rulings on what should be the subject of strict regulation are not enough to protect against the law of supply and demand. Any restriction on access to germline intervention established by a leading country in biotechnology will be taken advantage of by others to attract investments, researchers, and customers eager to gain access to what is banned in their own countries.

7.3 Conclusions

Three main conclusions can be drawn in the light of what has been discussed in this chapter:

– Biotechnologies are developing at present in a scenario characterised by three profoundly new elements with respect to what has been scientific and technological development until the present day. Firstly, biotechnologies form part of a conglomerate of relations made up of public powers, private enterprise and citizens, which determine their development entirely. Secondly, biotechnologies depend on increasingly greater financial resources, and obtaining these determines and orients them. Thirdly, alongside increasing financial dependence, biotechnologies are also experiencing decreasing dependence on laws and regulations bringing undesired effects in its wake.

– Biotechnologies are moving towards total intervention in human biology, as has already happened in non-human biology. This route began with the use of assisted reproduction techniques on humans and is frequently legitimised arguing that these uses of biotechnology can lead to creating better humans (human enhancement).

– Those authors who defend the right, or even the obligation of human enhancement by means of biotechnology use arguments they themselves would not accept if they were to subject them to rigorous analysis with which they judge opposing arguments to human enhancement, which they often qualify contemptuously as intuitive.

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