

Some Problems of Legal Regulation on Human Reproduction: The Case of Human Cloning

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INTRODUCTION AND TERMINOLOGY

“Cloning” can be defined as the procedure – natural or artificial- to produce “clones”. “Clones” are genetically identical organisms which come from a single individual through asexual reproduction and which are genetically identical to it (Romeo, 1997: 22). “Asexual” means that there is no intervention of masculine and feminine gametes in reproduction, that is, the birth of the clone do not come from a union of reproductive cells. Asexual reproduction exists in nature: bacteria, plants (cuttings), and even identical twins.

The word “cloning” is ambiguous, because it can be used to mean very different phenomena and procedures, even though they all have in common the fact of creating a biological “copy”. It can be set a classification of different kinds of “cloning” according to two criteria: the cloning technique and the cloning aim.

ACCORDING TO THE CLONING TECHNIQUE

- a) Reproduction of cells or DNA chains. Technically speaking these techniques are “cloning”, because they fit in our previous definition. Anyway, they have certain tradition in biology. However, we shall not discuss here on this kind of cloning, because it does not cause any ethical or legal issues similar to those caused by human (or even animal) cloning.
- b) Embryo division. It is routinely used in stockbreeding and it is starting to be used in human *in vitro* fertilisation in order to have a larger number of embryos to transfer. Basically, the technique consists in the division of 4 to 16 cells ovule fertilised *in vitro*, to create separated embryos. This system creates identical twins (artificially causing a phenomenon that sometimes occur in nature): they are identical between themselves, but different from their parents.
- c) Cloning by cell nuclear replacement. This kind of cloning has caused major controversy since the birth of “Dolly” the sheep, which demon-

strated that cloning mammals (the genetic replication of an adult individual) was possible. In this technique the nucleus (or its DNA) is removed from a donor cell and inserted in the cell of an ovule which has its own nucleus also removed. The resulting cell, developed *in vitro*, starts to divide and forms an embryo genetically identical to the donor cell. Then, it can be transferred to a surrogate mother.

Cell nuclear replacement had been used in mammals during the 80s, but only with embryo cells (embryo cloning by cell nuclear replacement). The innovation with Dolly the sheep is the use of adult cells to clone: the cloning of an adult individual (or at least a born one) instead of the cloning of an embryo. This technique produces offsprings genetically identical among themselves (perfect twins) as well as identical to their parent (with Dolly the sheep three adult female sheep were used: the cell donor, the ovule donor and the surrogate mother to bear the clone).

Therefore, there are two different cases in cloning by cell nuclear replacement: (a) using the nucleus of an embryo or foetal cell; and (b) using the nucleus of a somatic adult cell. This case produces something like perfect twins with different ages, an phenomenon unknown in nature.

ACCORDING TO THE AIM

- a) Reproductive cloning: the aim is to create complete and identical human beings. The concrete aim could be, for instance, to have offspring genetically identical to oneself. Used in animals, several possibilities have been proposed for it: to select the best specimens in stockbreeding, organ banks for xenotransplantation, cloning of transgenic animals to use them as bioreactors to produce drugs, pets for multimillionaires, etc.
- b) Non reproductive cloning. The first case could be the division (twinning) of *in vitro* embryos to have more embryos in artificial reproduction, in order to have spare ones or to use them in prenatal diagnostic (a genetic diagnosis in one embryo is valid for its twin). Twinning could also

be used with more aberrant purposes: to store some spare “embryo copies” of a son or daughter, in case of death. Despite the fact that all these cases are carried out through assisted reproduction, they are classified as “non reproductive” cloning because twinning produces perfect twins, but it does not produce “clones” from a “parent”.

The most important case of non reproductive cloning, anyway, is the embryo cloning to create tissues or organs. These tissues could be very useful because being genetically identical to the donor-recipient’s tissues, rejection could be avoided. Sometimes, the possibility of the killing (or mutilation) of a clone to save the donor, has been discussed. But the real case seems to be the “culture” of human embryos to use their cells (this involves the death of the embryo). In this case there are two different possibilities depending on the use of the two different techniques we already know: “embryo division” and “nuclear cell replacement” (or cloning in the strict sense of the word). In the first case, spare “copies” of an embryo would be stored after an *in vitro* fertilisation (which limits the beneficiaries to those born by artificial reproduction). In the second case, a clone embryo would be created from an adult individual cell, using an ovule which has its nucleus removed.

Reproductive cloning is generally (but not unanimously) rejected. But this rejection is moderated in non reproductive cloning if no adult clones are created. Non reproductive cloning is beginning to be accepted because it opens new fields of innovation on disease treatments: tissue and organs transplantation, degenerative diseases, etc. The main objection to non reproductive cloning has now been risen because of its consequences for human embryos: it is not objected as cloning, but because of its harm to human embryos. The real issue is the death of human embryos. For that reason, the debate has been linked in great measure with the status of the human embryo debate: whether the use and destruction of human embryos to obtain useful cells for treatments and whether embryo investigation on these uses are justified.

These new possibilities and this change of perspective in non reproductive cloning debate began in November 1998, when a research team of Wisconsin University directed by James Thompson, was able to derive “stem cells” from early human embryos (Thompson et al., 1998). Stem cells are unspecialised cells of the body in early stage of development. They have the ability to divide and differentiate into a large

number of different cell types that make up the tissues and organs of the body. This ability could be used to produce different human tissues to transplant and to develop new therapies. Since then, these new possibilities have focused the cloning debate on human embryos. In September 2000, a group of scientists of London University College opened an alternative source of stem cells: they derived stem cells –in laboratory rats- from neural cells (Kondo, Raff, 2000). Nevertheless, even though this new innovation is promising and raises less ethical objections, the debate is not over. On the contrary, embryonic stem cells seem to have the greatest potential to differentiate and seem to promise a quicker research development. Some recent political decisions targeted to allow the use of human embryos to develop this field of research have intensified the debate. Anyway, some economic and business interests are pressing to continue this path of research.

With all this collection of different techniques and troubles linked to them, perhaps we should have a suitable terminology to discuss these matters: to determine which is ethically and legally acceptable. The use of the word “cloning” to mean very different things could lead to confusion and could make a rigorous debate difficult. Obviously, in ethical discussion, the “cloning” of DNA chains has nothing to do with human reproduction by nuclear replacement “cloning”. Even the main disagreement in human reproductive and human non reproductive “cloning” lay on different levels: in the first case, on matters of principle linked with the inherent justifiability or non justifiability of human cloning; in the second case, on the justifiability or nonjustifiability of the use of human embryos for research or therapeutic purposes.

Terminological confusion could lead to a confusion in the judgement of different situations. I believe that, no matter what are our personal positions, we can agree that confusion is not a good start. To mix everything could cause a deep rejection of cloning, as a way of human reproduction, to stop the development of new therapies that require “non reproductive cloning”. On the contrary, an irresponsible acceptance of “cloning” caused by its possible medical developments could lead to an unjustifiable (from this point of view) acceptance of reproductive cloning.

I am not pretending to offer a new terminological proposition. It would be senseless. But it can be mentioned that there are some propositions in this way. For instance, a Spanish report on cloning has distinguished among: a) artificial twinning; b)

paracloning (using embryo or foetal cells); and c) true cloning (using cells from a born donor) (AAVV, 1999: 57).

EUROPEAN REGULATIONS

When achievement in mammal cloning was published, a debate began on the convenience of introducing legal regulations to limit or ban human cloning. The need for international homogeneous rules, at least at European level, is a common belief. The justification for this is, on the one hand, the fear of a possible ineffectiveness of present or future national regulations in the view of an eventual transfer of these activities to countries without regulations or with less strict ones. On the other hand, there is certain awareness of the fact that human race as itself is concerned by this matter.

Anyway, beyond the humanity's awareness, the concern of legal effectiveness or the fear of legal paradises, there are other points of view, which have shown the economic interests involved in this matter. The public expression of this point of view is not always open. It is sometimes expressed euphemistically as "don't want to get left behind"; something like saying "we don't really want to be permissive, but we have no choice if we don't want to be left behind by the leaders". Paradoxically, this argument is mainly used by the scientists and in the countries which are in the vanguard.

We are going to present the initiatives regarding human cloning taken by the Council of Europe and the European Union. Then, we will discuss the cases of three European states, which are good examples of the different ways of ruling in Europe.

THE EUROPEAN COUNCIL

In 1984 the Parliamentary Assembly of the Council of Europe recommended to the Committee of Ministers to call on the governments of the member states to forbid a series of "undesirable deviations" on the use of human embryos and fetuses, including cloning: "the creation of identical human beings by cloning or any other method, whether for race selection purposes or not" (Recommendation 1046) (Council of Europe, 1984).

But the most important document promoted by the European Council is the Convention on Human Rights and Biomedicine, endorsed by the Committee of Ministers in April 1997 (which came into effect in December 1999). This Convention does not include any reference to human cloning, but in

January 1998, an Additional Protocol to the Convention, on the Prohibition of Cloning Human Being (which will come into force in March 2001) was opened to signature in Paris. Its article 1.1 says: "Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited". At the end of 2000 the additional protocol had been signed by 29 states (the same ones which had signed the Convention), but had had only 5 ratifications. Among the absents were United Kingdom, Belgium and Germany. Germany considered that, having regulations even more restrictive than the protocol, there was no need to sign it (nevertheless, Spain had signed the protocol while human cloning is a statutory offence in Spain).

The legal importance of the Convention and its Additional Protocol should be emphasised. Unlike other kind of more or less formal declarations and recommendations, these are real international treaties, which bind their signatories to adapt their national regulations to it.

THE EUROPEAN UNION

The possible initiatives of the European Union on human cloning are limited by its competence: the European Union has no authority regarding general regulations on human cloning. So, declarations on human cloning issued by European institutions –like European Parliament– have only a symbolic, moral or political meaning, but not strictly a legal one. On the contrary, the European Union has ruled on human cloning in its patents regulations. Obviously, it does not provide a general legal framework on human cloning, but it does indirectly affect the matter. The European Union can also have a bearing on human cloning by funding (or not) scientific research on embryos: this is actually the main topic of discussion.

The European Parliament has traditionally declared its opposition to human cloning. In March 1997 a resolution against human cloning (458 votes in favour, 6 against and 25 abstentions) was approved. More recently, in September 2000, the Parliament discussed the matter again, with new circumstances and with a different point of view. It concerned the British government decision of permitting, in some circumstances, the non reproductive cloning of human embryos (decision which will be discussed in the next section). Unlike its first statement in 1997, there was not a discussion on human cloning in general, but on human embryos

cloning to obtain stem cells. The virtual unanimity of the 1997 voting changed radically: 237 votes in favour, 230 against and 43 abstentions. It seems that a large number of members of the parliament have considered that there is a deep difference between reproductive and non reproductive human cloning and, besides, that the legal protection of human embryos do not justify a general prohibition of their use as stem cells sources, considering their potential therapeutic and scientific utility.

The approved declaration included a call to the British government to reconsider its decision of introducing new regulations permitting human embryo cloning to obtain stem cells (thing that they did not achieve). A call to UNO to promote a universal prohibition of cloning all kinds of human beings (in any stage of their development) was also included. Finally, it was considered that there is no difference between reproductive cloning and therapeutic cloning. It would be interesting to determine whether the main point of discussion (and disagreement) was really human cloning or, in fact, embryo experimentation. I do not pretend that if embryo experimentation was the point then the parliament decision is wrong or fallacious. I just want to emphasise again that the use of the word “cloning” with different meanings can create confusion. (Some supporters of the declaration also denounced that any distinction between both kinds of cloning was a semantic strategy to weaken the moral rejection of cloning. It is the other side of the coin we had shown).

Regarding the call for UNO prohibition of human cloning, its General Assembly has indirectly endorsed a declaration of prohibition. In December 1998 the General Assembly approved the “Universal Declaration on the Human Genome and Human Rights” promoted by the UNESCO. In the 11th article it is said that “Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted”.

Anyway, the European Parliament decision clashed with the view supported by the European Commission and by the European Group on Ethics (a multidisciplinary advisory body chaired by Noëlle Lenoir). For the Commissioner of Research, unlike the European Parliament, reproductive cloning was “scientifically” completely different from therapeutic cloning, and stopping this one would put in danger a very promising research. [He is probably right telling the difference. But the point is to tell whether this difference has a moral importance and meaning. Probably it has moral relevance –there are good reasons to believe it- but even if science can establish

the facts, what to do is not a scientific question]. The Commissioner also disagreed with the Parliament about research funding: the parliamentary resolution had only a political meaning but it was not binding. The Commission declared to follow in this subject the European Group on Ethics in Science and New Technologies advises

The European Group on Ethics (EGE) issued a document on cloning in May 1997. This document recommended prohibition of reproductive cloning of human beings but non reproductive cloning was accepted in some circumstances. Regarding the British government decision, the EGE chair N. Lenoir stated in an interview in August 2000 that the decision was right legally speaking, as it did not violate European Law. Anyway, she thought that it would have been better for them to wait until the EGE document was issued (*Journal du Dimanche*, 20-8-2000).

The new document (“Ethical aspects of human stem cells”) was issued in November 2000. The EGE recognised the interest of the research on human stem cells and its apparently very promising therapeutic prospects, but called for prudence and considered that, at present, therapeutic cloning of embryos would be premature. Instead of the creation of new embryos by somatic cell nuclear transfer (therapeutic cloning) the EGE suggested to use “spare” embryos as an alternative source of stem cells (“spare” embryos, *in vitro* fertilised embryos which have not been used for reproduction, and are now stored). For the first time, the EGE recommended a specific Community budget for research in this field to be provided, including research with spare embryos (EGE, 2000: 16).

The EGE proposal actually asks for a moratorium on “therapeutic” cloning. This position could be unsatisfactory for both who are in favour and against it. But it is a proposal based on reasonable arguments. Some of those arguments should be emphasised here, because instead of being abstracts they are based on concrete facts considering the current state of scientific knowledge and practical considerations related to human rights, which could be affected. First of all, the EGE report keeps its distance from therapeutic cloning promises: they are recognised and appreciated, but only as prospects and with prudence. On the other hand, the patients’ eventual benefits are taken into account with moderate enthusiasm: the report recommends to ensure “that the demand for spare embryos and oocyte donation does not increase the burden on women” undergoing fertility treatment and stresses the need for safety and

protection of the patients' health as regards the use of stem cells in clinical testing.

As we have yet said, the European Union does have competence to regulate patents. The Directive 98/44/CE on the legal protection of biotechnological inventions (patenting of life) stipulates that "processes for cloning human beings" and "uses of human embryos for industrial or commercial purposes"... "shall be considered unpatentable". But it is only an *exclusion of patentability*, not a prohibition. On the other hand, it should be taken into account that even if these processes were patentable it would not mean that they were allowed. A patent gives only a negative right: it only prevents anyone from using this process (during a certain period of time) against the will of the patent's owner. But patent does not give to its owner a right to use the process or to market the good. For instance, the patent of a drug does not give to its owner a right to market it without complying with the relevant legal procedure. Anyway, despite of its rhetoric, this Directive stipulates the unpatentability of human cloning in a context of general patentability of life.

Lately, the Charter on Fundamental Rights of the European Union approved by the European Council on October 2000 prohibits "eugenic practices, in particular those aiming at the selection of persons" and "the reproductive cloning of human beings".

THE VARIETY OF LEGAL REGULATIONS IN EUROPE: UNITED KINGDOM, GERMANY AND SPAIN

A Permissive Approach: United Kingdom

One of the most famous, influent and controversial official report on new reproductive technologies was approved in United Kingdom. It was the *Report of the Committee of Inquiry into Human Fertilisation and Embryology*, known as *Warnock Report* (Warnock, 1984). This report mentioned cloning of human beings as an eventual future development in research, but it did not recommend any concrete legal measure. It only suggested that it could be an ethically unacceptable kind of research.

Human Fertilisation and Embryology Act 1990 stipulated "nuclear transfer" as statutory offence, but it did not include any general prohibition of human cloning. For that reason, Mary Warnock (exchair of the Warnock Committee) proposed in 1997 to amend the act to prohibit any kind of human cloning. This

same year the Commission of Science and Technology of the House of Commons proposed this prohibition. Finally, in December 2001, the Human Reproductive Cloning Act was approved "to prevent human reproductive cloning taking place in the United Kingdom by rendering it a criminal offence to place in the womb of a woman a human embryo that has been created other than by fertilisation".

Anyway, in 1998 an official report on *Cloning Issues in Reproduction, Science and Medicine* concluded that it should be considered to introduce legislation to ban reproductive human cloning regardless of the technique used. But it also considered that "therapeutic" embryo cloning could be acceptable in some cases to develop therapeutic treatments. In August 2000 the government announced that regulations to extend the grounds for research would have been introduced, using early embryos to include a sixth category: increasing understanding about human diseases and disorders and their cell-based treatments. The new regulations would have extended the circumstances for which cell nuclear replacement could be used to allow "therapeutic cloning", but cloning to produce an individual would have remained prohibited (Sleator, 2000).

This kind of research is permitted only if the Human Fertilisation and Embryology Authority licenses it for tightly defined purposes. But the research in United Kingdom is to a great extent in private hands, as well as it is in the United States. If research using human embryos were public funded United Kingdom could be one step ahead the United States, where research is not prohibited, but there is not a public funding. Anyway, research is connected between both countries: the American Geron Corporation is the owner of Roslin Institute in Edinburgh, where Dolly the sheep was born. This is the same corporation which funded the yet mentioned research directed by J. Thompson on stem cells in 1998. (Thompson and his collaborators worked in University buildings, but for this research they used only the corner of the laboratory, which was allegedly funded by Geron Corp.).

Undoubtedly, certain business interests influence British decisions. Some enterprises have moved to try to commercially exploit stem cells in future medical therapies. Most of them are working with adult stem cells (which pose fewer ethical problems), but others like Geron lead the exploitation of embryonic and foetal stem cells (Marshall, 2000).

A RESTRICTIVE APPROACH: GERMANY

In Germany, the development of legislation on artificial reproduction and human embryos has been parallel to the British one, but their laws are completely different. In November 1985 an official report (Benda Report), which inspired the 1990 Act, was issued. The Benda Report was very restrictive on artificial reproduction and embryo research, and it produced a penal law. So, the legal framework is defined by exclusion: what is not a statutory offence is supposed to be allowed. Among the offences with higher punishment (up to five years of imprisonment) there is human cloning. Human embryo research is also punished.

This restrictive approach is usually explained by the experience of Nazism and by the “eugenic” practices carried out during this regime (Salgo, 1989; Lenoir, 1994). Anyway, this law has been heavily criticised by a large number of jurists (Romeo, 1994) from a technical point of view (because it defines the legal framework only with prohibitions). But the critics have also suggested that the law has exceeded what penal law should rule and situates Germany far from other European countries (which explains why Germany has not signed the European Convention on Human Rights and biomedicine). Furthermore, there are doubts on its efficiency and its capability to deal with scientific development, as we will see in our study of Spanish legislation, which is more complete.

THE DIFFICULTIES OF A COMPLETE LEGAL REGULATION: THE CASE OF SPAIN

When Dolly the sheep was born and the human cloning became a real possibility, an argument was spread in Spain: we should keep calm because there was already a legal provision on cloning in Spain. There was a complete legal regulation on human embryos and human cloning was a criminal offence since 1995. Spanish regulations are really complete. They include, being the country an European Union member, the Directive 98/44/CE and Spain has signed the Additional Protocol on Cloning of the European Convention of Human Rights and Biomedicine; cloning is punished since 1995 by Penal Code and since 1998 there are complete regulations on assisted reproduction and embryo protection. Beside this, regarding its contents, Spanish legislation seems to be an adequate medium term between extremes like German or British

legislation.

So, are there enough reasons to be satisfied and optimistic? Probably not, at least in this one sense: the existence of a legal regulation does not provide a definitive answer. This seems to be the point of view of the Spanish National Commission on Human Assisted Reproduction (CNRHA), the official board, which in its first annual report (1999) studied the legal and ethical problems of human cloning. But probably there are deeper reasons to give up any naive satisfaction. As I shall try to show, there are at least two reasons for it: on one hand, it is difficult to definitively establish legal regulations capable to adapt to scientific developments; on the other hand, there are reasonable doubts about the effectiveness, in this field, of a mere legislation (and of a mere penal legislation) when this legislation has to be imposed. The exam of these problems could provide general considerations valid not only for Spanish law.

The dogmatic study of law usually examines concrete acts to determine which behaviours are forbidden, compulsory or allowed. We are not going to do a dogmatic study, so we shall do the other way round: we shall examine the different kinds of human cloning to determine if Spanish law prohibits them (as it is supposed to do) and how does it.

Reproductive cloning is generally considered as the most serious conduct. It is generally thought that it should be prohibited. In Spain the Penal Code punishes (up to five years of imprisonment) the “creation of equal human beings by cloning or any other procedures aiming at the race selection” (art. 161.2). So, reproductive cloning is clearly punished: creation of equal human beings by cloning. Anyway, it is clearly punished if we obviate the inaccuracy of talking about “equal” human beings (because clones are only “genetically” equal and they are not exactly equal because of the existence of non nuclear DNA); but this is not particularly problematic anyway. The real problem is the reference to “race selection”. Does it mean that reproductive cloning is only prohibited whether it is “aiming at the race selection”? Is reproductive cloning allowed if there are not eugenic or racist motives? It does not seem reasonable, but it is a mistake that should be corrected. In 1997 CNRHA proposed to amend the act to correct it (CNRHA, 1999).

Non reproductive cloning prohibition is more problematic: maybe the lawmakers were thinking mainly of reproductive cloning. The article of the Penal Code that we have examined does not seem to include non reproductive cloning: “creation of equal

human beings” seems to include only those who are already born, with exclusion of embryos or fetuses (legal reasons for this interpretation would need a long explanation, but they are related to Constitutional Law interpretation of Spanish Constitution on abortion). If art. 161.2 does not punish non reproductive cloning, we could examine art. 161.1, which punishes those who “fertilise human ovules with any different aim from human reproduction”. Non reproductive cloning is obviously a different aim from human reproduction (by its definition: *non* reproductive). But whether it is a “fertilisation” or not is doubtful, because no masculine gamete is needed. We can suppose that, instead of a fertilisation, it is “parthenogenesis” (stimulation of the development of an ovule which has not been fertilised). If we adopt this interpretation, non reproductive cloning would not be a criminal offence in Spain, but it would be punished with a fine. I do not want to determine which is the right interpretation (and its different legal consequences) but just to show that things are not as clear as they seem.

Anyway, non reproductive cloning is forbidden, even though it is not obvious which penalty should be applied. But, could non reproductive cloning be allowed in some cases by a legal amendment? From a legal –and constitutional– point of view it is doubtful. If reproductive cloning were allowed it would suppose embryo experimentation. Spanish law allows embryo experimentation in some cases, but there is an essential requirement: any experimentation which could lead to the death of the embryo should be carried out with “non viable” embryos. Or, from another point of view, the only interventions allowed in “viable” embryos are those which are aiming at promoting their own development. To allow reproductive cloning, Spanish law permitting experimentation with “viable” embryos should be passed. However, the Constitutional Court has established that is precisely the distinction between “viable” and “non viable” embryos (and its legal status) which made the current Spanish regulations compatible with Spanish Constitution (Sentences 212/96 and 116/99). So, non reproductive cloning could be contrary to Spanish Constitution (as interpreted by the Constitutional Court) if the use of “viable” embryos was needed.

To this point, the first difficulty of a legislation on human cloning has been examined: the difficulty to definitively establish legal regulations capable of adapting to scientific developments. Now, the second difficulty will be examined: the doubts about the

effectiveness in this field of a mere legislation (and of a mere penal legislation) when this legislation has to be compulsory.

So far, the prohibition of cloning has only played a symbolic role. It lets people think that Spanish law has already an answer. But if it were needed, would the Spanish law serve more than that? Would the punishment be dissuasive enough to prevent a person, who had resources and motives (whatever they might be) to do so, from carrying out human cloning? I do not think so. I consider that the experience of Spanish law implementation on assisted reproduction offers a valid example to show this. Some practices in assisted reproduction –even illegal practices– have tended to substitute or to modify the law (*de iure* or *de facto*). Some practices have resisted adapting themselves to the legal framework, because they have been carried out by people who in fact had the power to resist and to modify the law.

Any law pretends to adapt the reality to its principles. It is implicit in the existence of a law (if not, there would be no need for a law at all). Sometimes, a law has only a symbolic purpose: it is only an ideological declaration to gain legitimacy, not to modify the reality. But even in those cases, the law pretends to be (or to appear as) effective. In this case, the law has not adapted the reality to its principles; the contrary has exactly happened: it was the law, which has adapted itself. But the reason for this has not been a change in the social circumstances or a change in the values (it has not even been a change in the correlation of forces acting in society). The reason has been the real power –a private power– that has supported these practices. I shall put only an example (but there are a lot): Spanish act on assisted reproduction stipulates that gamete “donation” shall be “free” (a requirement which the Constitutional Court has considered an essential to allow this practice). However, to avoid difficulties in donor recruitment, reproductive clinics have paid and they still pay gamete donors. This illegal behaviour has not prompted any legal reaction. It has even imposed a new criterion, a new “rule”. The new rule was not created by a formal amendment, but by a change of the meaning of the term “free”: instead of “payment” they talk about “compensation”, no matter that the nature of the act has not changed at all. Even the CNRHA has accepted this logic. “Free” donation is no more a real rule. Now it is only an ideological justification, it is only rhetoric to pretend that the same practice is now legal (and adapted to the Constitution). There is no need to amend any act: a semantic change

allows these practices, no matter what the law stipulates.

This “amendment” has been carried out by informal means (strictly speaking, by illegal means). But sometimes, the real practices force a formal amendment by provoking a lack of efficiency of the law. In any case, the legal principles could not have any power to rule the practices when there are motivations and social private power strong enough to impose different principles by informal means. We can think that, when the time comes, it could happen the same thing with human cloning. If it was true, the topic that an existing legal prevision on cloning is enough would be only a way of keep people calm, but also a way to avoid a serious public debate.

Anyway, the conservative government has not contributed to a better approach. The government had to face two contradictory claims: confessional sectors which want to protect the embryos and those who claim for new possibilities of research with stored embryos (to some extent, the recommendations of the CNRHA). The government chose to do nothing: regulations on assisted reproduction were not changed, and all parliamentary propositions from the Opposition in this way were rejected. The government seems to hope that future developments will discover an efficient way to obtain stem cells from adult tissues. But just letting the time pass by needs some action: to have their report on stem cells, they have substituted the annoying CNRHA with a new Advisory Board on Ethics for Scientific and Technological Research, with a conservative and confessional profile.

FINAL CONSIDERATIONS

The discussion on possibility and justifiability of human cloning has obvious legal aspects, because this discussion is also about the eventual prohibition of human cloning. But the almost unanimous condemnation at least of reproductive cloning shows at the same time the suspicion of the legal instruments limitation to face up the problem. That is, it shows that there is awareness of dynamics that could be immune to citizen’s decisions.

Summing up the ideas presented so far, we have seen how the EGE report offers a good point of view and several ideas that should be emphasised. This report includes considerations based on concrete facts and on practical considerations related to human rights and attending on the individuals who could be affected: women and patients (in clinical testing).

The abstract discussion on the justifiability of cloning and on its future therapeutic promises should not make us forget these considerations.

The discussion on stem cells obtained from embryos is much related to the general topic of the embryo status. Like in other similar cases, it is not acceptable that in pluralistic societies some rules based only on religious and confessional beliefs are imposed to everybody. Now that commercial interests are involved, probably they will be more capable to change this imposition than reproductive rights were.

But these are only general considerations. Facing the problem of the establishment of a reasonable legislation we find many more problems. A permissive path like in Britain might open new possibilities to research (and to new therapeutics). But it only result in being in a hurry, as if research was a race to be the first. It is a race if research is seen as a business, as a race for the profits, based on privatisation of knowledge and its benefits by private corporations. It is not an acceptable way, because it leads to decisions guided by the egoist gain to the detriment of other considerations like justice, respect for the rights of the individuals, etc. “Therapeutic” justification is nearly marketing to convince the public.

A repressive way is not free of objections. In general I do not think that it is a good idea to oppose the penal law to science. Scientific research should not be stopped (probably it is not possible). A responsible scientific research is desirable, of course, but penal law does not seem the best way to promote it. Perhaps there is not a direct way to promote it, but there are means, political means, at least to avoid scientific research to be subordinated to certain powers (economic, military).

Anyway, the Spanish case clearly shows the difficulties of having an effective legislation. These difficulties are at least of three levels: a) the intrinsic difficulty of the object; b) the existence of private powers and practises capable to elude the law; and c) the structural limitations of law as a mean of regulation of social relations.

The law is asked to establish valid, fare and efficient criterions regarding cloning. But the law is faced with a paradox, almost a contradiction. Any firm and constant law is not capable of adapting itself to a social and scientific changeable framework. But any soft law ends up regulating nothing and it is easily malleable by those who have strategic positions and enough power to take decisions, which will affect the whole society.

KEYWORDS Cloning. European Regulation

ABSTRACT Recent development on cloning techniques and on human stem cells research have been followed by some attempts to provide a legal framework for these practices. In Europe, both the Council of Europe and the European Union have approved some initiatives. But is at a national level where these regulations are more relevant. European experience shows a wide range of approaches, from the permissive one of the United Kingdom, to the repressive one of Germany. Nevertheless, all of these regulations, have strong difficulties to become effective and regulative.

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