The Law on Somatic Cell Nuclear Transfer: Comparing the Andalusian statute

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1. Introduction

This article aims to analyze the Andalusian law 1/2007 regarding research on somatic cell nuclear transfer (SCNT) for therapeutic purposes in light of a general framework that deals with the protection of fundamental rights. The comparative approach will help to evaluate the pros and cons of the law because of its argumentative efficacy. On the one hand, we should consider the limited success of an analytical study that is limited exclusively to a national dimension; on the other hand, constitutional law currently finds an inescapable base for adequacy and efficacy in the awareness of and comparison with foreign experiences[1]. Comparison may permit us to overcome a closed and static conception of the law: confronting different legal experiences is a way to conceive of the law as a context open to different options[2].

From this perspective, the comparative method may orient and complete the Andalusian law's analysis, revealing the different normative approaches that characterize relevant foreign legal systems in the same field. At the same time, comparison as a legal dimension could be transformed in its own traditional objects, instruments, and outcomes: openness to cross-fertilization among different legal systems, according to which the essence of national provisions is often the result of a cultural circulation of legal models, implies knowing and understanding the factors of evolution of comparative law.

Even if this latter perspective cannot be the main object of this commentary, in this first part of the article it seems useful to stress how the traditional distinction within comparative law between "legal families" (such as civil law and common law) directed to demarcate homogeneous legal orders that are deeply linked because of their common legal structures and historical background, is moving towards a crisis, due to a cross fertilization among families which could stimulate a re-thinking of their previously firm traditional boundaries.

From this perspective, biolaw may assume a paradigmatic and innovative efficacy, contributing to the above mentioned re-definition of legal systems in light of a qualitative change within the legal means through which to regulate the scientific reality. Accordingly, one of the possible outcomes of the comparative method applied to biolaw may be the definition of new lines of normative

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[1] C. CASONATO C., *Introduzione al biodiritto*, Trento University Press, 2006, p. 3, now freely downloadable at http://www.jus.unitn.it/biodiritto/home.html.

[2] Ivi, p. 309.

evolution, departing from a static categorization in "legal families" towards an increasingly transversal and cross cutting "intra-familiar" fertilization.

As both the method and the content of the Andalusian law on SCNT make clear, this tendency towards a redefinition and re-systematization among national legal orders pertaining to different traditional families within comparative law is due to a transversal sharing of a common way to conceive the function of the law (such as legislative means). Therefore, the same function and method of legislative making process are at stake: the analysis of the Andalusian law could also have a general relevance which goes beyond its specific content (which will be however analysed in this commentary), becoming eventually a paradigmatic litmus test to check the grounding of this new "melting pot" theory among traditional legal families.

One point seems to be indisputable: within the biolegal field, the Spanish approach to legislative regulation more closely resembles the common law approach than the civil law one, apparently clashing with a historical and constitutional common background. This similarity will be shown by the formal structure of the Andalusian law on SCNT, which is grounded primarily on a full-scale set of definitions (with the aim of narrowing its own legislative sphere of intervention) and on a delegation of normative power to specialized (both ethically and scientifically) bodies and committees, which involves the participation of experts in the application and enforcement of legislative provisions, consistent with a case by case approach. This common approach to biolaw could emerge as a relevant and direct marker of a normative cross-fertilization among different legal systems, which is grounded on a common view of the legislative function: a legislative pattern able to recognize the essential value of social pluralism and the necessity of a dialogue between ideologically and culturally concurring perspectives, trying to apply within the legislative making process a civil ethic based on an acceptance of reality evaluated with rational and scientific criteria in light of the general interests[3].

This commentary will focus on a number of issues, ranging from definitions to economic profiles, from the ethical review to the protection of individual rights (privacy and the right to access). Two related issues will also be examined, expressing two different levels of criticism of the Andalusian law on SCNT. An *ex ante* level of criticism, dealing with the legitimacy – from both the scientific and the legal perspective – of the therapeutic cloning technique will be followed by a check on the legitimacy, efficacy, and adequacy of the goals and means provided by the law (*ex post* criticism), taking both the national (for instance, Law 14/2007 on Biomedical Research) and foreign (Italy, UK, US and California) legal orders as benchmarks for a comparative evaluation.

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[3] «*Una ética de carácter civico o civil (…) cuya validez radique en una aceptación de la realidad (…) confrontada con criterios de racionalidad y procedencia al servicio del interés general*». According to the *Exposición de Motivos* of the Spanish statute 35/1988 on Assisted Reproduction Procedures.

2. Definitions

According to the general premises expressed with regard to a cross fertilization process among traditional legal families within the biolegal field, the common law attitude to give specific and accurate definitions to the material covered by the act is also adopted in the Andalusian Act on SCNT. This approach, shared also by the more general Spanish law 14/2007 on biomedical research[4], is particularly valuable in matters like the one about which we are writing. Definitions in the biolaw field, which is particularly prone to both social and political divisiveness and to scientific aging and outdating, are crucial in order to understand the very object of the discipline at stake. Even the word bioethics is ambiguous and it can be used with either a narrow or a broad meaning depending on the context[5]; and, as a matter of fact, concepts such as life or death, cloning or embryo are deeply influenced by the cultural and ideological perspective adopted. When life begins is still an issue and the different alternatives go from the simple contact between the two gametes to the creation of the zygote up to the implantation of the fertilized egg in the uterus.

From this point of view, a number of legal systems abandoned the attempt to find or establish an accurate "theory of life". In *Roe v. Wade*, for instance, the Court stated: «We need not resolve the difficult question of when life begins. When those trained in the respective disciplines of medicine, philosophy, and theology are unable to arrive at any consensus, the judiciary, at this point in the development of man's knowledge, is not in a position to speculate as to the answer»[6]. And a more recent decision of an Italian Administrative Tribunal echoed this approach: «the constitutional provisions do not establish a definite beginning moment of human life and the extension of its protection in the development. The specific question is at the centre of a wide scientific, bioethical and religious debate (…) and it did not find a solution in a certain regulation»[7].

Even admitting that the law might establish a precise theory of life (which some states actually have established), though, the crucial legal question is not when life begins, but at which of the different stages of development the law should recognize the protection of (potential) life, and what kind of

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4 Law 14/2007, of July 3rd, on Biomedical Research, in English at http://www.catedraderechoygenomahumano.es

5 This way, for example, the Council of Europe tends to use the term bioethics with a narrow meaning, referring to the purely ethical dimension of biomedical sciences. Under this perspective, bioethics is no more than a part of ethics. On the other hand, UNESCO usually understands bioethics with a broad meaning, which includes also the legal regulation of biomedical activity, getting closer to biolaw. See R. Andorno, *First Steps in the Development of an International Biolaw*, in Gastmans Ch.; Dierickx K.; Nys H.; Schotsmans P. (eds), *New Pathways for European Bioethics*, Intersentia, Antwerpen – Oxford, 2007, 123.

6 *Roe v. Wade*, 410 U.S. 113, 160 (1973).

7 TAR Lazio, Decision n. 8465/2001 October 12th, 2001. The original version goes: «Osserva il collegio che le norme di rango costituzionale invocate non recano una nozione certa circa il momento iniziale della vita umana e l'estensione dell'ambito di tutela nel corso del suo sviluppo. Lo specifico problema forma oggetto di ampio dibattito in sede scientifica, bioetica e religiosa - aspetto di cui sono ben consapevoli le parti in causa - e non ha trovato soluzione in apposita regolamentazione»

protection it should provide[8]. Even a brief comparative survey shows that different legal systems establish very different regulations; and that different regulations are established even within the same legal system in different contexts. Accordingly, depending on the jurisdiction, recovery for the wrongful death of a fetus may be allowed (i) if the child is born alive, (ii) if the fetus is viable at its death, or (iii) for the death of any unborn fetus, including pre-viable fetuses. The consequence of this variety, existing also in other fields, such as birth and death certificates or feticide, is that «conception, quickening, viability, and live birth are all potential definitions of life. How life is defined for this single legal cause of action varies widely between jurisdictions and across time»[9].

Coming back to the definition issue, it is obvious from these examples that law (and particularly biolaw) cannot take for granted its object and is forced to select a single definition among the others, in order to clarify its content and to mark the boundary of its intervention.

Article 2 of the Andalusian Act on SCNT is significant, from this perspective, because it lists a number of definitions ranging from what is intended to be a somatic cell to the meaning of informed consent, from the understanding of the pre-embryo to an explanation of the nuclear transfer technique. If the word «fusion» of the male and female gametes in order to achieve fertilization raises some scientific doubts[10], the definition of the somatic pre-embryo is particularly revealing towards a certain balance of interests. Adopting an approach far-removed from the very restrictive Italian law on human assisted reproduction[11], the Andalusian statute defines the pre-embryo as the group of cells resulting up to the fourteenth day from the beginning of the process (art. 2, lett. f). This way, following the British approach, the statute on SCNT provides for a minimum level of protection of the somatic pre-embryo, ordering its destruction after fourteen days from the beginning of the implementation of the technique (art. 3.3).

The temporal limit of the fourteenth day of embryonic development as a condition for allowing research upon somatic embryos seems to represent a trend towards common criteria within the European legal framework (with the meaningful exception of Italy), in all those issues related to the utilization of embryonic entities for research purposes, suggesting a possible harmonization factor within the EU normative context[12].

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[8] See J.M. HORST, *The Meaning of "Life": The Morning-After Pill, the Question of When Life Begins, and Judicial Review*, in *Texas Journal of Women & the Law*, 2007, 16, 205.

[9] K.R. Smolensky, *Defining Life from the Perspective of Death: An Introduction to the Forced Symmetry Approach*, The University of Chicago Legal Forum, 2006, 57.

[10] The fusion process is somewhat contested.

[11] Among others, see E. Camassa, C. Casonato, *La procreazione medicalmente assistita: ombre e luci*, Trento University Press, Trento, 2005.

[12] CASABONA ROMEO C. M., *Los genes y sus leyes*, p. 196 ss., recognized the necessity of a minimum level of harmonization within EU legal framework.

This rigid and factually appreciable – both biologically and legally – criterion[13] may prove to be sufficiently open and flexible in order to permit its prospective updating, due to the new scientific knowledge which will demonstrate its subsequent scientific inadequacy. Also in this long time period perspective, the normative approach of the Andalusian legislature apparently follows the common law approach, according to which «the 14-day rule is an arbitrary cut off point» which could be discussed and revised if scientists or clinicians were able to provide convincing justification[14].

According to this normative perspective, open to the ongoing development of scientific knowledge, and in order to make more flexible the legislative means, it should be appropriate to provide for a "sunset provision" that allows -- or even forces -- the legislature to review periodically the content of the law. Such a provision should be considered as a legislative assumption of responsibility, in the awareness that scientific developments within biomedicine are so rapid that there is a high risk of legal obsolescence[15].

Moving to the content of the definition, from a comparative perspective which takes into account as one parameter the Spanish national level of regulation, it is striking that the somatic pre-embryo definition expresses a dual relevance.

On the one hand – as mentioned above – the Andalusian legislature confirms the consolidated gradualist perspective on the protection of human life, guaranteeing insofar continuity and coherence within the legislative intervention. The national legislature (Law 35/1988 and 42/1988; Law 14/2006 and 16/2007) has – as a matter of fact – systematically accepted and transposed into the law the constitutional principle affirmed by the *Tribunal Constitucional* (TC) according to which human life is an ongoing process which starts from gestation, during which a biological reality is assuming a human configuration bodily and sensitively[16]. Consistently, although a distinction among embryonic development phases (as any other conventional definition) may be

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[13] Even if severely censured within scientific and bioethics scholars. It is useful to leave clearly separate this context of utilization of fourteen days criterion from the further one, corresponding to the definition of pre-embryo contained in both the Law 14/2007 and 16/2007 («*el embrión in vitro constituido por el grupo de células resultantes de la división progresiva del ovocito desde que es fecundado hasta 14 días más tarde*»), adopting a distinction between different stages of biological development which is empty of legal effects and unnecessary (CASABONA ROMEO C. M., *La cuestión jurídica de la obtención de células troncales embrionarias humanas*, p. 88). See also, LACADENA J., *La Ley 14/2006 sobre Técnicas de Reproducción Humana Asistida*, op. cit., pag. 161, that speaks about a normative exploitation through the pre-embryo definition.

[14] «*For many, even those who support assisted reproduction and embryo research, an extension to the 14-day rule would be unacceptable. We accept that there is no case at present for an extension, or indeed reduction*», *Human Reproductive Technology and Law. Government Response to the Report from the House of Commons on Science and Technology Commitee*, session 2004-2005, Fifth Report, HC 7-1 (2005).

[15] «*los avances científicos en el campo de la Biomedicina son tan rápidos y espectaculares que se corre el peligro de que la ley quede desfasada muy pronto*», according to LACADENA J., *La Ley 14/2006 sobre Técnicas de Reproducción Humana Asistida: consideraciones científicas y éticas*, in *Revista de derecho y Genoma Humano- Law and the Human Genome Review*, 24, 2006, p. 183.

[16] Judgement 53/1985. As well-known, judgements n. 212/1996 and 116/1999 have confirmed the reasoning contained in the judgement 53/1985.

intrinsically objectionable[17], the legislative intervention within the regulation of the first stages of the beginning of life has introduced a number of legal definitions – "pre-embryo"[18], "embryo"[19] and "foetus"[20] – each one corresponding to different stages of development.

The fourteen day principle has been recognized by the Spanish legislature as the main criterion to distinguish among different legal definitions, in the light of procreative purposes (human assisted reproduction techniques) as much as research and experimentation ones (biomedical research and nuclear transfer technique)[21]. The continuity in recognizing the legal relevance of this chronological criterion seems to be guaranteed, because the Andalusian legislature also accepts this principle, applying it in the field of SCNT as a maximum time-limit within which to perform experimentation on the somatic pre-embryo and after which to destroy it.

Nevertheless, as mentioned above, a further level of relevance of the somatic pre-embryo definition can be detected, which seems to be characterized by an increasing degree of criticism. Taking into account the expression concretely utilized by the Andalusian legislator, it is possible to understand that the terms diverge from the traditional wording provided by the national legislation. As a matter of fact, reference has been made to a «*somatic* pre-embryo», thus changing the consolidated definition of «pre-embryo».

Does the Andalusian legislature thereby create a new legal category? Does this new wording entail exclusively a literal distinction, confirming conceptually the content of the national definition? Or does this innovation also imply a conceptual distinction, according to which it may be possible to recognize a new legal category which expands the different levels of protection of the embryo?

Making reference to the substantial wording of the definitions at stake, we could stress how a formal distinction can be recognized. On the one side – the national level – both Law 14/2006 (art. 1, paragraph 2) and Law 16/2007 (art. 3, lett. l) define a pre-embryo as an embryo constituted in vitro that is formed by the group of cells that are the result of the progressive division of the ovocite from the time it is fertilised until fourteen days after. On the other hand, the Andalusian Law makes reference to a *group of cells* resulting up to the fourteenth day from the beginning of the process, replacing the concept of «ovocite starting from the fertilisation» with the ethically neutral one of «cellular entity created by nuclear transfer technique».

This change derives not only from a factual distinction between different techniques for creation of an embryo, the *in vitro* fertilization and the nuclear transfer one, but also from a distinction among

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17 See above, note 14.

18 Law 35/1988 and now Law 14/2006.

19 Law 42/1988 and now Law 16/2007 on Biomedical research.

20 Law 16/2007.

21 From a comparative perspective, Rewerski P., *The need for a new U.S. Stem cell research policy: a comparative look at international stem cell research laws*, in *University of Illinois Journal of Law, Technology & Policy*, 7, 2007.

different purposes (see below), which therefore justifies a different recognition of its legal relevance[22]. The same biological entity – the pre-embryo – is thus defined in different ways, to which different levels of legal protection are attributed, not on the basis of biological facts but rather on the grounds of its origin (fertilisation v. nuclear transfer) and the purpose for which it was created (procreation v. research)[23].

Eventually, it seems reasonable to conclude that a new legal category has been introduced within the Spanish legal order, even if only at the regional level, increasing the different degrees which characterize the multilevel structure of life's legal protection, based on the difference in the techniques applied (in vitro fertilization on the one hand and nuclear transfer on the other) and the purposes[24]. It seems an analogical application of the gradualist approach provided by the TC to a biological entity unknown at the time of the TC ruling but consistent with it. In fact, TC has clearly specified how neither the not transferred (implanted) pre-embryos nor, all the more so, the simple gametes are human persons (STC 116/1999). The somatic pre-embryo seems to be situated in an intermediate category that lies somewhere in between the mere gametes and the not transferred pre-embryos, marking a new legal entity which cannot be accorded the same level of protection as embryos that have already been transferred to the woman's womb (STC 116/1999)[25].

The Italian approach to SCNT is situated on the opposite end of the legislative spectrum compared with the Spanish (national and regional) one. In Italy, there is an absence of specific legislative regulation in the field of cellular reprogramming techniques; however, this legislative vacuum is indirectly occupied by a legal source which effectively bans this technique through the provision of criminal penalties[26]. The reference is to the Italian Law n. 40/2004 on medically assisted procreation: it provides for a general ban of any cloning activity, including the "reproductive" one, defined as a process aimed at obtaining a human being who is a descendant of a unique starting cell,

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[22] An eventual point of criticism could be the so-called "label fraud" risk, that is to mask – through a determined *nomen juris* – a certain legal situation or regulation which doesn't coincide with its own formal denomination (see Casabona, *La cuestión jurídica de la obtención de células troncales embrionarias humanas con fines de investigación biomédica. Consideraciones de política legislativa*, in *Revista de Derecho y Genoma Humano-Law and the Human Genome Review*, 24, 2006, p. 91).

[23] Ivi, p. 90. According to Luk E. M., *The United Kingdom and Germany: Differing Views on Therapeutic Cloning and How the Belgian Resolution Brings Them Together*, in *Michigan State University College of Law Journal of Medicine and Law*, 10, 2006, «the essential difference between embryonic stem cell research and therapeutic cloning relates to how the embryo is created or obtained. In therapeutic cloning, nuclear transfer creates the embryo; while in embryonic stem cell research, embryos are obtained from couples that seek fertility treatment by in vitro fertilization ("IVF") and donate the unneeded or unused embryos to research».

[24] In this regard, De Miguel I., *El proyecto de Ley 121/000104 de Investigación Biomédica: luz verde a la "clonación terapéutica"*, in *Cuadernos Electrónicos de Filosofia del Derecho* (http://www.uv.es/CEFD/15/demiguel.pdf), 15, 2007, p. 4.

[25] Anyway, it cannot be considered a biological entity irrelevant for the law, which must guarantee proper protection' mechanisms (see Casabona, *Los genes y sus leyes*, p.).

[26] C. Casabona, *Preventive versus Symbolic Criminal Law in the Field of Human Biotechnology*, in C. Casonato, (ed.), *Life, Technology and Law*, CEDAM, Padova, pp. 231.

characterized by a common nuclear genetic heritage compared with another human being, dead or alive (art. 12, paragraph 7)[27].

As a fundamental legislative assumption[28] of the Italian law, the embryo is considered as a «subject» (art. 1), which must be guaranteed its own rights, in the same manner as the rights of other subjects. This embryo-centred perspective is the normative *file rouge* of the whole regulation, characterized by a thick and complex system of limits, sanctions, and prohibitions that are barely enforceable, as the resulting case law is clearly demonstrating[29].

According to the legislative purpose in protecting the embryo starting from the earliest stages of its biological development, the Italian Law 40 does not make any distinction among different legal definitions for regulating the *in vitro* embryo's treatment before its transfer to the woman's womb. In doing so, the Italian legislature does not adhere either to the gradualist approach delineated by the Spanish Constitutional Tribunal or to the fourteen day rule, which entails a legislative model characterized by "rigid flexibility"[30], rejecting both the UK and the Spanish approaches[31].

Whether it should be possible to assume that even within the Italian Law there is a distinction in the wording utilised to make reference to the biological entity derived from the assisted reproduction techniques, it is easily understandable how behind this linguistic definition there is not a normative pattern, as is true of the Spanish legal order. It is not the outcome of a gradualist approach through which is recognised the legal duty to distinguish among different situations (ex artt. 2 and 3, first paragraph, of Italian Constitution); on the contrary, the indiscriminate utilization of different words (*nasciturus*, test-tube embryo (conceived), embryo) in the text of the Italian Law, along with the absolute lack of any legal definition, can only be considered as the product of an unbalanced legislative choice and a potential factor of legal uncertainty and vagueness.

The Italian example also reveals how an apparently irrelevant issue such as the method and the formal structure of a law (inclusion of legal definitions) may strongly affect its very effectiveness, constitutional legitimacy and systematic coherence, because it expresses an *ex ante* legislative choice with regard to the normative model to be applied. The "fragile strictness" of the Italian

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[27] To guarantee the enforcement of such an absolute prohibition, the legislator has stated a criminal sanction corresponding to the imprisonment from ten to twenty years long (plus a fine from 600.000 to one million Euro) and the accessory sanction of the endless ban on exercising medical profession against the physician.

[28] The embryo's protection can be considered the effective theoretical and teleological ground – the essential core – of the legislative regulation more than the merely potential legislative aim to promote the solution for reproductive problems afflicting the (heterosexual) couples legitimated to have access to the reproductive techniques.

[29] This can be considered as the outcome of a legislative choice strongly and unilaterally oriented towards the embryo protection, incompatible with other constitutional principles and concretely inapplicable, according to Casonato C., *Introduzione al biodiritto*, 2006, p. 267.

[30] Penasa S., *La frágil rigidez de prohibiciones en la ley italiana de reproducción asistida contra la rigida flexibilidad del modelo español: contenido vs. procedimiento*, paper discussed at the 3d Meeting of the European Association of Global Bioethics (Bilbao, may, 4-5,2007) on "Research on stem cells: promises and difficulties".

[31] Thus confirming the unconventional trend within the normative models in the field of biolaw.

model[32] influences the possible application of new technological knowledge in the discussing issue (SCNT). In fact, after having completely banned the so-called reproductive cloning (art. 12, paragraph 7), art. 13 (paragraph 3, letter c) of the Law 40 likewise clearly states that any cloning interventions accomplished through nuclear transfer or premature division of the embryo are also banned, whether for procreative or research purposes.

Another clear distinction made by the Andalusian law on SCNT, and following the Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (adopted in Paris in 1998 and ratified by Spain in 2000) deals with the two different definitions of cloning: the reproductive and the therapeutic one. In the preamble and in art. 4, the law clearly differentiates the two techniques. As implicitly recognized in some part of the same law, this distinction is not so clearly based on the technique used for the two kinds of cloning, which is actually the same, but in the (different) purposes of the (same) technique. Thus, Article 1 speaks precisely about «exclusive therapeutic purposes» and art. 4 explicitly forbids any reproductive purpose. From this point of view, the above mentioned duty to destroy the pre-embryo is strictly connected with the prohibition of so called reproductive cloning[33].

3. The economic and financial issue: The absence of lucrative aim and donation

Some of the articles in the Act raise economic and financial issues.

The first paragraph of art. 3 provides the following: «Researching throughout the use of techniques of cellular reprogramming in human somatic cells with the purpose of its change into pluripotent stem cells, will be done on the basis of a research project which must be of scientific interest and *lacking any lucrative aim*» (emphasis added)[34]. But, is this a realistic view of things? One may ask if it is possible to find private or even public institutions willing to provide financial support while at the same time waiving any lucrative prospect -- of financial gain or other kinds of profit?

In combination with art. 9.3: «Researchers must make public the general results of the research projects once they have concluded (…) *notwithstanding the intellectual and industrial property rights* which could be derived from the research» (emphasis added). Are we facing the risk that,

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[32] Apart from to influence the specific modalities of the medical intervention on the woman, which significantly are included in the Chapter VI named "Embryo protection's measures".

[33] See Luk E. M., *The United Kingdom and Germany: Differing Views on Therapeutic Cloning and How the Belgian Resolution Brings Them Together*, supra note 21; Rhodes S. H., *Comment, The Difficulty of Regulating Reproductive and Therapeutic Cloning: Can the United States Learn Anything from the Laws of Other Countries?*, in *Pennsylvania State International Law Review*, 21, 341, 2003; R. Brownsword, *Stem Cells and Cloning: Where the Regulatory Consensus Fails*, in *New England Law Review*, 39, 2005.

[34] See Berlin I., Gorelick D., *The French Law on "Protection of Persons Undergoing Biomedical Research": Implications for the U.S.*, in *Journal of Law, Medicine & Ethics*, 31, 2003.

once the results of such research are made public, other groups of researchers or even a company in another country may patent them?

Article 5.5 on donation also raises a problem. While the reasoning behind paragraph 4, under which «Donation will never have lucrative or commercial nature», is well understandable and self-evident, the following paragraph seems more controversial: «Donation entails donors' rejection to receive any right of economic or of any other kind over the eventual results which derive direct or indirectly from the research project with the material donated»[35]. Is there a risk of exploitation of those who contribute the "raw materials" necessary for such research?[36]

4. Ethical review

Based on one of the fundamental principles for medical research included in the Declaration of Helsinki, the Andalusian statute provides for ethical review of any research project. In fact, article 3 provides for a double check, from the Committee of Research on cellular reprogramming and from the Autonomic Commission on Ethics and Health Research. From a classificatory perspective, these specialized bodies operate at a «micro level», corresponding to an additional review within the regulatory structure, through a number of localized ethical review committees. This kind of review is becoming one common element across different jurisdictions in regulating scientific research[37].

Considering this regulatory mechanism from a systemic perspective, the choice to provide procedural mechanisms for enforcing and applying legislative guidelines[38] may guarantee greater effectiveness of legislative regulation through continuity within its concrete application, consistent with a case by case approach which appears, again, to link the Spanish model to the common law approach.

Furthermore, the Autonomic Commission on Ethics and Health Research played an apparently relevant role also within the legislative making process, according to the *Exposición de Motivos*[39] of the Andalusian Law. An express reference to a Commission's report has been made, in which the Commission ruled in favour of biomedical research support also through nuclear transfer with therapeutic purposes, asking the Andalusian Government at the same time for a normative development capable of allowing this research technique. Even recognizing a normative

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[35] See G. R. Prettyman, Jr., *Ethical Reforms in Biotechnology Research Regulations*, in *Virginia Journal of Social Policy & the Law*, 15, 2007; D. M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, in *Washington & Lee Law Review*, 61, 2004.

[36] See infra a comparison with the Moore case.

[37] J.V. McHale, *Law and Clinical Research. From Rights to Regulation? An English Perspective*, in *Journal of Law, Medicine & Ethics*, 32, 2004.

[38] Attributing at the same time settled decision making powers to defined specialized bodies (the Committee and the Commission).

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interpretation of the nature of the *Exposición de Motivos*[40], the direct reference made to the Commission's report confirms a legislative method based on permeability among political and technical (in a broad sense) levels. This is a method – common again to the UK and the US regulatory system – which is becoming a more and more usual model for law-making processes at the national level (referring to both the Law 14/2006 and 16/2007 on Biomedical research)[41]. The involvement of expertise in both the law-making and law-enforcing processes expresses the relevance of the procedural mechanisms within the decisionmaking power, inspiring it and guaranteeing greater effectiveness and acceptance of the legislative provisions. Such a legislative model also recognizes a complementary role to the independent technical bodies[42].

Regarding the content of the Andalusian Law, the duplication of decisional bodies (Committee of Research on cellular reprogramming and Autonomic Commission on Ethics and Health Research), on the one hand, might be well-grounded in the precautionary principle, which imposes extreme caution in dealing with such a delicate matter. On the other hand, it might lead to a very stringent procedure to get the approval of the research projects. The positive or negative effect of this double check will depend on the homogeneity of the criteria adopted by the two bodies.

Yet another issue might arise from the lack of criteria in the statute for the composition of the Committee of Research on cellular reprogramming. Article 8 generally speaks about the «acknowledged prestige» of the components in the fields of biomedicine, law and bioethics, referring for everything else to regulations. Since the necessary interdisciplinarity and the delicacy of the criteria adopted for the composition of the ethical review committees, it would have been a better solution to provide in the law itself for a more precise framework for the organization and the composition of the body.

To increase the effectiveness and the enforcement of the Bodies' regulatory power, the example provided by the national legislation may provide useful lessons. In fact, Law 14/2006, in regulating

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[40] Article 88 of the Spanish constitution states that «*los proyectos de ley serán aprobado en Consejo de Ministros, que los someterá al Congreso, acompañados de una exposición de motivos y de los antecedentes necesarios para pronunciarse sobre ellos*». Spanish Constitutional Tribunal has constantly recognised how the lack of the *exposición de motivos*'s remission to the Parliament «*sólo tendría relevancia si hubiese menoscabado los derechos de los Diputados o grupos parlamentarios del Congreso*» (STC 108/1986). See ESCUDERO MÁRQUEZ G., *La iniciativa legislativa del Gobierno*, in *Cuadernos y debates*, n. 90, 2000; SAIZ MORENO F. e DA SILVA C. (coords.), *La calidad de las leyes*, Parlamento Vasco, Vitoria, 1989; SANTAMARÍA PASTOR J., *Art. 88*, in GARRIDO FALLA F. (ed.), *Comentarios a la Constitución*, Editorial Civitas, Madrid, 1985, p. 1267 ss.

[41] The role of the national authorized Commission it has been expressly recognized by the Law 14/2006's Exposición de Motivos, remainding how «*la Comisión Nacional de Reproducción Humana Asistida insistió desde la promulgación de la citada Ley en la necesidad de acometer con prontitud la reforma de la legislación vigente, con el fin de corregir las deficiencias advertidas y de acomodarla a la realidad actual*».

[42] CASONATO C., *Introduzione al biodiritto*, op. cit., pag. 130. The Canadian legislative experience is particularly meaningful: see CASONATO C., *Procreazione assistita e pluralismo: l'esempio dell'Assisted Human Reproduction Act canadese*, in CASONATO C., FROSINI T.E., GROPPI T. (a cura di), *La fecondazione assistita nel diritto comparato*, Giappichelli, 2007; SOMERVILLE M., *Social-Ethical Values Issues in the Political Public Square: Principles vs. Packages*, in *Journal of Law, Medicine & Ethics*, 2004, p. 736 ss.

the Human Assisted Reproduction National Commission, clearly states its object, composition and functions (art. 20). Notably, the content of the fourth paragraph of article 20[43] represents a useful pattern in order to reject the criticisms grounded on a vague and generic attribution of power within the Andalusian Law. Anyway, the Committee's functions provided by article 8 of the Andalusian Law seem to be sufficiently individualised and complete in order to guarantee an effective role in evaluating (letters a and b), checking (letters c, d and e) and sanctioning (letter f) functions.

Legislative technique based on vesting independent specialised bodies with a participatory function in the decisionmaking process through both preventive and favourable report of the Commission (art. 3, paragraph 5) and compulsory and binding authorization of the Committee (art. 3, paragraph 2), may be considered another balanced and effective normative option. The effectiveness of the Bodies' provided powers, especially in the light of the checking function on the research projects is crucial in order to guarantee the efficacy of the legislative delegation of competencies to these Bodies. A potential point of criticism may concern the achievement of a reasonable balance between the necessity to guarantee the legal certainty and the procedural adaptability to whose research projects not expressly provided by the law, especially considering the broad content of the aims (undefined «therapeutic purposes») of the Andalusian Law[44], which could combine in order to bring about a critical level of legal uncertainty[45].

Despite this eventual point of criticism and the issue of the Member's appointment procedure, the Andalusian Law seems to fulfil the main conditions in order to guarantee the efficacy and the enforceability of the normative model. In fact, the Law mentions both which experiments may be authorised (art. 3) and which commission or authority is allowed to grant specific authorizations (art. 3 and 8), in favour of well-described (art. 3, paragraph 1 and 4, art. 8, paragraph 2, letter b) and registered (art. 3, paragraph 6) projects, under its control and supervision (art. 8, paragraph from c to f)[46]. A potential vacuum within this authorizing and checking mechanism may be represented by

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43 «*Será preceptivo el informe de la Comisión Nacional de Reproducción Humana Asistida en los siguientes supuestos:*

a) Para la autorización de una técnica de reproducción humana asistida con carácter experimental, no recogida en el anexo.

b) Para la autorización ocasional para casos concretos y no previstos en esta Ley de las técnicas de diagnóstico preimplantacional, así como en los supuestos previstos en el artículo 12.2.

c) Para la autorización de prácticas terapéuticas previstas en el artículo 13.

d) Para la autorización de los proyectos de investigación en materia de reproducción asistida.

e) En el procedimiento de elaboración de disposiciones generales que versen sobre materias previstas en esta Ley o directamente relacionadas con la reproducción asistida.

f) En cualquier otro supuesto legal o reglamentariamente previsto».

44 According to article 1, first paragraph, the object of the Law consists in regulating the SCNT exclusively for therapeutic purposes.

45 CASABONA ROMEO C. M., , p. 363.

46 Ivi, p. 364.

the lack of enforceable and binding investigatory instruments[47], aimed at an exhaustive collaboration of research centres directly involved in the authorizing procedure[48]. The need to provide for organizational and operative means, essential for empowering the general legal provisions, comes out in all its normative prominence: without any concrete and enforceable means to know the concrete research projects and to impose the assumed decisions (maybe the project's suspension), these authorities will lack effective authorizing and evaluating powers, performing a purely symbolic function. Again, the UK system represents a useful basis for comparison because the *Human Fertilization and Embryology Authority* is vested with operative powers that permit effective enforcement of its regulatory pronouncements. For this reason, some scholars refer to its "near-legislative" nature[49].

5. Anonymity and confidentiality

A number of Countries regulate the anonymity of the donor of gametes or genetic material and the confidentiality of his/her data. Article 5 of the Andalusian statute states that «donation will always be anonymous and it must be guaranteed the confidentiality and security of data concerning the identity and personal data of donors». It is well known that anonymity and confidentiality, generally speaking, are not the same. Spanish law 14/2007 on biomedical research provides a very strict definition of anonymous data: «"Anonymised or irreversibly disassociated data": data that cannot be associated to an identified or identifiable person as the nexus with all information that identified

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47 On this issue, CRAIG P., *Administrative Law*, Sweet&Maxwell, Londra, 1989, p. 180 ss.; BRADLEY A. e EWING K., *Constitutional and Administrative Law*, Longman, New York, 1997; PATTINSON S., *Some problems challenging the UK's Human Fertilisation and Embryology Authority*, in *Medicine and Law*, n. 2, 2005, p. 393 ss.

48 It has to be avoided the risk that «*estas normas caigan en saco roto, como ha venido sucediendo en años anteriores*», quoting LACADENA J., *La Ley 14/2006 sobre Técnicas de Reproducción Humana Asistida: consideraciones científicas y éticas*, p. 178, making directly reference to the Law 14/2006 but from a generalizable perspective.

49 PLOMER A., *Derecho, ética y política en relación a la investigación con células troncales en Reino Unido y Estados Unidos*, op. cit., p. 124). In UK system the empowerment of the general provisions plays an essential role within the legislative regulation. According to section 39 («Powers of members and employees of Authority»), significantly under the Title «Enforcement», of Human Fertilization and Embryology Act (UK):

«(1) Any member or employee of the Authority entering and inspecting premises to which a licence relates may: (a) take possession of anything which he has reasonable grounds to believe may be required: (i) for the purpose of the functions of the Authority relating to the grant, variation, suspension and revocation of licences, or (ii) for the purpose of being used in evidence in any proceedings for an offence under this Act, and retain it for so long as it may be required for the purpose in question, and (b) for the purpose in question, take such steps as appear to be necessary for preserving any such thing or preventing interference with it, including requiring any person having the power to do so to give such assistance as may reasonably be required.

(2) In subsection (1) above: (a) the references to things include information recorded in any form, and (b) the reference to taking possession of anything includes, in the case of information recorded otherwise than in legible form, requiring any person having the power to do so to produce a copy of the information in legible form and taking possession of the copy.

(3) Nothing in this Act makes it unlawful for a member or employee of the Authority to keep any embryo or gametes in pursuance of that person's functions as such».

the subject has been destroyed or because such association demands a non-reasonable effort, understood as the use of disproportionate amounts of time, expense and work» (art. 3, lett. i). From this perspective, the Andalusian statute is not clear on the distinction between the anonymity of the donation and the confidentiality of the data. If data must be confidential, and not anonymous, in order to permit access by the donor to the project results relevant for the donor's health (art. 6.1. lett. d), it is not clear what is the meaning of the anonymity of donation provided for in art. 5.

A second point may be made regarding the provision concerning the donor's right of access to the relevant results for his/her health.

6. Access to relevant results: genetic counselling, "unexpected diagnosis" and consent

Genetic data – within the field of personal data – are particularly sensitive, further increasing the complexity of the multilayered[50] construction of the concepts of "privacy" and the "private sphere"[51]. According to Recommendation No. R (97) 5 on the Protection of Medical Data of the Committee of Minister of the Council of Europe (1997), genetic data «refers to all data, of whatever type, concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals», specifying indeed how «it also refers to all data on the carrying of any genetic information (genes) in an individual or genetic line relating to any aspect of health or disease, whether present as identifiable characteristics or not».

Inter alia, taking in consideration this first level of legal relevance of genetic data, strictly linked to the subject from whom the data has been derived, they can reveal predisposition to certain diseases; diseases that can be predicted with certainty (for example, monogenic diseases like Huntington's disease) or that can be presumed with a variable degree of probability depending on the individual's life style, nutrition, environmental context, and so on. So, compared with other biomedical information, genetic data are peculiar because of their predictive character, as well as the gap between the ability to diagnose and to treat the disease, and the psychological problems that can arise from the communication of a possibility, probability, or certainty of becoming afflicted with a disease.

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[50] Samuelson, *Privacy as intellectual property?*, in *Stanford Law Review*, 52, 2000, p. 1171, makes reference to a «multi-dimensional perspective on the nature of a person's interest in personal data».

[51] On genetic privacy, see R. Cole, *Authentic Democracy: Endowing Citizens with a Human Right in Their Genetic Information*, in *Hofstra Law Review*, 33, 2005.

In order to tackle the latter of these issues, more recent laws (both hard and soft law) combine genetic information with genetic counselling[52]. And taking into account the possibility of incidental diagnosis, new trends in best practices on biomedical research charge the researchers to ask the donor for the person (himself/herself, the family doctor, a third person) to be told about the unexpected information[53].

Neither of these problems are addressed by the Andalusian law, which does not mention either genetic counselling or the possibility of unexpected information about the donor's health[54].

According to the above mentioned international source (Recommendation No. R (97) 5), it is also stressed that «genetic line is the line constituted by genetic similarities resulting from procreation and shared by two or more individuals», directly recognizing the shared nature of genetic data among different "blood-related relatives", an intrinsic character which results in the multilevel nature of genetic data. The Working Document on Genetic Data, issued in 2004 by the Data Protection Working Party (Article 29)[55], has confirmed the complex nature of genetic data, affirming that «while genetic information is unique and distinguishes an individual from other individuals, it may also at the same time reveal information about and have implications for that individual's blood relatives (biological family)». Therefore, genetic data are at the same time unique (making reference to the "source-subject") and shared (from the viewpoint of his/her blood relatives). The irreducibly relational nature of genetic data appears, clearly demonstrating the duty to distinguish – also at the regulatory level – between the genetic data's (individual) source and the

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[52] In soft law, see, among others, art. 27 of the *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research*, 2005 («If research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them. That shall be done within a framework of health care or counselling ») and art. 8 of the new *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes* (May 2008): «1. When a genetic test is envisaged, the person concerned shall be provided with prior appropriate information in particular on the purpose and the nature of the test, as well as the implications of its results.

2.For predictive genetic tests as referred to in Article 12 of the Convention on Human Rights and Biomedicine, appropriate genetic counselling shall also be available for the person concerned.

The tests concerned are:

– tests predictive of a monogenic disease,

– tests serving to detect a genetic predisposition or genetic susceptibility to a disease,

– tests serving to identify the subject as a healthy carrier of a gene responsible for a disease.

The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family, including possible implications concerning procreation choices.

Genetic counselling shall be given in a non-directive manner.»

[53] D. A. Grimm, *Informed Consent for All! No distinction*, in *New Mexico Law Review*, 37, 2007, stress the fact that in the treatment context has a different purpose than in the research context, requiring a different level of protection and consent for the patient than for the research subject.

[54] Due to the impact genetic information has on individual identity, the degree of legal protection should be tailored to the context, according to K. M. Gatter, *Genetic Information and the Importance of Context: Implications for the Social Meaning of Genetic Information and Individual Identity*, in *Saint Louis University Law Journal*, 47, 2003.

[55] An independent advisory body constituted on the ground of art. 29 of 95/46/CE Directive, which can be considered a soft law source within the EU context.

potential subjects who may become involved due to the use of genetic data for both diagnostic and research purposes[56].

Different subjective spheres may interact and even clash, due to a biological sharing of genetic information which cannot be considered as legally irrelevant, raising at least the question «whether or not genetic data belong exclusively to the single, specific individual from whom they are collected, and to whether family members have the right to access to such data even in the absence of the individual's consent»[57]. The shared nature of genetic data seems to open new legal perspectives[58], according to which biological family members possess a right to be provided information that may have implications for their own health and future life[59].

This renewed development of the biological and familiar relationship is introducing a new net of rights and potentially clashing interactions within the biomedical field that the law cannot ignore[60]. The law must face a genetic privacy paradox, whereby any subject exercising the right to know his/her own genetic data impinges upon the freedom of others members of the same genetic family[61]. From this complex normative structure a new legal category seems to emerge: the so-called «co-subject»[62] made up of the members of the same genetic line of the source-subject, to whom must be granted an intermediate legal status, a hybrid legal protection in order to distinguish them from mere third parties[63].

In order to contextualise these theoretical assumptions, the Andalusian Law should have considered also the legal situation of the donor's co-subjects in regulating genetic counselling, "unexpected diagnosis" and consent procedure, because of the normative need to harmonize, and balance, the overlapping and sometimes clashing individual interests at stake. The essential rule should refer to the reciprocity and solidarity principles such as the free development of genetic privacy, due to the dual nature – both individual and collective – of informational self determination[64]. On the contrary, the Andalusian legislature, among many others, chose a mono-dimensional approach, focusing its

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[56] Rodotà S., *La vita e le regole. Tra diritto e non diritto*, Feltrinelli, 2006, p. 190, makes reference to a double relational structure, according to which both the source from who it has been derived and other subjects whose is referable to concur to define a genetic data.

[57] Working Document on Genetic Data, Data Protection Working Party (Article 29).

[58] It may be also included a gradual evolution from an exclusively privacy-property protection to a personality-property one.

[59] A new legally relevant category seems to emerge – the biological group – which «does not include family members such as one's spouse or foster children, whereas it also consists of entities outside the family circle – whether in law or factually – such as gamete donors or the woman who, at the time of childbirth, did not recognise her child and requested that her particulars should not be disclosed – this right being supported in certain legal systems», according to the Working Document on Genetic Data, Data Protection Working Party (Article 29).

[60] See S. N. Dembo, *What Your Genes Know Affects Them: Should Patient Confidentiality Prevent Disclosure of Genetic Test Results to a Patient's Biological Relatives?*, in *American Business Law Journal*, 43, 2006.

[61] Santosuosso, p. 538.

[62] Hondius F. W., Protecting medical and genetic data, in European Journal of Health Law, 4, 1997, p. 381.

[63] According to point 58 of the above mentioned Recommendation R 5 (97) of Council of Europe.

[64] Nicolás Jiménez P., *La protección jurídica de los datos genéticos de carácter personal*, Comares, Bilbao-Granada, 2006, p. 96.

protection solely upon the donor's subjective situation, without making any reference to biological family members who are potentially interested and involved in the unexpected results of research (articles 5 and 6). In so doing, the Andalusian Law on SCNT doesn't seem to share the Data Protection Working Party statement, according to which, given the highly sensitive nature of this issue, a balance must be found between a data subject's right not to disclose his/her genetic information and the potentially serious implications the disclosure and use of such information could have upon the members of a biological family.

From a comparative perspective, the UK Human Tissue Act (2004) explicitly states that the Human Tissue Authority has the power to dispense with the need for donor's consent, under certain circumstances (section 7). One of the required conditions to allow the Authority to dispense with the donor's consent is that «it is desirable in the interests of another person (including a future person) that the material be used for the purpose of obtaining scientific or medical information about the donor» (letter c), thereby applying a multi-dimensional approach to the disclosure and use of shared genetic information. Also the Italian legal order may be defined as multi-dimensional, even if only from a general perspective, due to the above-mentioned absolute ban of any research in the SCNT field. In fact, a recent Authorization[65] of the Personal Data Protection Authority, in regulating genetic data's treatment (2007), has stated – with regard to the data communication and dissemination (point 9 of Authorization) – that genetic data can be transmitted whether it is necessary to protect health and genetic identity of a third subject belonging to the same genetic line, even if exclusively in case of lack of consent for physical impossibility, for being of unsound mind or incapacity and in order to permit a conscious reproductive choice and for therapeutic or preventive treatments.

Eventually, the predictive feature of genetic data involves not just the donor, but all of his/her "blood-related relatives". This peculiar feature of genetic data further complicates the issue of informed consent. If the information gathered by the donation of one person may be extended to all family members (sometimes even to the group from which the person is drawn), and may jeopardize them in terms, for instance, of genetic discrimination, then the logic and spirit of informed consent would seem to require that information and consent be given also to and by them. In other words, anyone whose interests are at stake should be consulted.

If interpreted in this broad fashion, the privacy/consent issue becomes almost impossible to resolve, and as a result, it would put a complete stop to all research in genetics. Nevertheless, the problem remains, thus further reflection is required[66].

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65 Available in the Official Gazette, 65, 2007, March, the 19th.

66 See, among others, D. Hausman, *Protecting Groups from a Genetic Research*, *Bioethics*, 2008, 22, 3, 157.

7. Confronting the Andalusian statute with the U.S. and Californian Approach

A. Definitions

The Andalusian statute carefully avoids any mention of the term "human cloning" to describe the types of research that it authorizes. Instead, Article 2 of the Andalusian statute offers a scientific description of somatic cell nuclear transfer (SCNT) as "a technique of cellular reprogramming consisting of the transfer of the nucleus of a somatic cell to the cytoplasm of an ovocite previously enucleated." Article 2 then proceeds to categorize the product of SCNT -- a cloned embryo -- as a "somatic pre-embryo," which is "a group of cells resulting from the successive division of the cellular form created throughout techniques of cellular reprogramming, like the nuclear transfer or other similar techniques, from the moment such a technique is applied and up to fourteen days after." The only provision of the statute that employs the term cloning is Article 4, which forbids cloning human beings, defined as "researching with techniques of cellular reprogramming with somatic cells to generate pre-embryos with reproductive purposes." Thus, the term "cloning" is used solely to refer to cloning for reproductive purposes, which the Andalusian Act forbids. But cloning for therapeutic or research purposes is characterized as nuclear transfer or cellular reprogramming, rather than cloning, and is expressly permitted.

All of this suggests that Andalusia is attempting to avoid the controversial issue of human cloning through the clever use of definitions. In a similar fashion, some legislators in the U.S. have tried to sidestep the debate over human cloning by proposing bills that would define cloning as occurring only with the implantation of a cloned embryo in a woman's uterus.[67] For example, a law proposed in the U.S. Congress, the *Human Cloning Ban Act* of 2005, provides that "the term 'human cloning' means implanting or attempting to implant the product of nuclear transplantation into a uterus or the functional equivalent of a uterus."[68] If these proposed bills are enacted into U.S. law, only reproductive cloning would be prohibited and the creation of a cloned human embryo for the purpose of stem cell research would not even qualify as "human cloning." Both the Andalusian statute and the laws proposed in the U.S. Congress attempt to attain substantive objectives through the manipulation of language. This technique poses a risk of "label fraud" that resembles the approach of Humpty Dumpty in Lewis Carroll's famous story, Alice in Wonderland: "When *I* use a word," Humpty Dumpty said in a

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[67] Human Cloning Ban Act. (2005). 2005 Cong. US S 1520, 109th Cong, 1st Sess. S. 1520 (July 27, 2005); Human Cloning Prohibition Act. (2005). To prohibit human cloning and protect stem cell research, 2005 Cong. US S. 876, 109th Cong, 1st Sess (April 21, 2005); Human Cloning Prohibition Act. (2003). To prohibit human cloning and protect stem cell research, 2003 Cong U.S. S. 303, 108th Cong., 1st Sess (Feb. 5, 2003).

[68] 2005 Cong. U.S. H.R. 3932, 109th Cong., 1st Sess. (Sept. 28, 2005).

rather scornful tone, "it means just what I choose it to mean -- neither more nor less." "The question is," replied Alice, "whether you *can* make words mean so many different things."[69] Neither the U.S.nor Andalusia should reach the laudable result of permitting the cloning of human embryos for the purpose of stem cell research by masking the issue behind technical jargon or pretending that SCNT is not cloning. For this reason, I argue that these questions cannot be resolved by resort to scientific terminology, nor can they be evaded by the creation of new legal language.[70]

B. Convergences

Congress has never actually enacted any of these bills into law, thus there is no federal law that forbids human cloning or regulates stem cell research in the United States. However, the state of California -- like the region of Andalusia -- has enacted its own laws to comprehensively regulate stem cell research. In November 2004, California voters approved Proposition 71, the California Stem Cell Research and Cures Initiative, which created the California Institute for Regenerative Medicine (CIRM) and authorized the state to issue up to $3 billion in general obligation bonds to fund stem cell research. CIRM regulations apply only to research that is funded by the state, but a parallel set of guidelines promulgated by the California Department of Health and Human Services also regulate privately-funded research within California.

There are many similarities between the statutory schemes set forth by the Andalusian and Californian laws. Like Andalusia, California prohibits human reproductive cloning, such as reproductive uses of SCNT.[71] Like Andalusia, the California regulations permit stem cell research only when it is pre-approved by an expert body, which in California is known as a Stem Cell Research Oversight Committee (SCRO).[72] And both laws limit the time frame within which such research may occur -- to 14 days in Andalusia, and 12 days or the formation of the primitive streak in California.[73]

There are also remarkable parallels between the Californian and Andalusian provisions regulating the donation of oocytes and other "raw materials." Both statutes require voluntary and informed consent on the part of donors.[74] Both statutes prohibit compensation of donors, beyond

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69 LEWIS CARROLL, THROUGH THE LOOKING GLASS 100 (Puffin Classics ed. 1984) (1872).

70 Radhika Rao, Property, Privacy, and Other Legal Constructions of the Embryo.

71 17 Cal. Code of Regs. Section 100030 (a).

72 17 Cal. Code of Regs. Sections 100060 and 100070.

73 17 Cal. Code of Regs. Section 100030(b) provides that the following activities are not eligible for CIRM funding: "The culture in vitro of (i) any intact human embryo or (ii) any product of SCNT, parthogenesis or androgenesis, after the appearance of the primitive streak or after 12 days whichever is earlier. The 12 day prohibition does not count any time during which the embryos and/or cells have been stored frozen."

74 17 Cal. Code of Regs. Section 100080(a)(2)(A).

reimbursement for their actual expenses.[75] And both statutes definitively reject the right of donors to receive any profit from the results of such research. Article 5(5) of the Andalusian statute provides that "Donation entails donors' rejection to receive any right of economic or of any other kind over the eventual results which derive direct or indirectly from the research project with the material donated." And the California statute goes even further by including within its informed consent provision a requirement that donors be notified that they cannot share in any profits. Hence, in California, the donors of human gametes, embryos, somatic cells or other tissue used in the derivation of new stem cell lines must be warned: "Although the results of research including donated materials may be patentable or have commercial value, the donor will have no legal or financial interest in any commercial development resulting from the research."[76]

Accordingly, both Andalusia and California prohibit compensation to those who donate their body parts for stem cell research, and they also preclude donors from receiving any share of the profits that may result from such research. Such a result mirrors the famous ruling in *Moore v. Regents of the University of California*,[77] in which the California Supreme Court held that Mr. Moore's diseased spleen was no longer his property once it had been removed from his body. At the same time, the Court found that the Mo cell line – which had been created from Moore's spleen cells and, ironically, named after him – was the property of the researchers who had been granted a patent upon it. The court permitted Moore's claims for breach of fiduciary duty and lack of informed consent only because Moore's physician failed to inform him of his research interest in Moore's spleen and the possibility of profit. Yet the court rejected Moore's claim for conversion and a right to share in the profits resulting from the Mo cell line on the grounds that his spleen was not his property.

Several scholars have criticized the lopsided rule established by *Moore* because it demands altruism on the part of the donor, who is expected to give his or her body parts gratis in order to advance scientific research, while anticipating profits for everyone else who participates in the venture, including researchers, universities, and private corporations.[78] It appears unfair to expect altruism on the part of the donor while permitting everyone else who participates in the venture to reap a share of the profits. This points to an important divergence between the California regime and the Andalusian law. In California, researchers and the universities and companies that engage

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[75] 17 Cal. Code of Regs. Section 100080(a)(2)(B) provides that "Donors of human gametes, embryos, somatic cells or tissue did not receive valuable consideration. This provision does not prohibit reimbursement for permissible expenses."

[76] 17 Cal. Code of Regs. Section 100100(b)(I).

[77] *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120 (1990).

[78] See, e.g., Radhika Rao, Coercion, Commercialization, and Commodification: The Ethics of Compensation for Egg Donors in Stem Cell Research, 21 Berkeley Tech. L. J. 1055, 1061 (2006); David E. Winickoff, Bioethics and Stem Cell Banking in California, 21 Berkeley Tech. L.J. 1067, 1093 (2006) (referring to this as the problem of "asymmetrical altruism").

in stem cell research are assumed to gain ownership of any resulting inventions, and they are permitted to retain the bulk (75%) of their profits. Thus California regulations of stem cell research replicate the lopsided rule of Moore. But unlike California, Andalusia is not guilty of "asymmetrical altruism;" to the contrary, Article 3 also requires altruism of researchers, authorizing only research that is "of scientific interest and lacking any lucrative aim." Thus the Andalusian statute appears to be much more fair and evenhanded in its treatment of researchers and research subjects because it insists upon altruism from everyone who participates in such research. Despite its lofty aspirations, the Andalusian statute may be unrealistic and unworkable in its expectation that scientists, universities, and private corporations would be able and willing to engage in such research without any hope of profit.

C. Divergences

There are other divergences between the Andalusian and California laws. Both Andalusia and California prohibit reproductive cloning, but California also prohibits the introduction of human stem cells into nonhuman primate embryos; the introduction of any stem cells, human or nonhuman, into human embryos; the breeding of any animals into which human stem cells have been introduced; and the transfer to a uterus of a genetically modified human embryo. All of these additional prohibitions appear to flow from an excess of caution, and from popular fears regarding cloning and stem cell research.

In addition, California specifies that oocyte donors be provided information regarding "the risks of ovarian hyperstimulation syndrome, bleeding, infection, anesthesia and pregnancy." Moreover, women who donate eggs for CIRM-funded research suffer must be guaranteed free medical care if they suffer any harm or injury as a result of the oocyte donation process.[79] In the U.S. context, this California requirement of medical care appears unique and extraordinary in its protection of the health of women, but such a provision is obviously unnecessary in Spain, Italy, and other countries where the right to health care is guaranteed unconditionally to all citizens.

D. Privacy of Genetic Data

Finally, the California regulations require researchers either to use anonymous samples or to inform donors of the possibility of recontact. The regulations regarding informed consent require researchers to tell donors whether or not their identities will be ascertainable by those who work

[79] 17 Cal. Code of Regs. Section 100095(c) provides: "The CIRM-funded institution shall develop procedures to ensure that an individual who donates oocytes for CIRM-funded research has access to medical care that is required as a direct and proximate result of that donation. Such care shall be provided at no cost to the donor. If a donor is medically insured, the donor shall not be required to claim any treatment costs through her own insurance policy."

with the resulting cells or products.[80] If the donor's identity is to remain associated with the cells or products, then the investigator must also inform the donor of any plans for recontact whether for the purpose of providing information about research findings to donors or for the purpose of requesting additional health information. After donation, an investigator may recontact a donor only if the donor consents at the time of donation. Thus, the California regulations protect the privacy of donors, but they fail to consider the impact of such information upon biological family members who may share privacy interests in such data. Yet a requirement that everyone who shares a privacy interest in genetic data provide informed consent obviously would be extremely burdensome and would render the statutory scheme unworkable.

[80] 17 Cal. Code of Regs. Section 100100(b)(1)(B).