

This paper has been submitted to *Legisprudence* for a special issue on ‘experts and legislation’. I would like to get comments on the part concerning the merits and pitfalls of decentered regulation in order to supplement and rewrite my final chapter in *Self Regulation and the Future of the Regulatory State*.

DISTINGUISHING TRUE FROM OTHER HYBRIDS

A Case Study of the Merits and Pitfalls of Devolved Regulation in the UK

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Abstract

The model of ‘decentered regulation’ was claimed to offer the ideal instrument to cope with the specific challenges of technological innovation in a society characterized by diversity in moral beliefs. The central question of this article is whether the ‘model of decentered regulation’ indeed brought the solutions that were expected from it. This question will be answered by using the case study of the formulation of the rules concerning the creation of human animal hybrid embryos in the United Kingdom. The analysis of this issue will be used to reflect on four reasons that are brought forward in favor of the model of decentered regulation: 1) the inclusion of necessary scientific expertise; 2) a flexible and efficient mechanism of rule change; 3) coping with diversity in moral beliefs; 4) coping with the changeability of these beliefs in time.

Keywords: decentered regulation; biomedical technology; scientific experts; legal boundary conflicts; human-animal hybrid embryos

1 Introduction

The UK is one of the few countries in which the creation of human-animal hybrid embryos is allowed.¹ ²As is the case with the regulation of biomedical technology more general the contribution of scientific experts to the formulation of the rules concerning the use of embryos

1 A hybrid embryo is an embryo created by mixing the eggs and sperm of different species. A chimera embryo is a different form of human animal embryo: an animal or human embryo which contains cells from a different animal or human, in the case of an interspecies hybrid embryo these cells are from another species. Unlike a hybrid embryo, which is created by mixing the genes, a chimera contains cells which have different genetic information.

2 In countries as China, Japan and South Korea the creation of embryos by ‘somatic cell nuclear transfer’ is allowed and the creation of human-animal embryos not specifically prohibited.

in research has been indispensable because of the high technological character of this issue. However, unlike most issues of a high technological character, the creation of human-animal hybrid embryos provoked a fierce public and political debate. Therefore this issue lends itself very well to put the model of ‘decentered regulation’ to the test with respect to how it copes with diversity in and changeability of moral beliefs.³

The model of ‘decentered regulation’ anticipates the need of government for constant advice from technical specialists by giving scientific experts a structural position in the process of rule making. The case-to-case approach in this model at its turn is held to be capable to resolve the tension between the flexibility of legal rules, needed because of the dynamic development of technology and the changeability and diversity in moral beliefs, on the one hand, and, on the other hand, the precision required by legal certainty.

In this article the model of ‘decentered regulation’ will be put to the test by analyzing how it functioned in the regulation of the creation of human animal hybrid embryos in the UK. I will focus on the contribution of scientists to the formulation of rules concerning the creation of these forms of embryo because their role is a point of attack for the opponents of a model of decentred regulation

The opponents of the implementation of a decentred model in the regulation of biotechnological issues consider both the privileged access that is given to scientists in the model as well as the case-to-case approach problematic in the light of democracy. Firstly, in a democracy citizens should have equal access to governmental decision making. In cases of devolution of (part of) the power of rule-making to a lower authority it is important to create conditions in which different opinions and interests are balanced against each other. In stead of this, the privileged access given to scientific experts would, according to the opponents, bring with it a disproportionate extent of influence for them over the formulation of the rules. The efforts of legislators to anticipate this effect and compensate the privileged access by also involving other stakeholders in the lower authorities would not present the right solution. The idea that including for example members that represent social and religious knowledge would compensate for the power given to scientists is based on the assumption that these members can represent a countervailing power to the scientific technocrats. However, as knowledge of the scientific details is the crucial source of influence of these technocrats the question is whether non-scientists are equipped to fulfill this role of countervailing power. Another reason that is given by legislators for including these members is the creation of conditions that could further support for technological innovation in broader society. The question is: which of these purposes are in fact brought nearer by including these members?

Secondly, the case-to-case approach is considered problematic because it would rather automatically push things forward to liberalization of policy. According to Levitt (2004) this is because with each new case a momentum is created that thanks to media involvement and commercial pressures leads to the allowance of yet another technique in spite of the strong resistance of some groups.⁴ A more democratic way of decision making would be to consider

3 With the model of ‘decentered regulation’ I refer to the wide range of forms of regulation that nowadays exist and that are not centred on the state but decentered: Instead of the state, market parties associations and networks play a central role in this model of regulation.

4 See M Levitt, “Assisted Reproduction: Managing an Unruly Technology” (2004) 12 Health Care Analysis 41-49.

alternative techniques and weigh these up against each other, also with respect to the moral values involved.

In the first part of the paper I will present the analysis of the regulation of the creation of human-animal hybrid embryos in the UK. In section 1, I will describe the UK regulatory framework for the use of embryos in research as existed at the time the creation of human-animal hybrid embryos became an issue. The *1990 Human Fertilization and Embryology Act* and the *HFE Authority*, the statutory body that was set up with this act, are central to this regulatory framework. While the Act settled some issues concerning the moral boundaries of the use of human embryos in research, some questions about the moral status of the early human embryo were left unanswered. As will be elaborated on in this first section, the debate about these questions revived at the moment the creation of human-animal hybrid embryos became technically conceivable. The power to formulate rules concerning the creation of new forms of embryos to some extent is delegated to the *HFE Authority* and therefore two arenas have to be addressed in the analysis of the decision making concerning this issue. The first arena is the decision making about licensing specific research proposals by the *HFE Authority*. The second arena is the legislative process of amending the *HFE Act* that started in 2005 and ended with the *2008 HFE Act*. I will reconstruct the decision making processes in these two arenas respectively in section 2 and section 3 by first describing the points of access scientific experts have to these processes and subsequently the strategic use of language that is made in the presentation of their knowledge in order to establish a specific version of situations and events in the face of competing versions.⁵ A striking insight that will be presented here is that a crucial part of the knowledge contributed by scientific experts in the arena of the decision making of the *HFE* was contested. by the scientific experts particip[ating in the arena of the legislative process. In section 4, I will answer the question whether or not the model of decentered regulation in this case has fulfilled the expectations of its advocates.

2 The 1990 HFE Act and its unstable moral boundaries

The particular model of ‘decentered regulation’ that has been chosen in the UK, as in some other countries, to control the practice and development of embryology and fertility treatment can be characterized as ‘devolved regulation’.⁶ The *Human Fertilization and Embryology Act 2008* provides the legal framework for the use of embryos in research. Some of the rules in this Act are straightforward prohibitions, for example the prohibition on the development of an embryo in vitro beyond 14 days.⁷ However, the main part of this Act contains a more flexible, communicative, legislative approach that can be responsive to changing scientific, social or ethical understandings.

The *HFE Authority*, a statutory body with defined discretionary powers, is set up to administer the law within the boundaries of the Act. This *Authority* is responsible for licensing

5 This is what political reasoning is about according to D Stone, *Policy Paradox. The art of political decision making*. (W.W. Norton & Company New York and London, 2002).

6 This choice was preceded by singling out reproductive medicine as an area of such particular social concern and significance that the state must have a stake in its development.

7 With the *Human Reproductive Cloning Act 2001*, the placement of a human embryo other than by fertilization in the womb of a woman became an offence.

the use of embryos in research, which in the UK case includes the creation of embryos for research. In order to get the approval of the *HFE Authority*, researchers who wish to use embryos in their research must submit a research protocol that makes clear that the research is ‘necessary or desirable’ for one or more of the purposes of the *HFE Act*.⁸ In addition to being convinced on the latter point the Authority cannot issue a license unless it is satisfied that the use of an embryos is necessary for the research.⁹

As Dawson¹⁰ observed, the Authorities brief is a dual one as it combines the task of registration and inspection with the task of policy formulation. With respect to its task of inspection, the *HFE Authority* is required to ensure that licensed premises are inspected once in every calendar year unless a license committee considers that inspection is unnecessary.¹¹ The *HFE Authority* has a policy formulation role through its decisions about individual research cases and its consultations of the public.

In the decisions of the Authority controversial ethical issues are touched upon as may be witnessed by the reasonable amount of occasions at which these decisions have been challenged in court. This is not surprising. At the one hand, the research proposals submitted to the Authority each time involve the most new techniques of creating embryos. Therefore, a recurrent question the *HFE Authority* has to deal with is whether the resulting form of embryo fits into the legal category of a human embryo and would fall under the remit of the Authority.

At the other hand, some questions concerning the moral status of the early embryo were left unanswered with the formulation of the *1990 HFE Act*. The law is grounded on the idea of intrinsic worth because of the potentiality of the embryo to grow into a human being. In addition the act incorporates the idea that protection should increase as the embryo develops, because of the growing probability that it will become a human being. So the moral worth of the embryo in law is considered to be dependent on its degree of progress through the stages of its development. The implantation phase, completed with ‘in vivo embryos’ after fourteen days, is deemed important in this respect and that is the reason why the law explicitly prohibits the development of embryos in vitro beyond this period of time).¹² However, the exact relevance of the different stages of development is still contested. Until today, it is not possible to develop embryos in vitro longer than seven days, so the technological limit is more restricting than the legal limit. Therefore the legal limit of fourteen days of development in vitro has not been subject to debate. This is different for other issues such as what would determine the moral worth of the human embryo younger than fourteen days and where to draw the boundary of legal categories as ‘a full human genome’, ‘being alive’ and ‘where fertilization is complete’?

8 Desirable is assessed in terms of the contribution to scientific knowledge or human health that can be expected from the research. Necessary means that creating such embryos (instead of using other sources of stem cells) is necessary for the research.

9 Human Fertilisation and Embryology Act 1990, sch. 2, para. 3 (2) and (6); R Lee and D Morgan, *Human Fertilisation and Embryology. Regulating the Reproductive Revolution* (London, Blackstone Press Limited, 2001), p. 120.

10 A Dawson, ‘The Human Fertility and Embryology Authority: Evidence Based Policy Formation in a Contested Context’ (2004) 12 Health Care Analysis 2-3.

11 Lee and Morgan (n 9)116-17. In 1997 the Authority started with a three year licensing cycle, in which all clinics receive one broad-based general inspection once every three years with highly focused inspections in the intervening year.

12 Ibid 68-72

The answers to these questions are ambiguous. The *Quintavalla case* in 2003 is an example of how the *HFE Authority* as case-to-case decision maker is put at the forefront of ‘legal boundary conflicts’ of a high political character.¹³ The court case revolved around the legal category ‘where fertilization is complete’ and the question whether this part of the legal definition of a human embryo would exclude the human embryo that results from Cell Nuclear Replacement from falling under the *HFE Act 1990*.¹⁴ The appellant, representing the pressure group *Pro Life Alliance*, claimed that it did not because the *HFE Act 1990* only referred to embryos that were created by fertilization.¹⁵ This challenge was successful in the High Court but was overturned by the Court of Appeal, whose judgment was approved by the House of Lords taking a purposive approach to the interpretation of Law.¹⁶ With their successful challenge in the High Court the Pro Life Alliance paradoxically created a situation in which human cloning was temporarily not regulated.¹⁷ As the Government subsequently rushed through legislation in order to repair this caveat this situation only lasted for a short while.¹⁸

The question whether the creation of human-animal hybrid embryos should be allowed must be seen as the next ‘legal boundary conflict’ with respect to the *1990 HFE Act*. This time the political struggle revolved around the categories of ‘having a full human genome’ and ‘being alive’. The definitions of these categories appeared to be contested even among scientific experts. The first part of the debate was fought out in the arena of the *HFE Authority* decision making whether or not to license research proposals involving the creation of human-animal hybrid embryos. I will analyze this debate in the following section.

3 The arena of decision making by the HFE Authority

Scientific experts have several points of access to the decision making process of the HFE Authority. A first point of access is the body that takes the license decisions. There are several provisions in the HFEA concerning the composition of the Authority: ‘The Secretary of State shall make appointments and has to ensure that the Authority must be informed by the views of both men and women. At least a third but not more than half of the membership has to consist of persons with a background as medical practitioner, human embryo research or the commissioning, funding of or decision making on this research.’¹⁹ Most of these members, though not necessarily all, will qualify as scientific experts.

13 R (Quintavalle) versus the Secretary of State of Health [2003] UKHL 13.

14 Cell nuclear replacement (CNR) is a technique in which researchers take a cell (such as a skin cell) from an adult and extract the genetic information (the nucleus) from the cell. They then transfer that genetic information into an egg from which the genetic information has been removed, activating the egg so that it starts to divide.

15 The appellant pointed out that in s. 1 of the Act an embryo regulated by the Act is defined as ‘a live human embryo where fertilization is complete’ and that CNR does not involve a process of fertilization.

16 The House of Lords rejected the argument of the appellant: ‘The crucial point ... is that this was an Act passed for the protection of live human embryos created outside the human body. The essential thrust of section 1(1) (a) was directed to such embryos, not to the manner of their creation, which Parliament (entirely understandable on the then current state of scientific knowledge) took for granted.

17 According to commentators the reason why the Pro Life alliance did this was to unmask government as cheating the public in order to have the UK stay at the fore front of stem cell research. For this information I thank Joost Baarssen who as a student analyzed the debate about this Quintavalla Case.

18 Human Reproductive Cloning Act, 4 December, 2001.

19 There are several other provisions in the HFE Act 1990 concerning the composition of the Authority: The Secretary of State shall make appointments and has to ensure that the Authority must be informed by the views of both men and women. At least a third but not more than half of the membership has to consist of persons with a background as medical practitioner, human embryo research or the commissioning, funding of or decision making on this research. Persons belonging to these categories are disqualified from being appointed as chairman or deputy chairman in order to ensure that the overall direction of the authority is independent of the medical-scientific view. See Lee and Morgan (n9) 102-103.

A second point of access is the *Scientific and Clinical Advances Group* (SCAG) of the *HFE Authority*. This is a group of scientific experts that advises the Authority on questions concerning new scientific and clinical developments. A third point of access is the *HFEA's Horizontal Scanning Expert Panel* (HHSEP), a worldwide panel of experts that includes experts in stem cell technology from universities in the UK, Australia and Japan, specialists in assisted reproductive technologies from the US and Belgium and leading academics in cloning techniques, developmental genetics and cryopreservation.

In the arena of the *HFE Authority* the debate concerning the issue of the creation of human-animal hybrid embryos started to develop from the moment the *Scientific and Clinical Advances Group* (SCAG) and the *Ethics and Law Committee* (ELC) of the *HFE Authority* were asked by the *Department of Health* whether this form of embryo according to them was covered by the HFE Act (1990) and would fall under the remit of the Authority.²⁰ The department asked this question as part of the review of the *HFE Act 1990* that was announced on 21 January 2005. The department wanted both, the group of scientists and clinicians as well as the ethics committee, to review the role that mitochondrial DNA plays in the development of the embryos and whether embryos containing human DNA and both human and animal mitochondrial DNA would be human.²¹ In spring 2006 the SCAG responded to the department that the proportion of human derived and animal derived proteins should be considered when deciding if these hybrid embryos should be classified as having a human genome. The SCAG and the ELC agreed that the hybrids should be regarded as an 'embryo' for the purposes of the Act 1990 and that the creation, keeping or use of such an embryo in principle could be regarded as necessary or desirable. From this the ELC concluded that the license committee of the *HFE Authority* 'would have the discretion to authorize these activities in the case of application'.

However, in November 2006 the government proposed for a ban on the creation of the human-animal hybrids. At the moment scientists publicly had stated their wish to create human-animal hybrids by fusing human cells with rabbit cells, journalists reported about the planned research of the applicants using alarming headlines about 'Frankenbunnies', because cow or rabbit eggs would be used. For the government the public unease expressed in response to a public consultation was reason to make a statement about hybrid and chimera embryos in its White Paper: 'The government will propose that the creation of hybrid and chimera embryos *in vitro* should not be allowed'.²² Apparently, the combination of human and animal material in the embryo was considered a bridge too far, although the Government in the same white paper proposed to include in the amended Act power enabling regulations to set out circumstances in which the creation of hybrid and chimera embryos *in vitro* may in future be allowed under license for research purposes only.

20 The proposal to use animal eggs instead of human eggs originates from the shortage of human eggs that is the result from the fact that eggs donating is a physically demanding process for women that even can be harmful. The embryo that would result from this combination of human cells and animal eggs later in the debate was called 'cytoplasmic hybrid embryo'.

21 The creation of 'human-animal hybrids' until the two cell stage had already been practiced in the 'hamster test', a well established and explicitly endorsed test in which human sperm are mixed with hamster eggs to test the health and motility of the human sperm.

22 Government's White Paper 'Review of the Human Fertilisation and Embryology Act: proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos' (Cm 6989, 2006).

The *HFE Authority* had received two applications from scientific teams to carry out research using human cells and animal eggs to produce stem cells in November 2006.²³ The government proposal for a ban made the Authority less sure that an authorization of this research would survive legal scrutiny. Therefore it sought council's opinion about the question whether this research was covered by the legal meaning of embryos under the *HFE Act 1990*. The *Horizontal Scanning Expert Panel* (HHSEP) was asked a number of questions to inform council's opinion. The respondents from this panel agreed that the hybrid embryo would contain a complete human genome. However, no consensus could be found on whether a hybrid embryo would be capable of implantation and therefore the question whether this embryo could be categorized as alive was not decided.

The council subsequently informed the *Authority* that 'if (...) it cannot be shown definitively that the embryo does not have the normal potential to develop, it is most likely that the court would find that this constitutes a live human embryo for the purposes of the Act'. In the reasoning of the council, the courts are likely to see the embryo in a way that ensures that this type of research falls under the scope of regulation rather than not. Here the council is referring to the purposive approach to statutory interpretation used by the House of Lords in the *Quintavalle* case in 2003 in order to interpret the 1990 Act.

On 11 January 2007 the Authority ruled that, under current regulation, the research would fall under their remit. However, it postponed the actual decision about the applications in order to first have a 'full and proper public debate and consultation as to whether in principle, licenses for these sorts of research could be granted'.²⁴ Apparently, the Authority felt the urge to organize a public consultation itself, as 'the public unease' for the government had been reason to proposing not to allow the creation of hybrid embryos.

The strategic use of language in the consultation of the public

In the public consultation, the *HFE Authority* sought the views of the public, interest groups and the scientific community.²⁵ In the consultation document three types of human-animal hybrid embryos were distinguished and two of this three were juxtaposed: the true hybrid and the 'cytoplasmic hybrid'.²⁶ These two types were presented as follows: The category of 'hybrid embryo', also called 'true hybrid' contains embryos which are created by mixing human sperm and animal eggs or human eggs and animal sperm. This is what people think of when they think of hybrids: '...they don't think of cytoplasmic hybrid embryos created in stem cell research, instead they imagine the half-human, half-animal monsters, like the minotaur that are associated with myths and legends'.²⁷ However the only two species that are genetically similar enough to produce life are mules and hinneys. True hybrid embryos might possibly

23 The scientists responsible for the applications wanted to produce stem cells using human cells and animal eggs. Because the mitochondria from the donor egg are still present, the resulting embryo contains nuclear DNA from the human cell and mitochondrial DNA from the animal egg. This means that the resulting embryo would contain a small amount of animal DNA from the mitochondria present in the animal egg (less than 1%). The applicators for a license were Dr. Lyle Armstrong, Institute of Human Genetics, University of New Castle and Dr. Stephen Minger, Stem Cell Biology Laboratory, Wolfson Centre for Age-Related Diseases, Kings College London.

24 See www.hfea.gov.uk.

25 In fact the consultation was not only on human-animal hybrid embryos but also on human-animal chimeras. For reasons of clarity I will restrict the attention in this paper to the first category. The aim of the consultation was 'to consider this kind of research in the broad context of embryonic stem cell research'. See HFE Authority, 'Hybrids and Chimeras' (April 2007), 6..

26 The third type that fell within the category of 'hybrids' is the transgenic human embryo: forms of human embryo that have animal genes inserted into them during early development. The creation of these embryos has not been practiced yet, but the creation of transgenic animal embryos has.

27 HFE Authority (n27) 9.

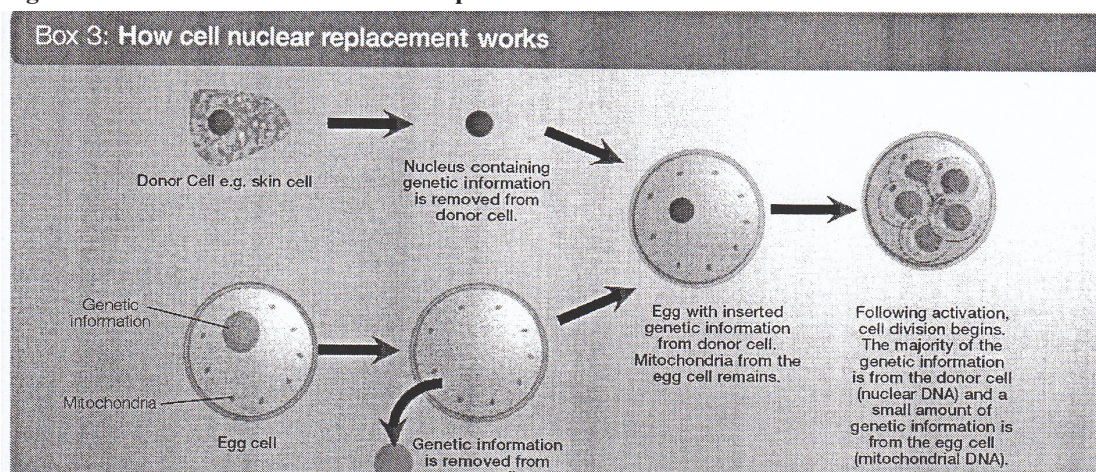
be created in the laboratory but ‘any attempt to create a living hybrid from two closely related species would be extremely unlikely to even produce a viable pregnancy’. It is also stated that: ‘These embryos would be different from ‘cytoplasmic hybrid embryos’ in that they would have an equal amount of DNA from the two species from which the eggs and the sperm are obtained’.²⁸ The ‘cytoplasmic hybrid embryo’ is created by combining a human nucleus with an enucleated animal egg and would contain less than 1% animal DNA.

In other words this document reassures the potential respondents to the consultation by juxtaposing the following picture of what people imagine when they think of human-animal hybrids to the schematic presentation of the cell nuclear replacement that will be applied in the submitted research proposals:

Fig. 1: This is what people are afraid of when imagining human-animal hybrids:



Fig. 2: But the research is more like the picture below:



Source: HFE Authority, April, 2007, p. 8.

In addition the Authority underscored the differences of ‘cytoplasmic hybrid embryos’ to ‘true hybrids’ by pointing at the amount of animal DNA. The description of ‘cytoplasmic hybrid embryos’ as containing 1% animal DNA at maximum was subsequently used in an opinion poll about the usage of embryos in research and 48% disagreed with the creation of such an embryo while over a third of the people agreed.²⁹

On 5 September 2007, the *HFE Authority* published its statement on its decision regarding hybrid embryos. The following conclusion is drawn from the consultation of the wider public: ‘public opinion is very finely divided with people generally opposed to this research unless it is tightly regulated and it is likely to lead to scientific or medical advancements’. By calling public opinion ‘divided’ the Authority refers to the outcome of the opinion poll that 48 % of the respondents was against the creation of ‘cytoplasmic hybrid embryos’. The claim that these respondents would withdraw their objection in case ‘the research would be tightly regulated’ is derived from the ‘public dialogue work’ that also has been part of the consultation.³⁰ The Authority combined this conclusion and the contribution of scientists to the consultation with the former legal advice and concluded that ‘cytoplasmic hybrid embryos’ as specific form of hybrid and chimera research, could be permitted.³¹

So, at the point the HFE Authority took its decision the scientific experts that had been involved in the process of decision making had found common ground with lay persons, at least the ones consulted, in the combination of the acceptance of the creation of ‘cytoplasmic hybrid embryos’ with the rejection of ‘true hybrids’. The following quantitative criterion of scientists has proven to be successful in convincing part of the opponents to human-animal hybrid embryos in this arena: acceptable were the forms of human-animal hybrids with less than 50 % animal derived DNA were thought to be acceptable in contradiction to the forms with 50 % or more animal derived DNA. With this distinction and the accompanying quantitative criterion the scientific experts participating in the arena of the decision making of the HFE Authority have shown to be responsive, at least to some extent, to the part of the public that thought of mixing human and animal gametes as repugnant.

However, from the responses the scientists of the Horizontal Scanning Expert Panel gave in the public consultation of the HFE Authority one gets the idea that this quantitative criterion is based on a misleading picture of embryonic development. The criterion above is based on what kind of DNA is put together in the test tube in the beginning of the process of the creation of the entity. By characterizing the mix of human and animal material by focusing on the ingredients that initially are put together the point of what embryonic development contains seems to be missed. According to the scientists of the *Horizontal Scanning Expert Panel* the mixing of the material activates processes that produce new material that is not human or animal to the same extent as the initial mix. Their general view was that ‘at some stage after embryonic genome activation all proteins produced (with the exception of those coded by the

29 In July 2007 a sample of 2073 residents of the UK was interviewed.

30 This public dialogue work consisted in: meetings and workshops in which various public perceptions, motivations and attitudes to the creation of human-animal embryos were explored. HFE Authority (n)Section 4.

31 About other kinds of human hybrid and human chimera research the statement says that ‘not only did the scientific community not wish to perform such research at present but also (...) the prospect was so distant that they could not envisage what forms this research would take in future (HFE A statement, 5 September 2007).

animal mitochondrial genes) would be human' (.³² While until the four to eight cell stages the embryo is relying on proteins and genetic messages that were present in the oocyte from the animal, this changes with the genome activation taking place in the four to eight cell stage. After this genome activation the stem cells formed would be almost entirely human. So from the four to eight cell stages until the blastocyst stage, the point at which the stem cells are derived, it could be considered human according to these international scientific experts consulted by the HFE Authority.³³

While the quantitative criterion above is based on where the genetic material is derived from, an animal or human, this information makes clear that the degree of either human or animal material in the early embryo changes with the stages of development the creature goes through.

4 The arena of the (pre) legislative process of amending the 1990 HFE Act

At the turn of the year 2006-2007, the prospect of the HFE Authority denying a license for creating human animal embryos incited a lobby of scientists and members of parliament. Their main activity consisted in sending a letter to the members of the Authority shortly before they would make a decision telling them it would be wise to support the research. The same day a summary of this letter was published in *The Times*.³⁴

This lobby is interesting with respect to the access of scientists to the legislative arena because it reveals the strong ties existing between scientists involved in stem cell research, such as Stephen Minger, Lyle Armstrong and Ian Wilmut and the members of the Select Committee Science and Technology.^{35 36} *The Select Committee* is charged with monitoring the work and activities of the Office of Science and Innovation, which is part of the Department of Trade and Industry. The lobby was led by Liberal Democrat MP Evan Harris, member of the *Select Committee* and explicitly supported by a conservative member as well as a Labour ex-member of this committee who held the former chair.³⁷

Other points of access for scientific experts were provided by the inquiry the *Select Committee Science and Technology* made into the government proposals for the new legislation for the use of embryos for research and the inquiry of the *Joint Committee on the Human Tissue and Embryos (Draft) Bill*.³⁸ The inquiry of the *Select Committee Sci-*

32 HFEA, 'Hybrids and Chimeras' (October 2007), Appendix H, section 6.

33 The blastocyst stage is preceded by the morula stage, a 16-32 cell stage. ,

34 *The Times*, 10 Jan, 2007.

35 Stephen Minger, Lyle Armstrong were the applicators for a license to create human animal hybrids, see n 24.

36 The Select Committee Science and Technology Committee is one of 18 departmental select committees in the House of Commons charged with monitoring the work and activities of a specific Government department. The Science and Technology Committee is unusual in that it monitors the Office of Science and Innovation, which is part of the Department of Trade and Industry, rather than a department in its own right. The Select Committee Science and Technology is made up of around 10 to 15 Members of the House of Commons.

37 The letter in the *Times* in addition to these persons was signed by other scientists, Nobel laureates amongst them, as well as social scientists, legal academics, medical ethicists and leaders of organizations of medical professional organizations and organizations of bio industry and bio science.

38 Report Select Committee Science and Technology, 'Government proposals for the regulation of hybrid and chimera embryos'. HC, 5 April, 2007; Joint Committee on the Human Tissue and Embryos (Draft) Bill, *Human Tissue and Embryos (Draft) Bill*, vol. I: Report, HC (2006-07) 630-I, HL Paper 169-I ; Joint Committee on the Human Tissue and Embryos (Draft) Bill, *Human Tissue and Embryos (Draft) Bill*, vol. II: Evidence, HC (2006-07), 630-II, HL Paper 169-II.

ence and Technology, among others, consisted in three oral evidence sessions during which it heard stem cell scientists as well as government officials, ethicists, a bishop and a leader of the organization *Human Genetics Alert*.³⁹ The *Joint Committee on the Human Tissue and Embryos (Draft) Bill* was established by the two Houses of Parliament in order to consider the draft bill presented by government in May 2007. The *Joint Committee* was asked to report on it to both Houses by 25 July 2007.⁴⁰ The report of the Joint Committee was informed by evidence coming from a few stem cell scientists, organizations involved in bioscience and government officials but also from organizations that are critical about the use of embryos in research, from religious as well as other backgrounds.^{41 42}

What strategic use is made of the language of the scientific experts participating in the (pre) legislative process? The Select Committee of Science and Technology held an inquiry because it conceived of the proposed ban on the creation of human-animal hybrid embryos as at odds with the recommendations of this committee in the last parliament.⁴³ According to this committee there were scientific aims that would make the creation of human-animal chimera or hybrid embryos necessary: the pursuit of knowledge about the genetic basis of disease and the direction of stem cells into future cell-based therapy. Furthermore, the stem cells produced would be medically useful in drug discovery and toxicity testing.⁴⁴

In their inquiry the committee started with considering what name should be chosen 'for what would result from the proposals to create embryos through somatic cell nuclear transfer of human genetic material into animal ova from which the main source of genetic material has been previously removed'.⁴⁵ Various names given by scientists were considered: Professor Shaw of King's college called them 'pseudo-hybrids', Dr Lyle Armstrong of Newcastle University 'interspecies embryos' and Professor Austin Smith of the University of Cambridge thought they would be better termed as 'cybrids'. Professor Sir David King argued that the entities that the scientists wanted to create 'should not be described as either chimeras or hybrids'.⁴⁶ He proposed to call them 'cytoplasmic hybrid embryos', which seems to be a bit contradictory to not wanting them to be called hybrid. The Science and Technology Committee decided to use Sir David King's description in the remainder of the report, without giving reasons for this choice.

The government followed the recommendation of the Select Committee and in its draft bill proposed to include the creation of 'cytoplasmic hybrids' in the categories of embryo that

39 Ibid 7

40 Its membership consisted of 9 members of the House of Commons and 9 members of the House of Lords. Five of the MPs were members of the Science and Society Committee or had been a member of the former Science and Society Committee.

41 Joint Committee, Vol. I (n 39) Appendix 2.

42 The committee also conducted an online consultation on four questions via its website, two questions related to interspecies research.

43 Report Select Committee of Science and Technology *'Human Reproductive Technology and the Law'* HC (2005) Eighth Special Report,.

44 Report Select Committee Science and Technology (n 39) 61.

45 Ibid 6

46 Sir David King was the UK Government's Chief Scientific Adviser and Head of the Government Office for Science from October 2000 to 31 December 2007.

may be authorized by a research license by the HFE Authority.⁴⁷ The ‘types of embryos created by combining together human and animal gametes or human embryos altered using animal DNA of animal cells’ were named “interspecies embryos”.

Congruent with the line of reasoning of the *HFE Authority*, government in the draft Bill proposed to forbid the creation of ‘true hybrids’⁴⁸ In the introduction to the draft bill Secretary of State for Health states about the list of forms of embryo that would be conditionally allowed ‘This list (...) does not include ‘true’ hybrids created from mixing human and animal gametes. In a the secretary adds “Other than as currently permitted for the purpose of testing the fertility or normality of human sperm’.⁴⁹

In contradiction to this exclusion of the category of ‘true’ hybrids in the draft bill, the *Joint Committee on the Human Tissue and Embryos (Draft) Bill* recommended the inclusion of this form of embryo in the categories that would conditionally be allowed. The reason was there was no ‘sound point of principle’ on which the distinction between true hybrids and the other categories would rest. The Joint Committee at this point explicitly referred to ethicist Holm, who as a witness before the committee had claimed that both categories of hybrid embryos were ‘equally objectionable on ethical grounds’.⁵⁰ Once researchers have crossed the species barrier, no valid distinction is to be made between an entity that is 99% human and an entity that is 50% human According to the Joint Committee this view was supported by many others and it referred to the contributions of the All Party Parliamentary Pro-Life Group, Christian Action Research and Education and the Christian Medical Fellowship. In addition it was mentioned that Vivienne Nathanson, Director of Professional Activities of the British Medical Association saw no sense in the distinction⁵¹

These organizations indeed were against the creation of all subcategories of interspecies embryos and, like ethicist Holm, objected to allowing this creation. However, the Joint Committee by giving a twist to Holm’s argument could use it to the advantage of their own purpose, which was to include the ‘true’ hybrid in the categories that would be legal. It would not make a difference to these organizations anyway, the Joint Committee stated.

47 In this draft bill, the interspecies embryos were to be explicitly excluded from the definition of an “embryo”. Instead these forms of embryo were to be regulated under a new section 4A with the title *Prohibitions in connection with genetic material not of human origin*. The ‘cytoplasmic hybrids’ fall under the description given in (b) of the following forms of interspecies embryo that were distinguished in this draft bill:

- (a) an embryo created by using human gametes and the gametes of an animal,
- (b) an embryo created by replacing the nucleus of an animal egg or a cell derived from an animal embryo with a human cell or the nucleus of a human cell,
- (c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal,
- (d) a human embryo that has been altered by the introduction of one or more animal cells, or
- (e) any other embryo that contains both –
 - (i) any haploid set of human chromosomes, and
 - (ii) any haploid set of animal chromosomes of any other sequence of nuclear or mitochondrial DNA of an animal.

See *Human Tissue and Embryos (Draft) Bill*, May 2007.

48 A way out of this ban was built into the proposal by stating that permission could be made possible by regulations made by the Secretary of State, see *Human Tissue and Embryos (Draft) Bill*, May 2007, p. X.

49 The Hamster test as well as the creation of (other) true hybrids would fall under the form of embryo as described in footnote 47 under (a) but is banned from being conditionally allowed by the statement of the Secretary of State. See *Human Tissue and Embryos (Draft) Bill*, May 2007, p.ix-x.

50 Joint Committee, Vol I (n 41) 46.

51 Ibid. The reason was that bringing the true hybrid also under the remit of the HFE Authority would make the rules more flexible and make it easier to allow the creation of true hybrids at the moment that this would become essential. See Joint Committee, Vol. II (n 41) 49.

The Minister opposed their arguments with the pragmatic argument that currently there was no call for research using ‘true’ hybrids and as public opinion was a concern she wanted to postpone the discussion on this point. The *Joint Committee* stated not to be persuaded by this argument and added to this evidence that ‘true’ hybrids already were created in the so-called ‘hamster-test’.⁵² This is a well established and explicitly endorsed test in which human sperm are mixed with hamster eggs to test the health and motility of the human sperm. Government officials sought to explain the difference between the ‘true’ hybrid resulting from this test and any other sort of ‘true’ hybrid but again their explanation appeared not to persuade the Joint Committee. In its report the committee persisted that no distinction should be made.

The reader could easily get the impression at this point that ethicists have had the last word concerning the inclusion of true human-animal hybrids in section 4 of the *2008 HFE Act*: While scientists brought forward a criterion for distinguishing ‘true hybrids’ from the other types of interspecies or human admixed embryos - the first being entities with a degree of 50 % or more of an animal genetic constitution - ethicists declared this criterion to be ethically non valid. However, a closer look at the information brought forward by a scientists witnessing before the Joint Committee makes clear that the underlying scientific facts were contested. Witness Professor Richard Gardner is asked what he thinks about the idea that a human genetic constitution of 50 per cent or more is a significant factor in determining whether an interspecies embryo should be defined as human. He answers that it depends on what you are talking about when using the concept ‘genetic constitution of the interspecies embryo’: the amount of genes in the mitochondria of the animal cell or the amount of DNA that the mitochondria contribute to the (new) cell.⁵³ He also declared that we cannot be certain about what will happen when you combine cells from two origins: ‘...one contributed can out-compete the other’. One can conclude from this that the degree of humanness of the resulting entity can not really be established by looking at the amount of human and animal DNA you put into it at the beginning of the process. Maybe, it could even be the case that the animal DNA out-competes the human DNA. This option was not accounted for in the reasoning about embryonic development that informed the quantitative criterion that was formulated by the scientists in the HFE Authority.

On 13 November 2008 the *2008 HFE Bill* became an Act of Parliament.⁵⁴ The name interspecies embryos that had been given to the human animal forms of embryo in the Bill, was changed by an amendment in the House of Lords into ‘human admixed embryo’. The ‘human admixed embryo’ refers to types of embryo which contain both human and animal DNA and five subcategories of these types are distinguished in section 4A(6). From the Explanatory Notes it becomes clear that the cytoplasmic hybrid embryo (section 4A(6)a) as well as the

52 Joint Committee, Vol. I (n 41) 46.

53 Gardner continues his argument ‘the amount of genes in the mitochondria is about 13 genes compared to 30.000 in the human nucleus genome whereas the total mass of mitochondria and the amount of DNA that they contribute to a cell could be extremely substantial’(Joint Committee, Vol. II (n 41) 207.

54 Human Fertilisation and Embryology Act 2008 (C22).

hybrid embryo (section 4A(6)b) is included in the subcategories of human animal forms of embryo that are conditionally allowed to be created.⁵⁵

5 Conclusion on the contribution of scientific experts

What does this analysis tell us about the contribution of scientific experts to the legislative rules concerning the use of embryos for research? The knowledge brought forward by the scientific experts in the arena of the HFE Authority was contested by scientific experts that were consulted in the arena of the legislative process. The knowledge about the constitution of the embryo that will result from mixing cells and/or gametes of different species is contested, as the exact constitution remains to be seen from future research. Notwithstanding this contested character of the knowledge about the future constitution of the embryo the Authority formulated a criterion concerning the proportion of animal and human derived DNA in the forms of embryo that are proposed to be created to underscore the contrast between ‘cytoplasmic hybrid embryos’ and ‘true hybrid embryos’. This distinction was put central in their public consultation. The effort of Authority to make this distinction relevant in law was meant to reassure the part of the public that expressed repugnance toward the idea of combining human and animal material. However, this effort failed. In the legislative arena the distinction between the two forms of embryo in terms of animal and human DNA turned out to make no difference to the opponents of the creation of human-animal forms of embryo. At that point it was also made clear that the criterion of more than 50 % human DNA was scientifically contested.

The contribution of scientific experts is indispensable for formulating new categories of human embryo for the law as they are unique in having at least some idea about the new entities that would be created with the planned research. However, the constitution of the entity to be created cannot really be predicted in detail and the knowledge scientific experts brought forward in different arenas of decision making in the UK is not equivocal. While in the first arena scientific criteria were molded in a shape that took the repugnance of opponents into account by making a distinction between different forms of human animal hybrids, this apparently was not longer considered necessary in the legislative arena. After all, the conclusion that a near majority would agree with the creation of cytoplasmic hybrid embryos had already been drawn in the report of the public consultation on hybrids and chimeras of the *HFE Authority*. This agreement subsequently functioned as a stepping stone for the proponents of the creation of all forms of human animal hybrids. At this point the reasoning of the *Joint Committee* was as follows: if the public agrees with creating ‘cytoplasmic hybrid embryos’ it must

⁵⁵ Different from the (Draft) Bill the cytoplasmic hybrid in the Act is described under (a) while the true hybrid falls under the description given under (b).

See Human Fertilisation and Embryology Act 2008 Section 4A(6)

(a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with -

(i) two human pronuclei or

(ii) one nucleus of a human gamete or of any other human cell, or

(iii) one human gamete or other human cell

(b) any other human embryo created by using

(i) human gametes and animal gametes, or

(ii) one human pronucleus or one animal pronucleus.

also agree with the creation of ‘true hybrids’ because the distinction is not ethically relevant and as we were made aware of recently also not scientifically sound.

This kind of providing false certainties will have a devastating effect on the trust of the people in scientific experts and in the regulation of technology in the long run. Therefore, it would be better for these experts to be more modest and give more room to moral and other considerations in the decision making about the rules.

6 The merits and pitfalls of this case of decentered regulation

In this last section I will turn to the central question of the article and elaborate on what this case study teaches us about the merits and pitfalls of the model of decentered regulation. I will start by describing the background of this model of regulation and contextualize the decision of legislators to bring this model into effect.

In the eighties of the last century, models of ‘decentered regulation’ were advocated in order to cope with the specific challenges technological innovation brings with it. In the literature on governance these challenges are characterized with three keywords complexity, dynamics and diversity.⁵⁶ The words complexity and dynamics in this context refer to the technological innovations: specialized expertise is required to understand them and the pace in which they develop and offer new possibilities implies that the legislator has to reconsider and adapt its policy on a constant base. The third keyword that characterizes the challenges of technological innovation in modern society is diversity. This refers to the diversity in the morals of people that nowadays exists: people express a variety of beliefs and opinions about the ethical boundaries of technological innovation and most of the time these are rather vague and leaving room for different options.

The idea that the model of decentered regulation can cope with complexity, dynamics and diversity echoed in the reasons given by legislators to choose for this model in the case of biomedical technology. In discussing the merits and pitfalls of the implementation of this model as revealed in the analysis above, I will reflect respectively on four of these reasons. First, specialized expertise is required to grasp all the relevant aspects involved in technological developments. By creating a body of scientific and other experts -in the case of the *HFE Authority* a subordinated body- that on a case-to-case basis decides whether the use of embryos in the research will be allowed by government makes sure that policy decisions are informed by the relevant specialized knowledge. In this case the legislator has tried to anticipate the risk of giving scientific experts disproportionate power over the rules by stipulating that in addition to medical and scientific experts also members ‘representing social, legal and religious knowledge and experience’ should be chosen as member of the HFE Authority.⁵⁷ However, this has not really solved the problem of the disproportionate power that in the model is given to scientific experts. Although the constitution of the new forms of human embryo to be created cannot be predicted in detail and the knowledge is contested it is given much weight

56 J Kooiman, ‘Findings, Speculations and Recommendations’ in J.Kooiman (ed), *Modern Governance. New Government-Society Interactions* (Sage Publications, London, 1993); J. Black ‘Critical Reflections on Regulations’(2002), LSE discussionsPapers.htm DP4 <www.lse.ac.uk/collections/CARR/documents>.

57 Lee and Morgan (n 9) 102-3.

because in a manner of speaking ‘it is all we have’. On top of that this knowledge is of such specialized character that the other participants in the decision making process cannot check it. Take for example the pivoting point in the analysis above: even the average well educated social scientist or ethicist will have difficulties to check claims about the degree of animal and human material in an embryo that will be created by replacing the nucleus of an animal egg cell with human cells.

A second reason to choose for a devolved model of regulation is the high pace at which biomedical technology is developing and constantly opening up new possibilities. Deciding on a case-to-case basis whether an innovation is within the boundaries formulated in an Act is thought to provide the mechanism that strikes the right balance between flexibility and precision as requirements for regulation. The case-to-case approach in the example turned out to offer indeed some flexibility to cope with new possibilities, such as new ways of creating embryos (Cell Nuclear Replacement) and new forms of embryo (human-animal hybrids). However, the claim of the proponents of the model of decentered regulation is the case-to-case approach would be more efficient in coping with such new possibilities than centralized legislation. The case study shows that devolution does not replace litigation and the need to change the law. The question whether Cell Nuclear Replacement fell within the 1990 HFE Act was challenged by the pro-Life alliance in the Quintavalla case in 2003. In the High Court Justice Crane had accepted the claim of the Pro-Life alliance that CNR did not fall under the legal definition of an embryo in the *1990 HFE Act*. In the chaos after this decision, the Government rushed through legislation explicitly banning reproductive cloning.⁵⁸ The case of human-animal hybrids, analyzed above, motivated the legislative process of amending the *1990 HFE Act*. Although the legislative process of changing law may have been suspended by the case-to-case decision making and the public consultations of the Authority, the need for law change was obviously not avoided.⁵⁹ From this it becomes clear that the model of decentered regulation does not necessarily exclude litigation and law change and that it remains to be seen whether it is more efficient than centralized legislation.

A third reason legislators give in defense of a model of ‘decentered regulation’ is that there is no widespread agreement on the fundamental ethical issues involved. The diversity problem clearly is an issue with regard to the use of embryos in research. No general agreement exists on the fundamental ethical issues involved. This is evidenced by the equivocal conceptual basis for the status of the human embryo.⁶⁰ How does the model of decentered regulation succeed in coping with this diversity problem? The *HFE Authority* provides space and time for reflection in the consideration of new developments in the use of embryos in research. The idea of the legislator was that this space would be used for paying attention to and acknowledging the view of a significant religious section of the population, represented by the

58 See n 7.

59 In order to establish and compare the efficiency of the decentered model and of the hierarchical model of regulation, information would be needed about the ‘normal’ length of the different kinds of decision making processes.

60 The law is grounded on the idea of intrinsic worth because of the potentiality of the embryo to grow into a human being and the idea that protection should increase as the embryo develops, because of the growing probability that it will become a human being. In legislation, fourteen days after conception is considered a significant moment. Although based on biological facts of the development of the embryo in the womb, the decision of legislators to make this moment rather than other moments in the development moral relevant is not uncontested. Lee and Morgan (n 9) 68-72.

Pro-Life Alliance and also for ‘allaying general fears about the possible abuse of science’.^{61 62} For the *Pro-Life Alliance* the early embryo from the moment of conception is a person with full moral standing and any use of the embryo in research contravenes its rights. So the acknowledgement of their view in the consideration of new developments in this use would be hard if not impossible. This is different for the group of people expressing their fear of and repugnance of a specific kind of embryo research. The case-study shows in what manner the Authority made an effort to be responsive to their worries: it suggested the creation of true hybrids should not be conditionally allowed in contrast to the creation of ‘cytoplasmic hybrid embryos’. But in the legislative arena a coalition of MP members of the Select Committee and scientists succeeded in pushing the boundaries further and including also the ‘true hybrids’ in the category of ‘human-admixed-embryos’ that would be conditionally allowed. So with hindsight the strategic use of language the Authority made by describing ‘cytoplasmic hybrid embryos’ as not being true hybrids can be seen as ‘the camel nose under the tent’, once the first form of human-animal-embryos was proposed to be legalized the other forms followed rather automatically. Instead of acknowledging dissenting views on the issue the function of the Authority seems to have been to make the majority of the public ripe for accepting the creation of one form of human-animal hybrid embryo. The model of decentered regulation has served as a two-stages rocket in securing the compliance of firstly a dissenting part of the public and subsequently parliament. The model facilitates this by providing in an extra arena for the powerful proponents to convince other actors that their specification and interpretation of the rules is the right interpretation.

This brings us to the fourth reason for legislators to apply a model of decentered regulation: there is interaction between the pace of scientific, technological, development and the way the political community ‘chooses’ to interpret moral principles and ideas. Changes in technological possibilities provoke changes in the underpinning social acceptance. This also is the case with the political community in considering new techniques involving the creation of embryos: the interpretation of moral principles such as respect for human life and human dignity, changes in time. To be more precise, these choices change with the promises concerning the cure of diseases that are attached to these new techniques. A feature of the *HFE Act* that can be traced back to the Warnock report is that it gives a central role in policy making to ‘what the people think’. As Dawson (2004) suggests the readiness to base policy on the opinion of the public could very well stem from the idea that this provides a democratic justification for the policy.⁶³ The case study shows that with the public consultations public opinion is not only scrutinized but also steered into a particular direction. In the case-study the *HFE Authority* with its public consultation tries to foster the acceptance of the creation of ‘cytoplasmic hybrid embryos’ by pointing to the promises it entails for improving human health and by underscoring that it is much less frightening than the creation of ‘true hybrids’.

In the introduction I referred to the conclusion of Levitt that the case-to-case approach of *the HFE Authority* each time creates a momentum pushing things forward to liberalization of policy.⁶⁴ This conclusion actually concerned the decision making of the Authority concerning Assisted Reproduction but seems to be true also for the policy concerning the use of human

61 Report of the Committee of Inquiry into Human Fertilisation and Embryology (Cmnd 9341, 1984).

62 M. Johnson and K. Petersen, ‘Instruments for the ART Regulation: What are the Most Appropriate mechanisms for Achieving Smart Regulation’ in S. Sclater Ebtehaj, F., Jackson, E. and M. Richards (eds), *Regulating Autonomy. Sex, Reproduction and Family*, (Hart Publishing, Oxford, 2009), 169-197.

63 Dawson (n 10)

64 Levitt (n 4)

embryos in research: After the UK legislator in 2001 conditionally allowed therapeutic cloning, in 2008 also the creation of embryos by combining human and animal material became conditionally permitted. The explanation Levitt gives for this phenomenon of liberalization is also applicable to this policy: Firstly, the public in consultations is asked each time to say yes or no to a specific technique, it is not asked about what should be the research and development priorities. It would for example be a wise thing to weigh up the expected effects of the new technique for human health against the effects of alternative techniques that would not involve the use of human embryos. Secondly, thanks to media involvement scientists and commercial pressures each time grasp their chance to portray the innovation as promising as possible with respect to human health. This brings in the commercial interests that are involved in the development of embryo and stem cell research. The pharmaceutical industry has a direct stake in the continuation of the innovation in this research, because of the medicines and therapies that are thought to result from it. This industry is also powerful in the sense of having resources, such as money, information and relations, which make it possible to exert much influence on the way innovations in the use of human embryos and the health results expected are portrayed in the media. Looked at from this perspective an interesting question would be whether the case-to-case approach empowers the pharmaceutical industry in influencing the rules rather than stimulating public debate. However, this question will not be addressed here as the role of the pharmaceutical industry was not part of the case study.

To **conclude** this article I will summarize the merits and pitfalls of the model of decentered regulation as conveyed in the analysis. The model guarantees the input of relevant scientific expertise. The case-to-case approach by a discretionary power serves to make the public ripe for accepting innovations in the use of embryos in research. The model facilitates the securing of compliance of the public because it makes sure that each new technique is considered at its own and because it provides in two stages of consideration of the technique. A clear disadvantage in the light of democracy is that it does not give the scientific experts involved a considerable extent of power over the formulation of the legal rules. As the most important source of this power is their knowledge of the scientific details this cannot be checked by non-scientists participating in the decision making committee to which (part of) the power of rule making is delegated. The question whether the model is more efficient than the classical model of rule making, is left unanswered yet.