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THE PROBLEM OF REPRODUCTIVE CLONING

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Francesco D. Busnelli ♦

Abstract

At the time of its emergence the issue of cloning did not paint itself as a legal problem. In the meanwhile it has transformed itself into a significant "testing ground" for the theoretical and practical analysis of the interplay between ethics and law. The paper begins with an overview of the key statements of the most significant international, European and national documents concerning the ethical and legal issues surrounding the several forms of cloning. Subsequently, the paper analyses the role of constitutional principles in dealing with the issue of cloning, in particular human cloning. In the final part, the paper draws attention to the damage evaluation principle, the principle of precaution and the principle of the best interest of the child as the principles which should guide any constructive dialogue on the issue of cloning.

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1. With regard to the issue of cloning, which so far has been on the fringe of my reflections on the law of biomedicine, my first reaction was to assume that this does not represent a problem for a lawyer. This attitude was supported by two reasons.

First, human cloning has been categorically condemned (if not prohibited) in several documents: the Resolution of the World Health Organization (14 May 1997); the UNESCO *Universal Declaration on the Human Genome and Human Rights* (3 December 1997, art. 11); the opinion of the Italian National Bioethics Committee (CNB) on *Cloning as a bioethical problem* (21 March 1997); the *Résponse au Président de la République au sujet du clonage reproductif* of the French National Consultative Bioethics Committee (CCNE, 22 April 1997); the Report of the American National Bioethics Advisory Commission (NBAC), with the subsequent "message" of the President of The United States, President Bill Clinton, concerning the "Cloning Prohibition Act" (9 June 1997); the Additional Protocol to the European Convention on Biomedicine, adopted in Paris on the 12th of January 1998; European Directive 98/44/CE *on the legal protection of biotechnological inventions* (6 July 1998, art. 6, par. 2, lett. a). At first glance, none of these documents leave room for subversive interventions by lawyers, who, by definition, cannot afford to be revolutionary.

Second, the scenario that the advocates of cloning propagate – "cloning in lieu of donors gametes, cloning as a source of organs or tissue, replacing a dead child"[1] – seems quite futuristic to me. Moreover, lawyers are not prophets.

2. Contrary to my first impression, cloning has proven to be a legal issue that causes an array of particular problems. In addition, it has become a significant "testing ground" to examine, both in theory and in practice, the interface of ethics and law (or, rather, ethics and rights) and, specifically, the interface between constitutional principles and legal rules.

3. By lifting the veil of the "*condamnation véhémente*",[2] we face the first problem in that there are several forms of cloning: from cloning to "clonings", so to speak.

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1 See J.A. Robertson, 'Liberty, Identity, and Human Cloning', 76 *Texas Law Review* 1998, 1378 ff.

2 See Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé (CCNE), *Réponse au Président de la République au sujet du clonage reproductif,* where the need to begin an in-depth analysis, and not to stop at the vehemence of feelings, is clearly stated.

Two recent European documents, for instance, clarify that animal cloning should not necessarily be banned, but only requires rules and safeguards. The *Draft Scientific Opinion of the Scientific Committee of EFSA (European Food Safety Authority)*[3] *"recommends that the health and welfare of clones are monitored during their full natural life".*

The *Opinion* of the *European Group of Ethics in Science and New Technologies* of the *European Commission (EGE) "does not see convincing arguments to justify the production of food from clones and their offspring".*[4] *"If in the future food products derived from cloned animals were to be introduced to the European market, the EGE recommends that the following requirements are met: Food safety; Animal welfare and Health; Traceability".*[5]

However, even in human cloning it is possible to distinguish between reproductive and non-reproductive cloning and, within this second type, to also distinguish between the production and culture of cells of embryonic or adult origin which have the ability to develop into an embryo, and the technique of producing embryos whose development is halted at a more or less advanced stage in order to obtain immune-compatible cells for cellular therapy.[6]

With regard to the first technique – i.e., research aimed at obtaining stem cells from non-embryonic sources such as an aborted fetus or adult cells – the opinion of the French CCNE appears to be widely shared. While noting that "it is a customary and long established practice of great usefulness for diagnosis and therapy", the French Committee concluded that "it raises ethical issues which are not fundamentally different from those raised by other aspects of biomedical research".[7]

As far as the second technique is concerned, however, there are conflicting opinions. The position of the French CCNE is absolutely resolute: it maintains that this technique, apart from being an infringement of the rule that forbids the creation of embryos for research purposes (l. 29 July 1994, art. 16-4), would be a "*monstrueuse inhumanité*", and points out that it "is astonished to see it promoted by scientists at times distinguished in their field".[8] On the contrary, the UK Report on "*Stem cell Research*" (2000)

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[3] *Draft Scientific Opinion on Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals,* endorsed for public consultation on 19 December 2007. The Opinion is accessible at http://www.efsa.eu.int

[4] *Ethical Aspects of Animal Cloning for Food Supply. Opinion* No. 23, issued to Commission President Barroso on 16 January 2008. The Opinion is accessible at http://ec.europa.eu/european group ethics/index en.htm

[5] *Ibid.* at *Conclusions.*

[6] See F.D. Busnelli & E.Palmerini, *Clonazione,* in Dig.IV-ed., Disc. Priv. sez. civ., Agg., Torino, 2000, 142 ff.

[7] CCNE, *op. cit.*, 26.

[8] *Ibid.*, 29.

(Donaldson R.) "recognises the special status of an embryo as a potential human being, but accepts that it is justified to create or use early embryos for serious research purposes which may benefit others", of course within "the 14 day limit". "Such embryos can be seen as being created simply as a means to an end and for use as a product source".

The middle ground is represented by the *NIH Guidelines for Research Using Human Stem Cells* (Sept. 2000); studies using *NIH* funds may be conducted "ONLY if the cells were derived from human embryos that were created for the purposes of fertility treatment and were in excess".

4. With regard to reproductive human cloning it is crucial to identify the basis for the strict ban that is commonly advocated in all of the abovementioned national and international documents.

Clearly enough, these share "the deep emotion"[9] brought about by the birth of Dolly, the cloned sheep, in February 1997. As a consequence, they share the concern that the method "that was used to create Dolly the sheep" might be applied, in the near future, to human beings.[10]

Likewise, these seem to have a mutual widespread feeling of repugnance that reproductive cloning has stirred up among people on both sides of the Atlantic. It has been reported[11] that even Dolly's creator confessed that he would find it offensive to clone human beings. However, as was rightly affirmed, "repulsion is not an argument" and "things considered to be repugnant yesterday are today accepted without any problems".[12] These kinds of reactions seem to be rather impulsively or emotionally determined.

More importantly, the impression of a general consensus seems to be rather superficial since the ethical foundations to which these documents refer turn out to be wholly different and reflect completely distinct legal (or, rather, constitutional) principles.

The American NBAC document solemnly affirms that cloning a human being is "morally unacceptable". However, it adds "at the present time", stressing that these techniques are not yet perfect from the standpoint of "safe usage". Therefore, the ethical basis for the ban is "the issue of safety"; and the legal procedure to enforce it is that of a

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[9] CCNE, *op. cit.,* 25.

[10] President's Remarks announcing the Proposed "*Cloning Prohibition Act of 1997*", 9 June 1997.

[11] L.R. Kass, 'The Wisdom of Repugnance: Why We Should Ban the Cloning of Humans', 32 *Valparaiso Univ. L. Review* 1998, 686, quoting a news report published in *The New York Times* in February 1997 whose title is intriguing: *Sports of the Times: Could Jordan Be Cloned? Not exactly.*

[12] L.R. Kass, *op. cit.*, 687.

moratorium. From an ethical standpoint, the "*if*" of reproductive cloning is not at issue. Rather, the critical question concerns which conditions have to be met for cloning to be allowed. In other words, the discussion turns to *how* and *when* to do it.

In the European documents, the moral unacceptability of reproductive cloning is put forward on a radically different basis. The Additional Protocol to the European Convention on Biomedicine affirms that cloning must be prohibited because it leads to an "instrumentalisation of human beings". Moreover, the French CCNE document refers, more drastically, to an "*intolérable chosification de la personne*",[13] while the Italian CBN condemns the "assault on the biological unit of human beings".[14]

In Europe, therefore, the ethical basis for the unconditional ("no derogation … shall be made"[15]) prohibition on cloning is to protect "human dignity". Indeed, the prohibition directly concerns the "*if*" of reproductive cloning.

Finally, the Resolution by the World Health Organization is more cautious. After stating that the use of cloning to reproduce human beings is not ethically acceptable, it finishes with "an invitation to the Director-General to take initiatives to clarify and evaluate the ethical, scientific and social consequences of cloning with regard to human health"; and the Director-General, on his part, calls for "wisdom",[16] provided that reproductive human cloning is still banned. Here, the aim of reaching a programmatic compromise at an institutional level and shortening the distances between two ethical conceptions, that nevertheless remain distinct, is clearly evident.

5. From a legal point of view the difference between the two ethical conceptions is reflected in the constitutional principles and foundations of the legal system involved.

5.1. A legal system that is built on the fundamental idea of individual liberty and freedom, not as a social value (*freedom for*) but as a "condition of ethical and moral conceptions" (*freedom from*)[17] readily acknowledges a principle of reproductive freedom in order to allow for the procreation of *"children of choice*".[18] Such a legal system bases the

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[13] CCNE, *op. cit*., 27.
[14] CNB, *La clonazione come problema etico*, 21 Marzo 1997.
[15] *Additional protocol to the Convention on human rights and biomedicine on the prohibition of cloning human beings,* art. 2.
[16] An "optimistic line" that emerges from the *Report* of Hiroshi Nakajima can be found in CNB, *La clonazione, op. cit.*
[17] H.T. Engelhardt, *The Foundations of Bioethics,* ,(New York/Oxford, 1996) 18.
[18] J.A. Robertson, *Children of Choice. Freedom and the New Reproductive Technologies*, (Princeton, 1994).

protection of the unborn child on the objective aims of the society.[19] In such a legal system it is, by principle, not possible to condemn reproductive cloning.

Therefore, the position of the scholar who thinks it should be regarded "as an exercise of procreative liberty and granted the special respect usually accorded to procreative choice", is clear. There would not be anything wrong – this is the given example – with the possibility of "a situation in which the parents want another child and are so delighted with the existing one that they simply want to create a twin of her, rather than take a chance on the genetic lottery".[20]

Less coherent, but nevertheless significant, is the position of the legal philosopher who, after having said that reproductive cloning must lead to an expansion and not to a restriction of liberty, demonstrates concern for a possible "explosion of claims for reproductive freedom": claims based on a "rampant individualism heedless of the interests of society".[21]

Quite worrying is the statement of a researcher, according to whom the liberal approach, "*quintessentially American",* turns out to be "regrettably inadequate as an approach to human procreation". He submits that the liberal approach is deprived of all the "anthropological, social and ontological elements that accompany the formation of a new life".[22]

5.2. By contrast, reproductive cloning does not seem appealing to a legal system that is based on the principal idea of protecting the dignity of all human beings;[24] it extends this protection to the unborn child,[25] giving him/her "an adequate protection in respect of the applications of biology and medicine";[26] that does not acknowledge "reproductive liberty" as a subjective right; that does not acknowledge abortion as an unquestionable right;[27] that finally is not orientated at the suppression of the "genetic lottery", but

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[19] D.E. Johnsen, 'The Creation of Fetal Rights: Conflicts with Women's Constitutional Rights to Liberty, Privacy, and Equal Protection'*,* 95 *Yale L. Journal* 1986, 599 ff.
[20] J.A. Robertson, 'Liberty, Identity, and Human Cloning'*, op. cit.,* 1349.
[21] R.C.L. Moffat, Cloning Freedom: Criminalization or Empowerment in Reproductive Policy?, *Valparaiso Univ. L. Review* 1998, 584, at 601 ff.
[22] L.R. Kass, *op. cit.,* 688 ff.
[24] Convention on biomedicine, art. 1. See also the Recital n. 4 of the Additional Protocol, where the extension of its application to "all human beings" is underlined.
[25] *Additional Protocol, op. cit.,* Recital n. 2.
[26] *Additional Protocol, op. cit. Draft explanatory Report.*
[27] A perfect example is offered by a decision of the German Constitutional Court. After having stressed that "a solution that guarantees either the life of the unborn or the right of the mother to abort is not possible", the court introduced the principle of "intolerableness" as a cause for exonerating the woman from "the duty

continues to consider the "mystery" of procreation as a value to be preserved and defended from the "fanatics of artifice".[28]

The legal philosopher's reflection on this issue is persuasive: if it has to be respected that every human life has the right to be a surprise in itself, it seems evident that a cloned being has first of all been deprived of his liberty and can only prosper under the protection of ignorance; therefore, nobody – not even a parent – has the right to deprive a future human being of his freedom.[29]

Clearly the jurist does not hesitate in affirming that the "choice" of the baby to be procreated is a "stretch of authority". The "right to responsible procreation" cannot become one subject's absolute abuse of power over another, reduced "to the rank of a product and a programmed object".[30] It is, more simply, an expression of the fundamental right, solemnly vested to parents through the International Conference in Teheran on Human rights in 1968, to "*déterminer librement et consciemment la dimension de leur famille et l'échelonnement des naissances*" (art. 16).

The warning of the researcher who fears the advent of what he (improperly) calls a "normative procreation" characterized by a new eugenics "*mou, démocratique, consensuelle"* is meaningful and consequently urges the preservation of "the values of a lay humanism, not subdued to the traditional religions, but also not attracted to the new techno-science mythologies".[31]

For all of these reasons, reproductive cloning is a problem. Strictly speaking, it is not a problem in itself, but an issue that reveals the wide gap between ethical conceptions and constitutional principles which divide western law.

In other words: it might be correct to admit that "so far as cloning is concerned, the issue itself is relatively trivial".[23] However, surely the discordance and the inevitable conflict between ethics and constitutional principles, pitilessly laid bare by the issue of

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to give birth". See *Bundesverfassunggsgericht,* 28 Mai 1993, *NJW*, 1993, 1751 ff. In broader terms, M.A. Glendon, *Abortion and Divorce in Western Law:American Failures, European Challenges,* (Cambridge (Mass.), 1987), 145 ff. talks about "abortion for cause" referring to the experiences of Germany, France, Italy, Spain, Portugal, Switzerland and the Netherlands.

[28] J. Testart, *L'oeuf transparent,* (Paris, 1986), 30 ff.

[29] H. Jonas, *Philosophical Essays. From Ancient Creed to Technological Man,* (Chicago, The University of Chicago Press, 1974), 249.

[30] J.L. Baudoin & C. Labrusse-Riou, *Produire l'homme. De quel droit?*, (Paris, 1987), 183 f.

[31] J. Testart, *Le magasin des enfants, Introduction,* (Paris, 1990), 33.

[23] R.C.L. Moffat, *op. cit.*, 605

cloning, is not so trivial and occurs, paradoxically, in a (not only economical, but also legal) context that is influenced by globalization.

The way to a shared ethic is still long, filled with obstacles, and it is not known where it will lead to: American Failures, European Challenges (as stated by Mary Ann Glendon[24])? Or perhaps American Challenges, European Failures? Or, finally, perhaps an overcoming of the two opposite systems?

It has already been asserted above that a lawyer is not a prophet. Nevertheless, he has the duty to compare the systems and to point out the principles that are useful in creating a constructive dialogue and to go forward along a road that is necessarily based on a "minimalist" ethic.

At least three principles can be pointed out at the moment: the damage evaluation principle; the principle of precaution; and the principle of the best interest of the child.

6.1. The damage evaluation principle is not new in the biomedical sphere. One of its applications has been Recommendation no. 1399 (1999), formulated by the Parliamentary Assembly of the European Council on xenotransplantation. The problem of weighing-up the health risks of xenotransplantation with its estimated benefits has been underlined, and since the risks of rejection and the transfer of diseases remain uncontrollable, the Assembly has recommended that a legally-binding moratorium on clinical experimentation be introduced in all Member States. Additionally, the Assembly has invited the Committee of Ministers to "take steps to make this moratorium a worldwide legal agreement".

A worldwide legal agreement on reproductive cloning could prove to be a helpful measure, but not a decisive one: even among the strongest supporters of the "reproductive liberty" principle and of the "children of choice", there are, in fact, those who invoke a prohibition of reproductive cloning because there are still not sufficient guarantees to make sure that children produced in this manner will live without significant health injuries.[25]

At the same time, a moratorium could prevent the development of a confrontation between opposite positions: those that discuss only the "*when*" and "*how*" of reproductive cloning, and those that are against the "*if*".

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[24] M.A. Glendon, *op. cit.*

[25] B. Gert, 'Thinking about Huxley's Brave New World: Was it Wrong to Create a Genetic Hierarchical Society? Is it Wrong to Prevent One?', in C.M. Mazzoni (ed.), *Ethics and Law in Biological Research*, (The Hague/London/New York, Kluwer Law International, 2002), 107.

The principle of precaution essentially concerns the role of scientific research in those territories placed at the new frontiers of "human rights and the dignity of the human beings with regard to the applications of biology and medicine".[34]

Disturbing, yet at the same time encouraging pages have been written on the ethics of scientific research: "the research does not self-guarantee its own moral property. However, the intrinsic ethical characteristic of research lies just in this: a researcher presupposes that the world in front of her/him has a meaning and he/she has a duty to uphold this meaning in the continuous construction of new things".[35]

In dealing with the relationship between ethics and the law it is now clear that "the principle that scientists are not responsible for the consequences of their own actions is not acceptable anymore today".[36]

Nevertheless, the liability of researchers, when put in legal terms, cannot be restricted within the legal framework of Roman Law: diligence, skill, caution.

Scientific projects necessitate the switch from a logic of prevention (useful to manage known risks) to a logic of precaution (that also covers unknown risks). In other words, we must "manage scientific uncertainty; and management of uncertainty is a requirement of the principle of precaution"[37]. Precaution aims "*à privilégier l'hypothèse du pire, lorsqu'on peut redouter un dommage irréversible même à long terme*".[38]

However, this does not establish a shift from fault liability to strict liability; this means "the adaption of fault liability to contexts of uncertainty".[39]

Without any doubt this position poses a possible limit to scientific initiatives. As was put in the recent French *Rapport au Premier Ministre*: "in the hands of a legislator or a judge" the principle of precaution "can be the best as well as the worst of solutions: the best when it succeeds in offering solutions really apt to ameliorate the safety of the people;

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[34] This is the full title of the European Convention on Biomedicine.
[35] F. D'Agostino, *Etica della ricerca scientifica,* in *Bioetica nella prospettiva della filosofia del diritto*, (Torino, 1996), 56 f.
[36] L. Battaglia, *Dimensioni della bioetica. La filosofia morale dinanzi alle sfide delle scienze della vita,* (Genova, 1999), 72, quoting Daniel Callahan.
[37] L. Baghestan-Perrey, 'Le principe de précaution: nouveau principe fondamental régissant les rapports entre le droit et la science'*, D.,* 1995, *Chron.,* 299.
[38] Jacques Chirac, President of the French Republic, in the with which he opened the 4th session of the UNESCO International Committee of Bioethics (CIB) (3 ottobre 1996).
[39] G. J. Martin, 'Précaution et évolution du droit'*, D.,* 19954, *Chron.,* 299.

the worst when it performs as a pillory that prevents any flexibility, discouraging any initiatives for innovation and progress"[40].

In its actual application, the principle of the best interest of the child should correct the unlimited freedom that, according to a libertarian conception, could legitimately reach licentiousness, giving freedom itself a "non-desirable reputation";[41] in other words, it could change reproductive freedom from "*freedom for*" into "*freedom to*", thereby implementing a social control on its exercise.

We can give the example of the English Human Fertilisation and Embryology Act 1990, according to which nothing is prohibited *a priori,* but everything is subject to selective scrutiny preventing health care providers from offering "a woman … treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth" [sec. 13 (5)].

The suggested use of the criterion of the best interest of the child would reduce the distance between "libertarian" models and "prohibitionist" ones.

Both models would contain a preventive control of lawfulness that would be performed by the rule-makers for the latter models and by the competent agents of the case-by-case approach for the former models.

Through all of these concepts some sort of a super-principle shines that might be described as the "responsibility principle".

This is the still relevant lesson of Hans Jonas, who invokes "a new kind of humility - a humility that, unlike any previous one, is not due to the narrowness but to the excess of our capabilities, that is the prominence of our ability to act on our ability to forecast, to evaluate and to judge".[42]

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[40] Ph. Kourilsky & G. Viney, *Le principe de précaution. Rapport au Premier Ministre,* (Paris, 2000), 213 f.
[41] R.C.L. Moffat, *op. cit.,* 603.
[42] H. Jonas, *op. cit.*, 60 f.