# The Need for a Procedural Approach to Human Embryonic Stem Cell Research: An Emerging Regulatory Model within EU

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## La necesidad de un enfoque procedimental de la investigación con células madre embrionarias: Un modelo regulatorio emergente en la UE

ABSTRACT: This paper proposes a classification of hESC research regulation by shifting from the statutory content of relevant national Laws to the method of decision-making process, in order to verify whether it is possible to identify a connection between the concrete characters of that process and its outcome. A set of procedural indexes are identified and applied to the analysed legal systems. According to an increasing fulfilment of indexes, we may individuate two main regulatory families: the 'value oriented' and the 'procedure oriented' ones. The latter is developing an increasing impact within European context: it is characterised by a mix of regulatory sources, each developing a specific function. Within this model, statutory law cannot infringe a regulatory space reserved to expertise and self-regulation, developing a subsidiary function; furthermore, it has to recognise the integrative role of expertise within statutory-making process.

KEYWORDS: human embryonic stem cell research, regulation, self-regulation, procedural indexes, legal system

RESUMEN: Este artículo ofrece una clasificación de las regulaciones de la investigación con células embrionarias basada en las características del procedimiento de toma de las decisiones político-legislativas. Ha sido identificado un conjunto de parámetros, cuya aplicación ha llevado a la identificación de dos modelos fundamentales. Este último se está imponiendo en el contexto europeo: está caracterizado por la presencia de una combinación de fuentes regulativas, cada una de las cuales desarrolla una función normativa específica. En este modelo, la ley tiene que respetar un área normativa reservada a la pericia (expertise) y a la auto-regulación, perteneciéndole exclusivamente una función subsidiaria; además, debe ser reconocido el papel integrador de la expertise a lo largo del procedimiento legislativo.

PALABRAS-CLAVE: investigación con células madre embrionarias, regulación, auto-regulación, índices procedimentales, sistema legal

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## 1. The legal dimension of Hamlet's Dilemma: To Legislate or Not To Legislate?

Decision making institutions within European Union are facing with a legal version of Hamlet's dilemma when they come to regulate human embryonic stem cell (hESC) research. It can be expressed by means of the question: To legislate or not to legislate? The question relates to the adequateness of statutory law in guaranteeing a sufficiently adaptable regulation in a field – hESC research – inevitably characterised by the fluidity and almost never ending progress of scientific

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knowledge and medical and experimental applications. Alternatively, regulation can be guaranteed by different (even concurring) regulatory sources, inside or outside traditional legal means (such as statutory law, case-law, secondary regulation): professional ethics codes; guidelines of professional organisation and international boards or scientific societies; self-regulation.

It is possible to summarise the problem of regulating hESC research following two different dimensions.

On the one hand, it is to be individuated who is entitled to regulate, in order to achieve a reasonable balancing between different rights and interests involved:

a) Does this task belong to the legislator, who should act alternatively by means of a strict or a 'principle based' regulation, leaving to each research institution or group to provide a concrete balancing, according to guidelines expressed by Law and controlled by a system of monitoring, evaluating and sanctioning institutional mechanisms?

b) Does it belong to Judges, according to a case by case approach, when a clash of interests emerges, providing for *ad hoc* judicial remedies?

c) Or does it belong to an authority, an independent body providing for binding regulation entitled with enforcement, control, inspection and updating functions?

d) Ultimately, does it pertain to self-regulation, according to which regulatory structure shows a diffuse and plural nature, in which professional representative bodies and then each research centre provide a specific set of rules?

On the other hand, these potential regulatory means may be considered as exclusive or alternative: in other words, has the relationship – the reaction – between different regulatory sources to be understood in the sense of reciprocal exclusiveness or mutual integration?

To answer this question, we propose different regulatory models:

a) 'communicating vessels' model: level of scientific uncertainty characterising hESC research regulates the measure of each different source. The more scientific uncertainty increases, the more heteronomous intervention by the legislator to introduce legally binding rules is justified;

b) 'integration' model: it is characterised by the 'specialisation' of different regulatory sources, each developing a specific function which

ISSN: 1989-7022 DILEMATA, año 3 (2011), nº 7, 39-55

goes to integrate the other ones;

c) 'subsidiarity' model: it recognises the centrality of self-regulation which is replaced with other sources exclusively when it is incapable to guarantee a satisfactory level of rights' protection.

## 2. Convergence within the European legal framework: the rise (and fall?) of statutory source.

Within the European legal framework, a prevalence of statutory intervention is emerging, as necessary (even if not sufficient) regulatory means. As I suggest in the introduction, the kind and number of activated sources characterise a legal system in terms of specific implemented regulatory models. Traditionally, many scholars propose classifications based on the content of regulations: according to the spectrum of admitted research and the limits introduced by law in terms of both researches' aims and means, we may face with closed or open models; liberal or restrictive[1]; imposing or permissive[2].

What happen if we try to modify classification indexes? The proposal is to shift from statutory content to the method of decision-making process, in order to verify whether it should be possible to identify a connection – a 'cause and effect' mechanism – between the concrete characters of that process and its outcome[3]. In other words: do transparency and expertise participation orient the content of the law? And in what direction? Which is the role of society – in terms of both people directly involved (patients, parents, researchers, representative associations) and people as a whole (that may be affected by the research's results) – within this process?

A comparison among different national legal systems has been conducted: these systems are UK, Spain, France and Italy. For the sake of the reasoning, the paper will focus on the analysis of French and Italian legal systems, as paradigms of respective regulatory models. Before analysing the regulatory substance of these systems, the focus has been directed to the procedures through which they choose – between different options – a specific regulatory mechanism. Which regulatory models can we derive from this analysis?

Research focus consists therefore in analysing and individuating concrete nature and elements characterising different decision-making and enforcement processes. To drive the analysis, it has been necessary to individuate a set of indexes and parameters, on the ground of which to identify the nature and function (and outcomes in terms of substantial

DILEMATA, año 3 (2011), nº 7, 39-55 ISSN: 1989-7022

effectiveness, constitutional legitimacy and social acceptability) of each model. Proposed indexes are the following:

a) Expertise involvement: both during the decision making and enforcement processes, it may increase – as it will be shown during the paper – a number of parameters, such as the degree of decision's legitimisation, which is incremented by a scientific source integrating the traditional democratic and constitutional ones; its feasibility, in terms of scientific and technical knowledge entering into the political mechanism; its accountability, public trust and confidence; its effective enforceability;

b) Legal definitions: legally binding definitions goes to identify the 'regulative content' of scientific or medical concepts and entities; their appropriateness depends on the level of scientific knowledge assumed within the decision-making process, in order to make them as acceptable, coherent and feasible as possible; the more the decision making process is participative and inclusive, the more that kind of regulatory means will be able to perform its theoretical function;

c) Updating clause: it evokes the inclusion of a provision providing for a Parliament's duty (or option) to analyse, evaluate and eventually reconsider the content of the Law on the ground of its concrete enforcement and efficacy; its consistency with scientific, but also social, ethical, and economical development; its adaptability to the hypothetical new asset; it allows to consider statutory intervention (and its decision making process) not exclusively in terms of a static and instantaneous means, which is done "one time for ever", but also as dynamic and progressive one, constantly adaptable to a changing scientific reality;

d) Technical rules: reference to expertise (but also to professional ethics rules) or medical practice finds a place in the Law, acting as mechanism of integration between heteronomous sources (statutory law) and the autonomous (self-regulatory) ones, deriving directly from the inside of the scientific-medical framework; it guarantees a potentially continuous process of integration between regulative source, the Law of Parliament recognising the function of expertise, and medical science as (indirect) regulative means;

e) Decision making criteria: the Law itself introduces a predefined and stable (compulsory) mechanism to change or modify regulation, based on a set of both institutional and substantial requirement to be performed for the legitimacy of the process (see last version of the French Law on Bioethics, 2011), in order to connote the latter in the sense of both society and expertise participation but also verifiability of its performances compared with aims, context and results;

ISSN: 1989-7022 DILEMATA, año 3 (2011), nº 7, 39-55

f) Law enforcement and law evaluation: the law provides a formalised mechanism through which it is possible to evaluate its own performances in the light of potential reforms and adjustment to scientific, ethical and social developments; it may occur by means of both institutionalised public forum (see French system) and ad hoc bodies, entitled to give opinions useful for monitoring law enforcement.

## 3. The outcome: 'value oriented' and 'procedure oriented' models.

The comparison is aimed at demonstrating how and how much the *quomodo* of the decision-making process determines and connotes statutory assessments. This conditioning effect expresses itself especially when the legislator acts exercising its discretionary power, which is oriented and also limited by participation/consultation and control/monitoring mechanisms. They guarantee – although according to different degrees of pervasiveness and systematisation – not only adequateness but also transparency, accountability and legitimacy of regulation[4]. According to an increasing fulfilment of anticipated indexes, we may individuate two main regulatory families, not exactly coinciding with the traditional legal ones (civil law and common law): the 'value oriented' and the 'procedure oriented'.

### 3. 1.The value oriented model: a closed and self-referential decision-making process.

Italy represents an example of a model embracing both decision-making process closure and (presumed) self-sufficiency of the law, which is functional to an absolute embryo protection, banning any intervention not aiming at diagnostic or therapeutic purposes in favour of the same embryo[5]. It has to be outlined that Italy lacks a specific regulation on hESC research. Therefore, regulation has to be derived from a number of provisions regarding embryo research and experimentation. Anyway, this statutory "emptiness" produces, especially for researchers directly involved in this kind of research, an unavoidable condition of uncertainty related to the concrete legitimate space recognised to hESC research by the Law[6].

Facing with both a lack of direct prohibition and an ambiguous statutory orientation, the only relevant statutory source is Law 40/2004[7]. Therefore, it has to be analysed whether (and how much) Law 40 complies with the above mentioned indexes, in order to: a) trace a set of rules regulating hESC research; b) verify the existence of a connection between characters of decision-making process and nature of the Italian model:

DILEMATA, año 3 (2011), nº 7, 39-55 ISSN: 1989-7022

a) Expertise involvement: no *ad hoc* commissions or advisory bodies have been appointed by Parliament before the beginning of the legislative making process, and very few hearings took place during the latter. Concretely, parliamentary debates have been based on hearings and opinions collected during the debate on a Bill proposed in 1997. During the discussion at the Italian Deputies Chamber (*Camera dei Deputati*), the Commission on Social Affairs decided to adopt a bill based on hearings carried out in 1997. It was decided to not carry out new hearings. Later, the Senate of the Republic (*Senato della Repubblica*) conducted technical hearings, in order to be able to evaluate the necessity of modification within the text of the bill. Nevertheless, no relevant modification derived from this consultative process;

b) Legal definition: unlike other comparable regulations (such as the regulation on genetic data treatment provided by the Italian Authority on Personal Data Protection, see below), Law 40 does not contain a set of definition capable to circumscribe its application and to support interpretation; this lack drives from an evident inconsistency within the statutory architecture: for instance, the same legal entity that is define as *'concepitus'* in art. 1, is then identified as 'embryo' in articles 13 and 14, producing at least a feeling of legal uncertainty and approximation;

c) Updating clause: this clause is not provided by Law 40, even if it is a solution known by the Italian legal system. The above mentioned regulation on genetic data treatment limits its efficacy to a predefined temporal limit (18 months), after which it has been re-discussed and modified accordingly to scientific progress; Law 40 only partially refers to this means, when it prescribes that the Health Minister's Guidelines on ART have to be renewed every 3 years (art. 7);

d) Technical rules: Law 40 contains technical rules and references to scientific development. This is true both indirectly, for instance when art. 4 introduces the general principles of gradualism and 'less invasive therapeutic means' in applying ARTs techniques, leaving the physician – according to the more advanced medical acquirement – concretely to identify it; and directly, when art. 14 provides a clause according to which physicians, when it comes to decide the quantity of embryos to be produced and transferred to the woman's womb, have to act «taking into account scientific developments»[8];

e) Decision-making criteria: this index is also completely lacking. Law does not require to open decision-making process to society or expertise participation, such as it happens in France. Nevertheless, it in-

troduces a possible means for monitoring and evaluating law performances: art. 15 delegates Minister of Health to produce an annual report regarding the enforcement of Law 40 and its effects on ART; but it does not derive from it any duty or direct consequences in terms of law evaluation and reform;

f) Law enforcement and law evaluation: Law 40 does not provide any expertise participation mechanisms within the enforcement process, as it happens in almost every other legal system. As stressed before, Italian regulation on genetic data treatment should be taken as a paradigm to be implemented also to ART and hESC research regulation: The law (the so-called Code of Privacy, 2003) establishes a set of general principles, and accordingly delegates to a technical, independent, body (the National Authority for Personal Data Protection) the power to provide a more complete and systematic regulation, approaching different relevant areas (admitted aims of treatment; subjects legitimised for treating data; procedural, institutional and substantial requirements; informational and consent related duties) open to its own renewal, and also to monitor and control its effective enforcement.

In short, the Italian legal system does not provide a specific and formal regulation of hESC research, leaving researchers in a "limbo" of legal uncertainty (embryo research is explicitly forbidden but import of hESC line is not explicitly banned) and it is open to the exclusion of this kind of research from public founding[9]. On the other hand, the Law 40/2004 on ARTs is not able to guarantee an adequate level of legal certainty, also (and essentially) due to a self-referred and closed decision-making process. It is possible to conclude that Italy fails almost every index. And even if formally fulfilled (such as technical rules), they are empowered unsatisfactorily. Therefore, it is possible to consider whether excluding expertise involvement from legislative-making process deprives Legislator of a useful cognitive means which might have permitted a more adequate proportionality between legislative purposes and means.

What happens when we consider other legal systems?

### 3.2. 'Procedure oriented' models: its growing enforcement within the European legal framework.

The 'procedure oriented' approach allows a number of interventions on the embryo, conditioning the effective implementation of an authorisation, monitoring and sanctioning mechanism by means of independent public bodies to which the legislator delegates the enforcement of the law. Within this model, statutory source is activated but it is also sup-

ISSN: 1989-7022 DILEMATA, año 3 (2011), nº 7, 39-55

DILEMATA, año 3 (2011), nº 7, 39-55 ISSN: 1989-7022

ported by different sources which develop an integrative function, both *ex ante*, in the decision making process as informational and consultative means, and *ex post*, on the ground of a delegation of enforcement and monitoring (and also sanctioning) functions.

It may be temperate (like the Spanish one, allowing nuclear transfer) or liberal, allowing also the creation of embryos for research purposes (UK). United Kingdom – liberal system – is the legal order in which almost all indexes are satisfied, since the beginning of ART and hESC research regulation[10]. Spain – a liberal temperate one – is implementing a similar approach, both *ex ante* within legislative making process and *ex post*, harmonising ART and hESC research regulation.

All these legal systems share a common procedural method, which achieves different stages of strength and completeness but within a tendency towards an increasing implementation.

The case of France is paradigmatic in showing the rise of this model. It may be defined as an intermediate model: a hybrid regulatory model, grounded on the co-existence of a general ban of both hESC and embryo research on the one hand, and a derogative mechanism allowing it whether a set of condition and requirement are fulfilled on the other. For the sake of the reasoning, it has been considered more appropriate to focus on this legal system, as it – contrary to the more liberal ones, such as Spain or UK – has not consolidated a decision making process yet.

French decision-making process can be divided into three phases, each representing different stages of an incremental tendency towards a complete procedural model. The first stage (1994) has been characterised by a systemic and organic intervention within the biomedical field[11]. In this stage, expertise developer a effective impact on the content of the Law, by means of a set of reports and opinions provided by technical bodies, *ad hoc* commissions, and committees. In the second stage of the legislative making process (2004)[12], this tendency has been consolidated and expanded also with regard to the *ex post* participatory mechanisms in the implementation phase. The National Agency on Biomedicine (2006), a centralised and independent body, has been instituted by the Law 2004-800, entitled with authorization, inspection and control functions in the field of hESC research[13]. The third phase has just concluded (Law 2011-814)[14]. At this stage, the method of a participatory and open decision-making process has been strengthened on the ground of a multidimensional perspective: Consultation of citizens and laypersons, by means of the *États Généraux de la Bioéthique* (EGB)[15]; the «*Mission Parlementaire d'Information sur la Révision de la*

ISSN: 1989-7022 DILEMATA, año 3 (2011), nº 7, 39-55

*Loi de Bioéthique*» (MPI), established by the French Parliament (*Assemblée Nationale,* entitled to enforce the Law), to define a set of ethical and legal questions derived by new scientific developments (2008)[16]; finally, the consultation of both political and judicial bodies (Senate and Council of State) and experts in the scientific, ethical and legal fields (National Agency on Biomedicine, National Consultative Commission for Ethics in Life Sciences and Health Care, Parliamentary Office for the Evaluation of Scientific and Technological Choices)[17].

Progressive strengthening of consultation and participation mechanisms within both the decision making (up to the last degree represented by the *États Généraux de la Bioéthique*) and the enforcement (delegating to the National Agency the power to apply statutory content providing for specific authorisations) processes seem to clearly demonstrate that it is not a unintentional process, but rather a constitutive element of a consolidating model.

The fulfilment of the proposed indexes seems to confirm this conclusion:

a) Expertise involvement: as outlined above, expertise is "metabolised" within both the decision-making and enforcement processes; this tendency is increasing, up to include a provision calling French Parliament to open a session of the *États Généraux de la Bioéthique* every time it intends to reform the Act; participatory nature characterises also the enforcement phase, by means of the appointment of the National Agency on Biomedicine (2006), entitled to authorise and control specific research projects, within a decision-making process involving also a Consultative Council and the Minister of Health, which is entitled to interdict or suspend the research (art. 41, Law 2011-814, amending art. L2151-5 *Code de la Santé Publique*);

b) Legal definitions: it is the only lacking index, as the Law on Bioethics does not provide for a set of legal definitions;

c) Updating clause: it represents a distinctive element of the French model. The last version of the Law on Bioethics (2011) has confirmed the duty for the French Parliament to examine the whole statutory text at least every seven years (instead of the previous term of five years). The purpose of this clause is to verify law adequateness with regard to scientific – but also ethical and social – progress and changes which might occur. It has to be underlined – in order to confirm a direct 'cause-effect' relationship between the *quomodo* of the decision-making process and statutory contents – that this mechanism has been originally proposed by the recommendations derived

DILEMATA, año 3 (2011), nº 7, 39-55 ISSN: 1989-7022

from the first consultative process (Law n. 1994-654, art. 40). It guarantees both adaptability and adequateness, assuring at the same time a democratic perspective, because it is the Legislator's responsibility – by exercising its discretionary power – to make it effective[18];

d) Technical rules: the delegation to an *ad hoc* authority requires *per se* a set of conditions and criteria to which the authorisation of hESC research is conditioned (in general terms, the same effectiveness and substantial efficacy of the law is subordinated to them): in order to verify their fulfilment, they have to be previously concreted according to the *lex artis* and scientific development. Article 41 of the Law 2011-814, providing the conditions to be fulfilled by each research project, refers to scientific concepts – such as 'scientific relevance', 'greater medical developments' – which have not a predetermined meaning but have to be made explicit with regard to the specific and concrete case to be evaluated, according to the ongoing technological and scientific developments;

e) Decision making criteria: as stressed before, the French law has built a systemic mechanism characterising the decision making process, which goes indirectly to procedurally drive (even if not substantially orient or condition) the enforcement of Parliament's discretionary power: according to art. 46 of Law 2011-814, any reform concerning ethical and social issues related to developments in the fields of biology, medicine and health, has to be preceded by a public debate similar to the *États Généraux*[19];

f) Law enforcement and law evaluation: The French law is characterised by a specific Title that addresses the 'Application and evaluation of the Law on Bioethics' (Title IX). It provides for the duty to re-examine the Law at least every seven years on the ground of the results of a set of reports and consultations required by Law; every six year, the *Office Parlementaire d'Évaluation des Choix Scientifiques et Technologiques* has to evaluate the enforcement of the law (art. 47) in order to check its adequacy according to social, scientific and ethical development. It has also to provide a useful report in the light of the law reform. French 'procedure oriented' approach is reinforced also by means of a rule according to which, in any case, the *États Généraux de la Bioéthique* will be held every five years, even if a reform bill is not planned (art. 46).

Last version of the Law on Bioethics is the result of a broad consultative process, which involves legal, political, scientific and social subjects. What is the outcome in term of impact on the content of the Law?

The Law 2011-814, passed by French Senate last June, does not mod-

ISSN: 1989-7022 DILEMATA, año 3 (2011), nº 7, 39-55

ify the 'exception to a prohibition'[20] mechanism but it introduces an enlargement of admitted purposes. Also based on the *États Généraux*'s final Report, the Agency on Biomedicine may henceforth authorise researches aimed not exclusively at achieving therapeutic progresses (as it was the case according to the old version of the Law on Bioethics, of 2004) but also those researches intended to guarantee «any medical progress» Therefore, the National Agency on Biomedicine will authorize also research projects aimed at diagnostic and preventive purposes. Furthermore, even if the mechanism 'exception to a general prohibition' has been confirmed, it has been relaxed: in fact, the clause according to which researches may be authorised only within five years to the entry into force of an executive decree (moratorium mechanism) has been removed.

Decision making process conceived as a multi-layered and multi-disciplinary consultative method (i.e. by means of the *États Généraux de la Bioéthique* at least every 7 years) has been incorporated into the Law, accompanied and integrated by a set of evaluative and informative means (reports to political subjects, Parliament and Government, public information) which acquires the nature of mandatory requirement. Accordingly, the participative nature of the decision-making process evolves, from being a voluntary option, to a compulsory mechanism which the legislator has to implement when reforming the Law.

The legal consequences of this shift of paradigm (more exactly, evolution or 'statutorisation' of paradigm) are not limited to the procedural level. The evolution directly develops substantial effects in terms of legitimacy of the Act[21] as well: should it be possible to hypothesize a remedy through which citizens or representative organisations were allowed to stand before a Court asking it to recognise Parliament's responsibility for not having applied and fulfilled the required participatory means? Should a Law be declared unconstitutional because of a lack of those procedural requirements calling both directly for a procedural illegitimacy and indirectly for a scientific unreasonableness of its content?

To conclude, with regard to the French model, an incremental tendency towards a complete procedural model is identifiable, even by means of a mechanism that does not automatically imply the a-critical reception of consultation's outcomes: This approach does not alter either the democratic-representative nature of the law or the level of legislative discretionary power. The legislator decides to provide a mechanism aimed at guaranteeing the more scientifically reasonable and socially acceptable exercise of its own function, but keeps itself the power to decide the degree that the influence of the experts must have. In other words, Parliament's duty affects the means, not the outcomes of the de-

DILEMATA, año 3 (2011), nº 7, 39-55 ISSN: 1989-7022

cision-making process.

In order to answer the above mentioned question (is there a connection between the method of statutory making process and the law content?), in the case of France the enforcement of a procedural method seems to have as a consequence a more liberal regulation.

## 4. The raising of a common procedural method, before and beyond statutory contents?

Although a specific regulation is lacking at the EU level, and only the soft law provided by international societies or organisations offers guidelines in this context[22], it is possible to theorise a common regulatory way for hESC research. The model is the procedural one, characterised by a set of indexes which can be totally or partially fulfilled, but which expresses a common theory of both the decision-making process and the task of statutory law[23].

It recalls an approach that it has been defined – although in a different context – «*reflexive legal regulation*» : It is grounded on a trust-building structure, which may increase public confidence by means of authoritativeness, liability, procedural transparency and clarity of evidence, conditions which are guaranteed by the formulation, establishment, administration and review of regulatory policy[24].

It seems not excessive to push this analytical conclusions a step forward: procedural approach is emerging also within those legal systems – such as Italy – apparently not fulfilling 'proceduralisation indexes' and characterised by a strict statutory regulation, based on the protection of non-balancing values (embryo protection; sanctity of life starting from its beginning and so on). Evidence of this tendency arises from the Italian legal system when taking into consideration other sources: constitutional case-law, self-regulation (professional ethics code) and administrative regulation:

> a) Italian constitutional case law: Italian Constitutional Court is regularly enforcing a *scientific reasonableness* principle, according to which statutory intervention on medical treatment adequateness may not derive exclusively from political discretionary power, but should be based on verification of available scientific knowledge and experimental evidence, acquired by technical bodies – both national or supranational – deputed for this, since the essential importance that, for these purposes, they hold. According to the Court, statutory intervention should be the result of such an examination (see decision

ISSN: 1989-7022 DILEMATA, año 3 (2011), nº 7, 39-55

no. 282/2002; 338/2003; 159/2009). Court has applied this principle also with regard to the limits against the freedom of private enterprise, in which hESC research may be included: statutory intervention limiting freedom of private enterprise, by applying precaution and prevention principles, is constitutionally justified exclusively if it is expressed by means of general principles based on the verification of the state of the art of scientific knowledge acquired by institutions and bodies deputed for this (decision no. 116/2006). Accordingly, it seems to emerge a procedural burden to verify available scientific knowledge by means of either national or international delegated bodies or the related duty to put the result of this verification into the statutory text[26];

b) Self-regulation: The role of both technical bodies and professional ethics codes is recognised by the Italian Constitutional Court. On the one hand, Constitutional Court case-law constantly recognises the essential relevance performed by scientific bodies in regulating scientific activity within the legislative making process (see decision. 185/1998; 188/2000; 282/2002; 159/2009). According to the Court, technical-scientific bodies must develop an essential relevance within medical field – in both therapeutic and experimental activity – because their opinions are invested of a binding regulative efficacy. Furthermore, the Court makes reference to a *reserved* competence of technical-scientific bodies in determining scientific content of therapeutic activity (decision n. 188/2000). On the other hand, it is recognised to professional ethics codes a direct function of protecting fundamental rights involved in therapeutic and research activity, as professional ethics codes contribute to determine fundamental principles guiding this context (decision n. 282/2002). Direct regulatory function has been recently confirmed by the European Court of Human Rights (see decision *S.H. and Others v. Austria*, no. 57813/00, April, 1st, 2010, First Section). In this decision the European Court singled out a clear relationship between the dimension of margin of appreciation to be recognised to the Member State when regulating ARTs (heterologous insemination in this particular case) and the regulative space to be reserved for self-regulation and professional ethics codes. The Court, in so doing, confirms that statutory intervention hits a boundary precisely in the pre-existence of a set of professional ethics rules, which constrain «specialised medical doctors, who have particular knowledge and experience in this field». This indirectly confirms the subsidiary nature of the statutory source within the biomedical field;

c) Administrative regulation: As stressed above, a potential model of

DILEMATA, año 3 (2011), nº 7, 39-55 ISSN: 1989-7022

procedure approach comes from the inside of Italian legal system. We refer to genetic data treatment regulation, in which Legislator delegates an independent administrative body – National Authority for Personal Data Protection – to provide a comprehensive regulation (General Authorisation for Genetic Data Treatment, 2011). The regulatory strategy recalls the procedure approach: a 'soft' statutory intervention, which recognises a wide margin of appreciation to both an independent technical body and the involved researchers and research institutions. This analogy seems to be confirmed ny applying the provided indexes. Considering the General Authorisation, which represents the main regulatory source, it is possible to appreciate how many of them are fulfilled: a) Expertise involvement; e) Decision making criteria: art. 90 of Code of Privacy (legislative decree n. 196/2003) establishes that Authority has to follow a decision-making process involving the Minister of Health, who shall act on the opinion handed down, to that end, by the *Consiglio Superiore di Sanità*[27]. The authority is also entitled to carry out public consultations for acquiring opinions and accounts particularly from both public and private health institutions, and professionals and patients' associations (see the Guidelines on Online Examination Records, 2009). Otherwise, the authority chose not to exercise this participatory means in the case of the Authorisation for genetic data treatment, opting for non-public hearings of qualified (but not specified) experts; b) Legal definition: the General Authorisation – as well as the Code of Privacy – provides a set of definitions (Paragraph 1) concerning scientific and technical notions involved in its enforcement (such as 'genetic data', 'biological sample', 'genetic test'); in order to guarantee their scientific appropriateness, able to affect Authorisation effective implementation, they have been updated – also on the ground of the above mentioned experts' consultation – in the last version of the Authorisation (June, 24th, 2011); c) Updating clause and f) Law enforcement and law evaluation: the authorisation is a temporary and 'fixed term' act, to be effective only for eighteen months, in order to permit its integration or adjustment in relation to the rapid development of research and technologies applied to genetics and the evolution of knowledge in the field.

Once recognised its increasing impact within the European legal framework, we can connect 'procedure oriented' model with the questions raised in the Introduction: Who is entitled to regulate? And how to regulate?

'Procedure oriented' approach recalls the 'integration model', as it is characterised by a mix of different regulatory sources each developing a determined function: statutory law providing for a set of general rules

ISSN: 1989-7022 DILEMATA, año 3 (2011), nº 7, 39-55

and principles to be enforced case-by-case by independent technical bodies (authorities) and integrated by self-regulation and professional ethics rules. Therefore, statutory law is a required but not sufficient regulatory means[28]: it may (and sometimes has to) intervene, but Parliamentary discretionary power must be exercised in a scientifically reasonable way, in order to guarantee its own constitutional legitimacy, concrete effectiveness and scientific consistency[29]. On the one hand, the law cannot infringe a regulatory space reserved to expertise and self-regulation, developing a subsidiary/complementary function; on the other, it has to recognise the integrative role of expertise within decision-making process. This regulatory structure may be defined holistically, in terms of both the plurality of activated sources and their required mutual integration.

The matter therefore has to move to a new Hamlet's Dilemma: How and how much to legislate?

## Notes

**1.** Isasi, R. M. and Knoppers, B. M., "Beyond the permissibility of embryonic and stem cell research: substantive requirements and procedural safeguards", *Human Reproduction*, 21, 2006, pp. 2474–2481.

**2.** Jones, D. G. and Towns, C. R., "Navigating the quagmire: the regulation of human embryonic stem cell research", *Human Reproduction*, vol. 21, No. 5, 2005, pp. 1113-1116, identify four dominant positions, analysing their adequacy in terms of ethical consistency and the consequences for realising or retarding therapeutic potential p. 1113).

**3.** Although in the context of ARTs, see Johnson, 'Regulating the Science and Therapeutic Application of Human Embryo Research: Managing the Tension between Biomedical Creativity and Public Concern' in JR Spencer and A Du Bois-Pedain (eds.), Freedom and Responsibility in Reproductive Choice, 2006, 98 ss.

**4.** Bronwsword, R., "Regulating Human Genetics: new Dilemmas for a New Millenium", *Medical Law Review*, 12, 2004, pp. 14-39, stresses how «procedural integration, while important, only reaches so far. If the outcome of the process is a regulatory decision that offends deeply held ethical convictions, procedural property can neither guarantee the legitimacy of that decision nor legitimate it» (p. 27).

**5.** According to Deech, R. and Smajdor, A., "From IVF to Immortality - Controversy in the Era of Reproductive Technology", 2007, p. 209, «the law introduces a set of prohibitions rather than constructing a general regulatory framework for the conduct of assisted reproduction and/or research».

**6.** Gottweis, H., Salter, B. and Waldby, C., "The Global Politics of Human Embryonic Stem Cell Science", 2009, Palgrave, pp. 77-79, offer a useful overview of the Italian legal context. See also Cattaneo, E. and Corbellini, G., "Science under politics", *European Molecular Biology organisation reports*, Vol. 12, No. 1, 2001, pp. 19-22.

**7.** Penasa, S., "La questione delle cellule staminali. Il quadro giuridico**",** in Canestrari, S., Ferrando, G., Mazzoni, C. M., Rodotà, S. and Zatti P. (eds.), *Il governo del corpo. Volume I, Trattato di biodiritto*, Giuffrè, 2011, pp. 1101-1117.

DILEMATA, año 3 (2011), nº 7, 39-55 ISSN: 1989-7022

**8.** The judiciary history of this provision is particularly evocative and paradigmatic. The original version (the one passed by the Italian Parliament) accompanied the reference to *lex artis* with both a rigid and binding pre-determination of the maximum number of producible embryos (three) and a duty to transfer them by means of a single and simultaneous transfer. This statutory "assault" of a scientifically reserved space substantially nullifies the reference to l*ex artis*: in 2009, Italian Constitutional Court intervened quashing down both the limitation and the duty, rescuing the "openness" factor regarding scientific knowledge developments («taking into account scientific developments») from its statutory bonds, to guarantee a more flexible and malleable law enforcement. See Levi Setti, P. E. et altri, "Italian Constitutional Court modifications of a restrictive assisted reproduction technology law significantly improve pregnancy rate", *Human Reproduction*, Vol. 26, No. 2, 2010, pp. 376-381.

**9.** See a recent Italian Council of State's decision (No. 5973/2009), allowing Minister of Health to exclude hESC research from the research projects admitted to public founding.

**10.** See recently Plows, A., Debating Human Genetics. Contemporary issues in public policy and ethics, Routledge, 2011, pp. 40-55.

**11.** The so called Law on Bioethics: Law n. 94-653, July, 1994, «*relative au respect du corps humain*»; and Law n. 94-654, July, 1994, «*relative à l'assistance médicale à la procréation, au diagnostic prénatal et au don et à l'utilisation des éléments et produits du corps humain*».

**12.** Law n. 2004-800, of August 6, 2004, that modified the Law of 1994, on which, among others, Michaud, J., "Réflexions sur la loi relative à la bioéthique", *Médicine & Droit,* No. 70, 2005, pp. 1-2; Chemtob-Conce, M.C., "La révision des lois de bioéthique", *Médicine & Droit*, No. 66-67, 2004, pp. 71-80; Hennette-Vauchez, S. (ed.), Bioéthique, Biodroit, Biopolitique. Réflexions à l'occasion de la loi 6 août 2004, L.G.D.J., 2006.

**13.** See http://www.agence-biomedecine.fr/agence/missions.html.

**14.** *LOI n° 2011-814 du 7 juillet 2011 relative à la bioéthique*, available at http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000024323102.

**15.** Several panels of citizens had the opportunity to express their informed opinion on a selected set of topics concerning the law revision, after having received special training by an expert committee (see http://www.etatsgenerauxdelabioethique.fr ).

**16.** See http://www.assemblee-nationale.fr/13/dossiers/revision lois bioethiques.asp.

**17.** For corresponding opinions and studies, see http://www.etatsgenerauxdelabioethique.fr /base-legislative-et-documentaire/la-loi-et-les-rapports-officiels-en-vue-de-la-revision-de-la-loi.html.

**18.** Surprisingly, *États généraux de la bioéthique* outcome has been a consensus in the abolition of the temporal conditioning clause: see Merviel, P., Cabry, R., Lourdel, E., Brasseur, F., Devaux A. and Copin H., "La révision de la loi de bioéthique: analyse comparative des contributions de différents organismes publics ou professionnels. Assistance médicale à la procréation, recherche sur l'embryon et les cellules souches, banque de sang du cordon ombilical", *Gynécologie Obstétrique & Fertilité*, No. 37, 2009, pp. 733–741.

**19.** Article 46 specifies also that the *États généraux* are organised by National Consultative Committee on Ethics in Health and Life Sciences, after having consulted competent parliamentary commissions and the *Office parlementaire d'évaluation des choix scientifiques et technologiques*.

**20.** Quoting Hennette-Vauchez, S., "Words Count: How interest in Stem Cell Has Made the Embryo Available – A look at the French Law of Bioethics", *Medical Law Review*, Vol. 17, 2009, p. 65.

ISSN: 1989-7022 DILEMATA, año 3 (2011), nº 7, 39-55

**21.** Not directly referring to French context but analysing the relationship between method of decision-making process and political legitimacy of parliamentary lawmaking, see Hennette-Vauchez, S., "Reasonableness and Biolaw", in Bongiovanni, G., Sartor, G. and Valentini C. (eds.), *Reasonableness and Law*, Springer, 2009, pp. 356 ss.

**22.** See CODEX (operated by the Swedish Research Council in cooperation with The Centre for research ethics & bioethics at Uppsala University) for having access to and information on the guidelines, ethics codes and laws that regulate and place ethical demands on the research process: regarding stem cell research, see http://www.codex.uu.se/en/medicin2.shtml.

**23.** Also Isasi, R., "Policy Interoperability in Stem Cell Research: Demystifying Harmonization", *Stem Cell Reviews and Reports*, 5, 2009, pp. 108-115, by applying different indexes recognises «a trend towards policy convergence surrounding fundamental ethical issues» (p. 114).

**24.** According to Jabbari, D., "The role of law in reproductive medicine: a new approach2 (1990) 16 Jour. Med. Ethics 36, this approach can guarantee «*the capacity to regulate the complexity of modern social conditions*», by means of an emphasis «*upon procedure rather than substance*», in order to «*foster public and expert participation*».

**25.** Johnson, M. H. and Petersen, K., "Public interest or public meddling? Towards an objective framework for the regulation of assisted reproduction technologies", *Human Reproduction*, Vol. 23 , No. 3, 2008, p. 723, proposes a «five-step model» regulation, in order to «shift the focus of regulation from simply enforcing regulatory objectives towards questioning and testing those objectives and the methods being used to implement them».

**26.** Let's refer to Penasa, S., La "ragionevolezza scientifica" delle leggi nella giurisprudenza costituzionale, *Quaderni costituzionali*, No. 4, 2009, pp. 817-842. See a draft English version at http://www.jus.unitn.it/biodiritto/pubblicazioni/docs/SimonePenasa.pdf.

**27.** The Minister's technical and scientific consulting body.

**28.** Halliday, S., "A Comparative Approach To The Regulation of Human Embryonic Stem Cell Research In Europe", *Medical Law Review*, 12, 2004, p. 68, claims the inability of the law to respond both adequately and quickly to scientific progress.

**29.** Johnson, M. H., "Should the use of assisted reproduction techniques be deregulated?", *Human Reproduction*, Vol. 13, No. 7, p. 1775, recognises seven criteria «for a statutory regulatory body to be maximally effective».