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# Bioethics, Politics and Business

*Edited by Salla Lötjönen and Helena von Troil*

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**Nordic Council of Ministers**
Store Strandstræde 18
DK-1255 Copenhagen K
Phone (+45) 3396 0200
Fax (+45) 3396 0202

**Nordic Council**
Store Strandstræde 18
DK-1255 Copenhagen K
Phone (+45) 3396 0400
Fax (+45) 3311 1870

**www.norden.org**

The *Nordic Committee on Bioetics* was established 1988 to identify and survey ethical issues related to legislation, research and developments in biotechnology in the Nordic countries and internationally. The committee has two members from each of the Nordic countries. It contributes to the public debate by organising workshops on selected items, publishing reports and policy documents, and spreading information to national authorities and national ethical committees.

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# Contents

# Foreword

## The Power of Bioethics, Politics and Business

In the decision-making involving biosciences and biotechnology, both politicians and the general public have come to increasingly rely on different kinds of experts and specialised bodies. Interest groups such as industry, religious authorities and consumer organisations also try to influence political decision-making, and the role of the media has not always been – it is claimed – as neutral as the public perceives it to be. At the same time, according to the democratic ideal, ultimate power should rest with the parliamentarians and with the people. Who has the power in decision-making in biotechnology? Can there be legitimate expertise in bioethics? How can we improve the power balance? These are some of the questions this book seeks to answer.

The articles in this book are based on papers delivered at two seminars: the first of them, entitled *Business and Bioethics*, concentrated on identifying and analysing the roles and potential conflicts of interest between the scientists, the biotechnological industry and the policy-makers.[1] The second seminar, called *Bioethics or Biopolitics?* widened the perspective first of all to analyse decision-making in the area of biotechnology from the point of view of the democratic ideal, and secondly, to view the interrelationship between bioethics, politics and certain power players such as the expert bodies and the media.[2]

The book is divided into three parts. In the first part, we present the articles dealing with the role of biopolitics and the expert bodies in relation to the democratic ideal. Vilhjálmur Árnason provides us with definitions of the central concepts and discusses the implications of democracy for biopolitics and the role of the citizens in biopolitical decision-making.

[1] The seminar was held in Malmö, Sweden, 15–16 October 2006. The full seminar programme can be found on the internet site of the Nordic Committee on Bioethics www.ncbio.org .

[2] This seminar was held in Espoo, Finland, 11–12 June 2007. The full seminar programme can be found on the internet site of the Nordic Committee on Bioethics www.ncbio.org

Klemens Kappel and Veikko Launis analyse the justification and role of national ethics advisory boards and research ethics committees in their respective articles. Stellan Welin complements these in his account on the history and development of the ethics committee system and an example of the role of expert bodies with regard to the creation of national policy on embryonic stem cell research in Sweden. Finally, Jill Loga gives a Norwegian example of ad hoc expert commissions – yet another role played by experts in policy-making.

In the second part, we look at the special role of the media in relation to decision-making in bioethics and biopolitics. Torben Hviid Nielsen and Maja Horst present two case studies of the media's ability to shape opinion on stem cell research and cloning in Denmark and Norway. Helena von Troil looks at the development of the GMO debate, in which the media also played a significant role. Finally Ulla Järvi discusses the pros and cons of science journalism.

The third and the last part of the book looks at the links between the biotechnology industry and bioethical decision-making. Peter C. Gøtzsche sets the scene in his paper with examples showing the impact of conflicts of interest between commercial interests and the common good. Then, Lise Holst gives an example of responsible business practice. In the last two articles, Boo Edgar and Salla Lötjönen analyse similar conflicts arising from public-private partnerships and try to find a compromise between the profit-oriented and the common good-oriented approaches to create a way forward for mutually beneficial co-existence.

This book is in a way a farewell to Nordic bioethics by both of the editors. Helena von Troil has been an invaluable Secretary General to the Nordic Committee on Bioethics for just over six years, 2002–08, and Salla Lötjönen has served as a Finnish member of the Committee for six years, 2002–07, chairing the Committee in 2006. It is time to hand the reins over to new people with new energy and fresh ideas, although bioethics and science education will doubtless continue to influence our lives in more ways than we can anticipate.

May 2008

*Salla Lötjönen*
Adjunct Professor, University of Helsinki, Finland
Lecturer in Health Care Ethics and Law,
University of Manchester, United Kingdom

*Helena von Troil*
Science communicator,
Archeon Ltd.

# Förord

## Makt, Bioetik, Politik och Business

Både politiker och allmänhet har alltmer börjat ty sig till olika typer av experter och expertorgan när det gäller beslutsfattandet i biovetenskaper och bioteknologi. Intressegrupper som industrin, religiösa auktoriteter och konsumentorganisationer försöker även de påverka det politiska beslutsfattandet. Somliga påstår också att mediernas roll inte alltid har varit fullt så neutral som allmänheten har trott. Samtidigt är det ju så, att det demokratiska idealet förutsätter att det är parlamentarikerna och folket som har den slutliga makten. Vem har då makten när beslut fattas som berör bioteknologi? Kan det finnas legitim expertis i bioetik? Hur kan vi förbättra maktbalansen? Detta är några av de frågor som denhär boken försöker besvara.

Bokens artiklar baserar sig på inlägg vid två olika seminarier. Det första av dem, kallat *Business and Bioethics*, strävade till att identifiera och analysera de olika aktörernas roller och eventuella intressekonflikter. Med aktörer avsågs i detta fall forskare, bioteknologiindustrin och beslutsfattarna.[3] Det andra seminariet, kallat *Bioethics or Biopolitics?*, vidgade perspektivet för det första till att analysera beslutsfattandet inom bioteknologi ur det demokratiska idealets synvinkel och för det andra till att granska förhållandena mellan bioetik, politik och vissa maktaktörer som t.ex. expertorgan och medierna.[4]

Boken är delad i tre delar. I den första delen presenterar vi artiklar som handlar om biopolitikens och expertorganenas roll i relation till det demokratiska idealet. Vilhjálmur Árnason ger oss definitioner på centrala begrepp och diskuterar demokratins implikationer för biopolitik och

[3] Seminariet hölls i Malmö, Sverige, 15–16 oktober 2006. Seminarieprogrammet finns på Nordisk kommitté för bioetiks internet hemsida www.ncbio.org

[4] Seminariet hölls i Esbo, Finland, 11–12 juni 2007. Seminarieprogrammet finns på Nordisk kommitté för bioetiks internet hemsida www.ncbio.org

medborgarnas roll i biopolitiskt beslutsfattande. Klemens Kappel och Veikko Launis analyserar nationella rådgivande etiska kommittéers och forskningsetiska kommittéers roll och legitimitet. Stellan Welin kompletterar dessa med sin beskrivning av hur systemet med etiska kommittéer uppstod och utvecklades. Han ger också ett exempel på rollen som ett expertorgan spelade då man gjorde upp en nationell strategi för forskning på embryonala stamceller i Sverige. Slutligen ger Jill Loga ett norskt exempel på ad hoc expertkommittéer - ytterligare en roll spelad av experter i politiskt beslutsfattande.

I den andra delen studerar vi medierans speciella roll i beslutsfattandet i bioetik och biopolitik. Torben Hviid Nielsen och Maja Horst presenterar två fallstudier om mediernas förmåga att skapa opinion om kloning och stamcellsforskning i Norge och Danmark. Helena von Troil beskriver utvecklingen av GMO-debatten där medierna också spelade en viktig roll. Till sist diskuterar Ulla Järvi för- och nackdelarna med vetenskapsjournalistik.

Den tredje och sista delen av boken handlar om förhållandet mellan bioteknologiindustrin och bioetiskt beslutsfattande. Peter C. Gøtzsche ger i sin artikel exempel på följderna av konflikter mellan kommersiella intressen och allmännyttan. Sedan ger Lise Holst ett exempel på ansvarskännande affärspraxis. I de två sista artiklarna analyserar Boo Edgar och Salla Lötjönen konflikter som uppstår i partnerskap mellan det offentliga och det privata. De försöker finna en kompromiss mellan det vinstorienterade förhållningssättet och det som är mera inriktat på allmännyttan för att skapa förutsättningar för samexistens som gagnar alla parter.

Denhär boken är på sätt och vis de båda redaktörernas farväl till nordisk bioetik. Helena von Troil har i över sex år, 2002–2008, varit generalsekreterare för Nordisk kommitté för bioetik. Salla Lötjönen har varit finländsk kommittémedlem i sex år, 2002–2007, och ordförande för kommittén 2006. Det är dags att ge över tyglarna till andra personer med ny energi och fräscha idéer, även om bioetik och vetenskapskommunikation utan tvekan kommer att påverka våra liv på fler sätt än vi idag kan ana.

Maj 2008

*Salla Lötjönen*
Docent, Helsingfors universitet, Finland
Föreläsare i hälsovårdsetik och juridik,
Manchester univeristet, Storbritannien

*Helena von Troil*
Vetenskapskommunikatör,
Archeon Ab

# Biopolitics in a Democratic Society

Professor *Vilhjálmur Árnason*, Department of Philosophy & Centre for Ethics
University of Iceland, Reykjavik, Iceland

## Introduction

In this paper I start by discussing briefly the notions of biopolitics and democracy. I then ask what implications the fact that we live in a democratic society may have for biopolitics. I distinguish between three different conceptions of the citizen implied in biopolitical discourse and relate them to different functions of democracy. I argue that there is a need to encourage and facilitate a more active public engagement while raising the citizens' scientific awareness. Finally, I consider some of the complexities related to the task of fostering scientific citizenship in contemporary society and describe an example where biopolicy is carried out in the spirit of deliberative democracy.

## Biopolitics

I take the notion of biopolitics to encompass the way in which biotechnology and bioscience are dealt with at the political level: such as issues of governance, review processes, policy making, public information and social debate concerning biotechnological projects. This understanding of biopolitics implies the political application of bioethics and involvement of "bioethicists" in regulatory and advisory institutions. Bioethics has increasingly become an institutionalized practice and is thus inevitably an aspect of biopolitics. As a practical study of bio-issues in society, which inevitably implies the political dimension, bioethics is also politically implicated in a more general sense. It is crucial, therefore, for bioethical theorists to become more aware of these biopolitical implications and reflect critically upon the role and effects of bioethics in this regard. Although of major importance, it is not enough to inquire into the ethical

implications of a particular biotechnical policy; they must be placed in a wider context of culture and society.[5] Without such critical reflection, bioethics risks being an innocent accomplice of the powers that be, or a mere instrument of science and technology. In this way, bioethics also assumes a questionable legitimizing role for biotechnological projects.

This I do not say in the ironic spirit of Foucauldian biopower, the regulation and self-regulation of a docile population in light of bioscientific knowledge. In that theoretical context, democracy can be primarily regarded as a vehicle of horizontal power which inevitably entangles the subjects in the processes of socialization and self-formation. From this perspective, the task of theoretical analysis is to discover and disclose the different manifestations of biopower without any emancipatory appeal to a more rational rule of free citizens. This is an important and realistic analysis of biopolitics, but I find it also important to be guided by a vision of possibilities to increase public awareness about biotechnology, aiming at better understanding of science and wider opportunities for the public to influence biopolicy-making. For this task it is necessary to ask what it means to be a citizen in a democratic society and what implications that may have for biopolitics.

## Democracy

Democracy is a complicated and multifaceted notion, but in this context I will for the sake of analysis distinguish generally between its two main functions. As an institutional framework, the main function of democracy is to maintain the division and balance of power and thus to protect citizens against the misuse of state power. From this perspective, democracy is made manifest in the rule of law and constitutional grounding of civil rights. As we will see, this function of democracy is tested at many levels and in various aspects, and has in fact predominated so far in the area of biopolitics.

The other main function of democracy is to ensure that the majority will is represented in the government of society and that political decisions are made in the public interest. In this second function as a method of decision-making, there is an interesting tension between the attempt to respect the general will on the one hand and to further the common good

[5] Cf. Árnason & Hjörleifsson, 2007.

on the other hand. The volitional aspect as such requires only that public policies reflect the preferences of the majority and these are most obviously expressed through voting. The requirement of furthering the common good, however, implies epistemological aspects which call for expert knowledge, and contemporary democratic politics is largely influenced by science and technology which are intended to meet this requirement.[6] In this regard the point is not to follow the aggregate of relatively uninformed preferences in popular voting but to leave the thinking about complicated issues to experts whose task it is to steer us on a course for the common good.

One way to relieve this tension between the requirements of respecting the majority will and furthering the common good is to increase public deliberation about political issues. Here we encounter a classical dimension of democracy as a rule of dialogue: "An essential feature of democratic government … is that it is government through discussion, by persuasion instead of by force".[7] This feature can also be extended beyond representative government and parliament to the public forum in the community at large. In order to meet this challenge, it is important to look for ways to facilitate public dialogue in society with the aim of both informing the citizens and giving them opportunities to deliberate, voice concerns and exchange viewpoints and arguments concerning policies in areas where decisions are to be made. In this way the emphasis falls upon the quality of the information and reflection about the issues that precedes decisions and elections no less than upon the voting outcome. This has been characterized as a "talk-centric" rather than "vote-centric" view on democracy and is commonly discussed under the heading of deliberative democracy.[8] It seems to me that all these features and functions of democracy have important implications for biopolitics.

## Implications for Biopolitics

In line with the two main functions of democracy outlined above, it is important to look both at institutional requirements and at methods and

[6] For a critical analysis of this, see e.g. J. Habermas, 1970. See also E. Lagerspetz, 2008.
[7] D.D Raphael, 1970: 150.
[8] Kymlicka, 2002: 290; Bohman & Rehg, 1997; Benhabib, 1996.

aims of decision-making relating to biopolitics. As for the institutional requirements, I find three issues of democratic biopolitics to be of primary importance. The first is a clear separation of the roles of public authorities and the private sector. The need to maintain this *separation of powers* has become increasingly urgent as biotechnology is attracting ever more attention from private companies and investors on the market. It is understandable that private companies are primarily ruled by the profit motive, and even though that may often coincide with the common good, one cannot expect private biotech companies to be guardians of public interests. It is, on the other hand, the primary role of public authorities to protect the rights of the citizens and to ensure that private biobusiness is properly regulated. It follows from this that criticism of biopolitics should not be primarily aimed at private biocompanies since the responsibilities for policies and governance rest with the public authorities.[9]

The second aspect of institutional requirements in democratic biopolitics is the role of *expert knowledge* in regulatory and advisory agencies. This relates both to the procedure for nominations to such agencies as well as to their practices. The former concerns the general democratic requirement of limiting or balancing the power of political authorities and to avoid conflicts of interests. It is in line with this requirement that members of regulatory and advisory agencies are nominated by professional institutions and not directly by the political authorities themselves. Professional and academic institutions can be expected to provide independent expert knowledge. The independence of these institutions suggests that they have the general aim of respecting the principles of scientific practice and moral conduct rather than serving the political authorities or the private sector. This does not necessarily mean that its members are always neutral or unbiased. Independence is never absolute, it can only be specified with regard to the interests at stake in a particular context.

The second institutional requirement in regulation of biotechnology and scientific research concerns *transparency* of decision-making. This requirement has both a procedural and a substantive aspect. By the procedural requirement I mean that the rules, principles and codes that guide decision-making in such agencies are made known to the public. The

[9] For discussion of this in relation to the Icelandic Health Sector Database, see Árnason, 2004; Árnason & Árnason, 2004 and Árnason & Hjörleifsson, 2008.

substantive requirement, on the other hand, means that contents of policy decisions are accessible to the general public. It is sometimes argued that these requirements of transparency are necessary preconditions for public trust in institutions. There is no guarantee for that, however, since increased knowledge does not necessarily lead to more trust.[10] But there are strong reasons for arguing that these requirements will lead to more *trustworthy* institutions.

Institutional trustworthiness is a necessary feature of biopolitics in a democratic society. But it is not sufficient. Decisions in regulatory agencies are most often based upon scientific and moral expertise. Public consultation is often limited to professional organizations and other stakeholders in the area. This is supposed to ensure that policy reflects the scientific practices and status of knowledge in the field, while respecting the ethical principles of scientific practice and research. In a democratic society, however, policy receives its legitimacy from the fact that it is accepted by the general public or at least is not contrary to the will of the majority. In order to meet this criterion, it is important to look for ways to facilitate public dialogue in society with the aim of both informing the citizens and giving them opportunities to deliberate and exchange viewpoints and arguments concerning policies in the areas of science and biotechnology. If this is to feed into the law-making process, such public consultation obviously needs to precede the parliamentary deliberations. Experience has shown that law-making in this field is more likely to meet with public approval if the citizens have been consulted and had an opportunity to voice concerns.

Public debate will thus serve both to inform the citizens of the scientific issues, and scientists and policy-makers about public concerns, and enable consensus about controversial matters. The importance of this has grown as society has become increasingly pluralistic, where people of different cultural backgrounds and religious views are to abide by the same laws. One of the main conditions for an informed public dialogue is a strong professional media which can explain these often complex issues in such a way that they are understandable to the lay person, without sacrificing either objectivity or substantive information. While good scientific reporting in the media is crucial for facilitating public debate, a me-

[10] Cf. O'Neill, 2002. See also Sutrop, 2007.

dia that is open to the public is essential for conveying the public concerns to the politicians and policy-makers.

## Conceptions of the Citizen

Biopolitics and bioethical discourse have different conceptions of the citizens that play major role in policies about scientific research and biotechnology. These views resonate with general positions about the major roles of democracy. In this section I will describe two views of the citizen that I take to be prevailing in social and theoretical discourse about bioethical issues. I call them the protective view and the utility view. I will then explore an alternative vision of the citizen which I find largely ignored but which has more democratic features than the other two.

The protective view of the citizen draws its name from the fact that either explicitly or implicitly the ethical regulation of biotechnology and research on humans emphasizes above all the *protection* of people. Some of the major moral objectives are protection of privacy, protection against risks (a requirement of welfare) and protection of vulnerable research subjects (a requirement of justice). In all these cases, measures are to be taken that safeguard research participants and citizens in general from the possible hazards of biotechnology and misuse of information. Protection of autonomy is a more complicated matter but as it is usually fleshed out in the requirement of informed consent, it is most often reduced to a formal procedure which poses little or no challenge to the participant as an active moral agent.

This emphasis on protection is clearly necessary to protect the interests of human participants in research. But my point is that it is unduly limited to evaluate the interests of people mainly, not to say exclusively, from this perspective. If we relate this to the idea of democracy we see that these requirements of security fit well with the function of democracy to protect citizens against the misuse of both state power and market forces. This most often translates into the right of citizens to protection of their "private domain" from forces that can manipulate them and make harmful use of their personal information. In the national debate sparked by the Icelandic Health Sector Database case, an organization was formed with the specific purpose of protecting the rights of the citizens against misuse by public authorities and a powerful private company, partly dri-

ven by market forces. Appropriately, the association is called "Mannvernd" in Icelandic, literally human protection, which resonates well with "Persónuvernd", the name of the Icelandic Data Protection Agency. It is clearly necessary to protect citizens against the misuse of both private and public power in democratic society, but if it is overly emphasized it can divert our attention from other important aspects.

Staying with the Icelandic HSD example, it is instructive to note that the protective view has been partly (and especially in relation to the issue of consent[11]) in tension with a position which I label the utility view. I use the label to emphasize the *benefits* that can be reaped from biotechnology and genetic research. These benefits can be related to health, such as drug development, more effective predictive and preventive medicine, or to other sectors, such as increased employment opportunities for young scientists and other social and economic advantages that may flow from having thriving research companies. This medical and social utility position has prevailed within political and economic discourse about biotechnology. These are important considerations, but the promised benefits can be questionable and in any event they do not provide sufficient justifications for biopolitics.

It can be argued that the utility view of biotechnology relates to the function of democracy to ensure that decisions are made in the collective interest and that they further the common good. In fact, this argument from collective interests is often used to criticize the protective position, which is accused of emphasizing individual rights at the cost of social goods. This argument can be met from two angles. First, many of the health care benefits that are promised by biotechnology are both debatable and uncertain. Moreover, even if they could bring benefits to the wealthier parts of the globe, they would contribute nothing to the most pressing task of improving basic health care in poor countries. Second, it is a misleading description of the protective position to say that it focuses on individual interests that are contrary to general social goods. Effective regulation of biotechnology, which protects people against undue risk, hinders discrimination and manipulation of individuals, is in the public interest in the long run, even though it constrains researchers. From this perspective, insisting on a sharp division between individual and collective interests is misleading.

[11] Cf. Árnason & Hjörleifsson, 2008.

In the context of my discussion of the relationship of these views to democracy, their common shortcomings and limits are more conspicuous than their differences. Views that emphasize either people's protection or well-being in the ways I have described, tend to cast people in a passive role and disregard the active elements of human agency which are crucial for the democratic citizen. While the protective position puts security of individuals above all other considerations, the utility view regards the population as a collective resource for biotechnology. It is not surprising, then, that a prevailing position in biopolitics is a combination of the two views. This combination takes the following form, for example in discussions about population databases. In order to mine the population for maximum benefits, privacy protection needs to be extraordinarily strong. In this way, strong data security becomes one of the very preconditions of the utility view.

This is not surprising insofar as these two conceptions of the citizen tend to complement each other in contemporary society. These conceptions emphasize, on the one hand, the person in the domestic private sphere for whom the safeguarding of freedom from illegitimate interference is of primary importance. On the other, the citizen is seen as a consumer and worker in the economic sphere, contributing to the economic prosperity of society, largely thanks to high standards of public health. In this way, the protective and the utility positions relate more to people as private persons, consumers, workers and patients than democratic citizens. They disregard people as active and reflective citizens in democratic society and do not provide reasons for implementing policies that facilitate actions of the citizens in the public sphere. In the next section I will consider the possible implications for biopolitics of taking these elements of the active citizen into account.

## Empowering citizens: Challenges and Complexities

This view does not reject either the protective or the beneficial positions but seeks to overcome their shortcomings by taking other considerations into account. Clearly, one should not be forced to choose between protecting individual privacy, contributing to society or by increasing the awareness of the citizenry about science and biotechnology. But raising awareness obviously requires different biopolicies. I will only mention

here two preconditions for a new biopolitics that embodies this idea of the democratic citizen: improved scientific education and increased public deliberation about biopolitical matters.

The conception of the citizen on which education programs are based is of great importance in modern high-tech societies. Wider scientific literacy will surely boost biopolitical awareness and pave the way for policies that facilitate wider public engagement. Another precondition for biopolitics of a more democratic stamp is a strengthened professional media and scientific journalism, which provides the citizens with reliable information and critical analysis of socio-political implications of biotechnology. Together, improved scientific education and media facilitate informed public deliberation about biopolitical matters. This, however, will not do unless the channels and sites of public dialogue are strengthened in society, and the opportunities for action and reflection by citizens are extended. This requires, in fact, that bioethics is not sharply distinguished from biopolitics.[12]

The idea is clear but the task is certainly not easy. One thing to avoid, for example, is designing public consultations mainly as a strategic mechanism to generate public acceptance and institutional trust. This would surely result in more docile public, more willing to abide by the biopolicies that are shaped by the authorities. It is an important objective to increase trustworthiness of public policies but it is not the objective of democratic policies to construct citizens who are "vehicles" of a comprehensive biopower and "mechanisms of domination" over which they have no control. From this ironic perspective it may not matter much how biopolicies are formed because the choice is merely between a vertical or horizontal exercise of power. The Foucauldian perspective is of great heuristic use in the analysis of biopolitics, but it provides no guidance for the task of framing more constructive democratic biopolicies. For that it is necessary to create opportunities for citizens to develop their thinking and increase their understanding of science and impact on biopolicies. This vision implies a belief in the intrinsic value of consultation and public dialogue, more in the spirit of democratic deliberation.

The ideas of deliberative democracy are valuable in this context because they favor public will formation through informed discussion over and above lobbying and exerting pressure. One of the main spokesmen of

[12] Cf. Hoyer & Tutton, 2005.

deliberative democracy, Joshua Cohen, writes in the spirit of Habermas: "outcomes are democratically legitimate if and only if they could be the object of a free and reasoned agreement among equals".[13] This should not be understood as a realistic aim as much as a *critical idea* which can help us identify the role of power, coercion and ignorance in social decision-making. The critical idea of freedom in public deliberation is that all citizens should have opportunity to have their concerns heard, and even to make the rules of the debate a topic in itself.[14] Such a discussion encourages people to adopt a civic standpoint rather than think only from the point of view of their particular interests. This critical idea can thus be used to distinguish claims based on narrow self-interest of those conducive to the general public interest.

Although the guiding vision is important, we need, as Alan Irwin suggests, to "move beyond general exhortation alone over such matters and instead explore the social processes, underlying assumptions and operational principles through which scientific citizenship is constructed in particular settings".[15] It is important to move the discussion of public participation "from the level of sloganizing to an important focus for both social scientific and practical investigation and experimentation".[16] Among the complexities faced by efforts to democratize biopolicies are the following: What sort of information is provided and how is it is provided to the public? How are issues to be framed for public debate? How is public consultation to be institutionally located? No doubt, there will be a constant tension between science, politics and the public will, but this tension will take on various forms depending on the issue. The challenge is to transform this tension into a creative power for innovative policy making.

[13] Bohman & Rehg, 1997: 10.
[14] Benhabib, 1996: 79.
[15] Irwin, 2001: 15.
[16] Ibid., 16.

## Example

It is of the nature of creative democratic politics that it is in constant search for more efficient channels for informed public decision-making and to increase the impact of citizens on policy-making.[17] There is no universal solution to how this should be done, but the important thing is to be willing to make the effort to look for the appropriate approach in each case. One interesting attempt in the area of democratic biopolitics has been made in Ontario, Canada, where citizens' councils have been established in order to help guide drug policy.[18] This is partly occasioned by the fact that authorities face very difficult decisions regarding drug listing and reimbursement, not least because some of the new cancer drugs are extremely expensive but considerably more effective than the older alternatives. The councils consist of 12–20 members from a cross-section of the community to represent the city's cultural diversity. Participants should be independent of special interests or affiliations that could affect their judgment, such as links with pharmaceutical companies, health care services and patient organizations. The council has intensive meetings over two days, 3–4 times a year. The group gets all the information it asks for, can consult with specialists in the field as expert witnesses. On the basis of the information acquired, the members engage in an in-depth deliberation of the policy or issue. A report is prepared with recommendations for the authorities to consider in the formation and implementation of drug policy.

I take this as an interesting example of general will formation in the spirit of deliberative democracy. In this social experiment a systematic attempt is made to engage and educate ordinary citizens in reflection about policy-making in the area of biotechnology. Clearly, such a policy goes far beyond seeing citizens as passive objects in need of protection or of practical use to business. It appeals to them as thinking beings whose reflections matter to biopolicy. This policy-making attempt also indicates a sensible way to reconcile tensions between expert knowledge and the public will by facilitating the conditions for informed deliberation. It should then be possible to sail between the Charybdis of policies based on expert knowledge, often closely related to special interests in the field,

[17] Cf. Arblaster, 1987.

[18] www.ices.on.ca/file/Citizens_Council_Report_Nov-06.pdf

and the Scylla of populist policies that reflect the forces of lobbyism. In the first case, democracy works only after the fact when the citizens have the option to turn the authorities responsible for the policies out of office. In the latter case, democracy may work prematurely, as it were, in order to please the loudest and strongest interest groups. The idea of democracy as a rational dialogue is the only sensible way to avoid these pitfalls and the task of creative biopolitics is to be in constant search for ways of channeling the informed and deliberated will of the citizens.

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# National Ethics Advisory Boards: Do they have a Legitimate Role in Liberal Democracy?

Associate Professor *Klemens Kappel*
Philosophy Section, Department of Media, Cognition and Communication,
University of Copenhagen, Denmark

## 1. The Role of National Ethics Advisory Boards

National ethics advisory boards (NEABs), and the recommendations on bioethical questions they provide, have generally been welcomed as part of an important effort to ensure that ethical considerations are taken into account in research, commercial exploitation and regulation of biotechnology. However, occasionally concerns are voiced. How can anyone be in a position to speak authoritatively about ethics? Can there be experts in ethics in any genuine sense of the word? Is it for the state to appoint experts in ethics, thereby privileging certain views over others? And why should we treat bioethical questions as fundamentally different from other value questions, such as those involved in ordinary political controversies, where no expert advice is called for, or at least no one would think of appointing an ethics committee?

Anyone familiar with public debate about issues in bioethics will recognise these sorts of reservations concerning the legitimate role of national ethical advisory boards. Systematic philosophical discussion of this set of questions is rare, however.[19] The present paper is meant to be a step in that direction.

The paper is structured as follows. In section 2, I discuss the notion of advising on ethical matters, offering a way in which we might legiti-

[19] For a useful review of some of the issues, (Dodds 2006). Other good papers are (Brock 1987; Weinstein 1994; Kymlicka 1996). See also the papers in (Kuhse and Singer 2006). For a general discussion of the problems of expertise, see the papers collected in (Selinger and Crease 2007).

mately think of proper advice giving. In section 3, I turn to the problem of locating a legitimate place for state sponsored ethics advice in liberal democracies, along with some recommendations based on the findings of section 2.

First, however, it would be helpful to delineate the responsibilities that ethical advisory boards have. Here I take the Danish Council of Ethics as a model. There are no doubt important differences between NEABs in different countries, but they will not, I hope, matter for the discussion that follows. Paradigmatic NEAB duties include, I assume, roughly the following:

- NEABs are supposed to issue recommendations or advice about, for example, government policy, law, regulatory needs, institutional design or ethical guidelines in various domains. Such recommendations are typically directed at governments, parliaments, or various public institutions or government officials. In addition, ethics advisory boards may also provide moral guidance to the general public.
- NEABs should attempt to sort out and clarify factual and normative issues pertaining to questions in bioethics. This includes investigating the implications of various pieces of legislation and international conventions with regard to a particular question.
- NEABs should strive to educate the public about issues in bioethics, for example by providing teaching material, by providing input to journalists, and by organising public meetings about relevant topics.
- Finally, NEABs should initiate and stimulate public debate in order to ensure democratic legitimacy of political decisions.

Clearly, the major concerns about the role of NEABs pertain to (1). Why should we appoint a special committee to advise government, parliament and general public about questions in ethics? Are ethical questions not subjective in nature? Is it not for parliament to decide these matters, if a political decision is called for at all? Hence, in their pure form, the roles depicted in (2)–(4) do not raise the same sort of concerns. Nonetheless, particular efforts and initiatives falling under (2) – (4) are often not in this sense pure. For example, efforts undertaken by a NEAB to clarify, educate and stimulate debate about matters in bioethics will very often convey specific ways of framing a particular problem in bioethics which,

indirectly, could be taken as a recommendation of certain views over others. Thus, the difficulties raised by (1) will often be relevant for efforts to fill out the other role of NEABs. Nonetheless, for expositional simplicity I shall simply discuss (1) and leave aside the complexities raised by the other roles.

Notice also that Research Ethics Committees (RECs), whether they are local, national or international, are typically charged with overseeing compliance by specific research projects with the Helsinki Declaration or similar sets of principles or national legislation. This is very different from what I take to be NEABs' role. RECs are bound by a set of principles guiding research, and the task of a REC is to assess whether a particular research project complies with relevant legislation and principles. The RECs should not endorse one ethical view about what principles ought to regulate research.

Hospital ethics committees that deal with issues that arise in clinical practice are somewhat similar to Research Ethics Committees in this respect. Therefore, these kinds of committees are not the primary focus for the concerns I want to discuss here.

Notice also that some bioethics advisory boards are given responsibility for developing biopolicy.[20] Members of these boards are appointed by government, and their role is to prepare legislation and policies. They raise issues that are somewhat different from the topic of this paper.

There are, I think, two somewhat connected sets of issues that are raised concerning the legitimacy of the tasks NEABs are appointed to fulfil. One concerns the type of expertise in ethics that seems to be required to ensure sound advice-giving. The suspicion is simply that since there can be no genuine expertise in ethics, no one is in a position to offer advice in ethics, properly speaking. The other problem concerns the roles NEABs play in liberal democracies. Why should questions in bioethics be treated differently from other questions of value that are dealt with in parliament? I shall discuss each problem in turn, starting with the problem of expertise in ethics.

[20] See (Dodds 2006).

## 2. Trust-Based Advice in Ethics

### *2.1 Advice in ethics*

To consider what advice in ethics requires, we first need to be clear about what advice is. I take advice (recommendations, counsel, guidance) to be any speech act which urges some other party to act in a certain way, or to adopt particular beliefs, values or behavioural norms.[21] Advice in *ethics*, more specifically, involves taking a stance regarding particular ethical values or norms. Advice in ethics therefore involves endorsing a particular ethical view, at least indirectly. Recommending the government not to legalise active euthanasia on ethical grounds, or advocating the view that lesbian parenting is a bad thing, are examples of advice in ethics in the sense I am interested in. Such advice is different from mere expressions of anger, joy or frustration – non-moral emotions, the expression of which may also be accompanied by an urge to see someone do something. Similarly, advice on fashion, gardening or cooking is unlike advice in ethics, even if it too can be based on values, insofar as it is not typically based on ethical values.

For the discussion to follow, it is crucial to observe a distinction between conditional and non-conditional advice in ethics. Conditional advice is of the following form:

> If you accept V, you ought to F

where V is a placeholder for any sort of ethical value, and where F should be replaced by an action of any sort, including the action of adopting certain views or moral stances. Non-conditional advice, by contrast, omits the antecedent of the conditional and issues injunctions of the form:

> You ought to F

One important difference between conditional and non-conditional advice is that conditional advice can be issued sincerely by someone who does not accept the values referred to in the antecedent (or the consequent, for that matter). By issuing conditional advice, one only commits oneself to the conditional, not to any of its parts. Thus, one can offer conditional

[21] I here take the notion of a speech act to cover also a recommendation put forward in writing.

advice on moral matters without being committed to any moral view (one need only commit oneself to certain norms of reasoning, and arguably this is a different matter from committing oneself to ethical norms).

Often, advising in ethics will be non-transparent, typically by being partly implicit rather than fully explicit, and in some cases by being indeterminate. Suppose I recommend banning human stem cell research should be prohibited. I may do so without explicitly stating that I regard the destruction of a human embryo as an ethically wrong act, but – depending on circumstances – this may be implied by what I say. That is, by recommending something concerning the legal status of human stem cell research, I also convey a view about the ethics of embryo destruction, even if I do not actually spell it out. In some cases, perhaps many, the ethical views come withbehind a particular recommendation will be unclear, and in some of these cases it may simply be indeterminate.

Although tangential to the main issue I wish to discuss, I want to note in passing another extremely important aspect of NEAB work that involves recommending factual views, i.e. (maybe by implication) that certain views are regarded as true. Many controversies in bioethics derive from factual disagreements, at least this is what the overt form of the discussions often seems to suggest. Consider, for example, the controversies over legalising euthanasia along the lines known from the Netherlands. A pivotal issue is whether abuse would be likely following legalisation of euthanasia. Indeed, for many people this factual question is probably the most important question regarding euthanasia. NEABs can be extremely influential here, because of their unique position to propagate certain views on crucial factual questions. A NEAB may, for example, express the view that no substantial abuse is likely to take place if euthanasia is not legalised, but that negative side effects are likely if euthanasia is legalised. When a view like this is consistently propagated by a NEAB, it may soon be regarded as an established truth, by which time the impact on politics and public opinion will have been very substantial. Hence, NEABs' role as fact-makers, as it were, gives them a huge responsibility, and raises important issues concerning the composition of these boards, and how they form opinions on controversial factual questions. As I said, it concerns advice on factual matters, but here I will concentrate on the problems of advice-giving in ethics.

### *2.2 Scepticism about advising in ethics*

Often advice provided by NEABs will be a mixture of recommendations, factual views, conditional advice, and non-transparent non-conditional recommendations of certain ethical views. But I now wish to ignore all that and turn to the simple case of fully transparent non-conditional advice.

There is a well-known simple objection to the appropriateness of advising in ethics as provided by NEABs: no-one is in a position to properly issue non-conditional ethical advice to others. The objection can be stated very simply as the following two-premise argument (the sceptical argument, for short):

1. Issuing advice requires being in an epistemically privileged position regarding the subject matter of the advice. That is, one must (a) be in a better position to know the truth regarding the subject matter at stake than those one is advising, and (b) one must justifiably regard oneself as being in such an position.
2. With respect to non-conditional ethical advice, one is never in an epistemically privileged position.
3. Therefore, issuing non-conditional advice in ethics is always inappropriate.

Premise (1) states two general necessary conditions for the propriety of offering advice on some matter. To see the force of (1), consider someone who offers his sincere advice that you should wear a raincoat a year from now in order to avoid getting soaked. Of course, you would immediately be suspicious on the ground that you would doubt this person's ability to access reliable information about what the weather will be like a year from now. Moreover, you would wonder how this person could sincerely regard himself as being in a position to offer advice on this matter. If he is sincere about his advice, he must regard himself as possessing a capacity to foresee the weather far into the future. But how can he honestly believe that he has this capacity?

To see that (a) and (b) are two independent conditions, consider someone who actually is capable of forming unusually reliable beliefs regarding a certain subject matter, but does not believe that he is. Would he be in a proper position to offer advice on this matter? In my view, this is not

the case. In order to offer advice properly, you should not only be a reliable informant on the subject in question, but you should also justifiably regard yourself as being that, and this is an additional condition.

In the realm of ethics, it implies that by issuing advice one implicitly commits oneself to a view about one's epistemic position regarding the relevant moral values. Clearly, if no one can be in a better epistemic position regarding questions in ethics than anyone else, this puts pressure on the possibility of offering advice in this area. This is what premise (2) states.

No doubt many people today would not hesitate to accept the truth of premise (2), since they adopt some form of *non-cognitivism* with respect to ethics. Non-cognitivism is the meta-ethical view that ethical beliefs are mere emotions, or similar subjective states, that are incapable of being true or false. Having specific ethical beliefs is, in this respect, just like being emotionally attached to one trend in fashion rather than another. Your taste in clothing may be different from mine, but it makes no sense to suggest that any of us harbours a false taste. Similarly, my stance in ethics may be different from yours, but no closer to the truth, since there is no truth to be found in ethics. Clearly, non-cognitivism strongly supports the truth of premise (2) in the sceptical argument.

Outside the narrow circles of professional philosophers, various forms of non-cognitivism are so ingrained that few people today even conceive of the possibility of (2) being false. In current meta-ethics, however, several influential schools of thought actually reject non-cognitivism in favour of various forms of cognitivism, i.e. views holding that ethical beliefs can be true or false, just like other beliefs, and that we can sometimes know ethical truths. Though I cannot discuss this point more in detail, it is interesting to note, however, that *even* the most commonly discussed forms of cognitivism in meta-ethics do not clearly support a rejection of (2). That is, even if we reject non-cognitivism and grant that ethical views might be true or false and that some people are better situated to form true views about ethical questions, we might still hesitate to reject (2). The reason for this is that there is simply too much disagreement among those who reflect on questions in ethics about methods and results for anyone to be in a position to sincerely assert that they - rather than someone else with whom they disagree - are in an epistemically superior position.

To spell out the problem in more detail, consider the following example. Suppose I adhere to a particular view in ethics, but that someone else, who is equally sincere and reflective, adopts a view incompatible with mine. Moreover, suppose that after a careful examination of all the arguments and reasons we can come up with, the disagreement is intact. How am I to say that I am right and he is wrong? This difficulty arises even if I am in fact right, that is, if my view is somehow correct or true. Such cases of intractable disagreement are, I believe, common in ethics, and their currency partly explains the protracted disagreements we find in bioethics. The general implication of this seems to be that the condition for providing advice outlined in (1) is often not met. Very often, when facing the most crucial questions in bioethics, we are not in a position to justifiably regard our own position as epistemically superior to that of some reflective and sincere opponent.[22]

What this shows is that the spirit, if not the letter, of premise (2) may be very robust in the sense that it does not hang on a very specific view on the nature of ethics. Meta-ethical views that are otherwise opposed to each other, tend to support the general drift of (2), albeit for somewhat different reasons. If we still accept (1), then the sceptical conclusion regarding advice in ethics stated in (3) seems very well supported indeed.

### *2.3 Trust-based advice in ethics*

Despite its persuasiveness, the sceptical stance regarding advice in ethics is misguided, or so I shall argue at least. I shall now offer a view about what has gone wrong in the argument presented above. Consider the following case. Suppose an audience invites you to advise on some question of ethics, knowing full well that what they will hear will be your personal views, the status of which they take to be just as the non-cognitivist says. Clearly, it cannot be inappropriate for you to do what is requested of you, that is, to proffer the advice. This is a counterexample to the sceptical argument presented above, and in my judgement nothing of what was said above has the force to undermine the counterexample. It immediately follows that the conclusion (3) in the sceptical argument is false. Since

[22] There is some disagreement about the epistemological features of disagreement. See the recent discussions of the epistemological significance of disagreement. See (Kelly 2005; Feldman 2006; Christensen 2007).

the argument is valid, at least one premise must be false. As the counter example presented grants the truth of (2), we should look at premise (1).

Indeed, we should reject (1) as it stands, or perhaps rather its relevance to advising in ethics. The formula for advising in ethics that I want to propose is simply this. Suppose I ask for your advice on some matter of ethical importance. I do so because I trust that you are a decent person, that is, I trust that, by and large, you share the same values as I do, and I trust that you are capable of reasonable and clear thinking, and are willing to invest some time on the question or have already done so. Granted this, I would like to hear your opinion on the matter. In effect, I am asking for a short-cut to what I myself should be thinking about it, if only I had the time or opportunity to reflect upon it. This is why my request for your advice is conditioned on my trust that you share my values, and my trust in you as a capable and sincere thinker. When I trust that you share my basic values, I have some reason to take your advice on some matter, even if I am presently not able to see through the reasons for your advice.

As is readily seen, my reason for adopting your advice is not that I regard you as having privileged access to the true set of ethical values. It is just that I trust that you share *my* values. Thus we can say that I receive your advice on the ground of *moral trust*, rather than on the basis of *epistemic trust*. Epistemic trust is trust that someone who offers advice or testimony on some factual matter is indeed in an epistemic position to do so. Usually, taking expert advice requires viewing the individual or institution offering the advice as being in an epistemically privileged position along the lines stated in premise (1) above. My suggestion is simply that advice in ethics requires *moral trust*, where this is a matter of trusting that someone shares the same basic ethical values as your own. Advising in ethics does not require epistemic trust. I need not think that the values of the advice-giver are epistemically superior to mine, only that they are similar to mine.[23]

Note that I do not offer this view as an analysis of our concept of advice in ethics, if indeed there is such a uniform concept. What I suggest is a possible philosophical underpinning of our practice of advice-giving, not a conceptual analysis of a concept of advice in ethics. For all I wish to say, there may be some people whose concept of advice in ethics requires

[23] For someone who emphasizes a terminological difference between 'morality' and 'ethics' the term 'moral trust' may seem unfortunate. But nothing here depends on terminology.

that the advisor is in an epistemically superior position with respect to the ethical values upon which the advice is based.

Note also that the notion of advice in ethics that I am proposing does not neglect the importance of reflection. If I trust that we share the same basic values and that you are capable, and willing, to ponder an issue rationally, my trust may extend to the situation where reflection leads you to revise your views about basic values. I may trust that the reflections that moved you to revise your basic views are reasonable, and had I had the opportunity to think about the issues myself, I would have adopted similar revisions.

There are some interesting features of advice based on trust. If someone advises me to adopt a particular stance on a moral question, I have reason to accept this advice in so far as I morally trust the person, that is, share the values upon which the advice is based. This indicates that advice in ethics, even if overtly non-conditional in form, is really to be thought of as conditional. Advice in ethics is best understood as conditional advice rather than non-conditional.

For the recipient, advice in ethics is conditional upon acceptance on the ethical values upon which it is based. It follows that advice in ethics in a sense comes with a moral commitment on the part of the receiver. As a recipient of the advice, for it to be practically relevant, I must commit myself to the antecedent implied in the advice. There are no moral experts to whom non-conditional commitment to basic ethical values can be deferred.

In this way, ethics advice is very different from advice concerning factual matters, say advice of scientific experts. Accepting such advice does not in the same sense require one to undertake a commitment to the truth of the basic scientific views or findings upon which it is based. This commitment can be deferred to the experts. Trusting the experts is trusting that they are right in their basic factual views, not in claiming that one is oneself in an epistemic position to assert the truth of these views. To see this, consider a case in which you have accepted some piece of scientific advice that turns out to be false. There is a sense in which you are epistemically blameless in such cases. There is no similar sense in which those who receive advice in ethics can be absolved of moral responsibility for commitment to the ethical values forming the basis of the advice.

According to non-cognitivism, there is no sense in which basic values can turn out to be wrong. It follows that one can never be properly

blamed for holding a false ethical view. Nonetheless, as a recipient of moral advice, you are in a sense responsible for the advice you choose to follow. People with different values can criticise you for listening to advice based on what they see as the wrong set of ethical values. Also, your uptake of advice can involve another kind of mistake. This is if you accept advice from someone whom you should not trust, that is, someone who does not share your values, or who does not reflect properly about what sort of advice some basic values support. Often, of course, you are not in a position to know this in advance, and in such cases your mistaken acceptance of the advice given may be blameless, but it is nonetheless a mistake.

Properly issued factual advice normally involves an epistemic asymmetry. A is in a position to advise B on some matter only if A is in an epistemically better position than B regarding this matter. So, with respect to factual advice, B has a reason to pay attention to the advice offered by A, even if B totally disagrees with A. Proper advice on factual matters depends on an epistemic asymmetry, and therefore comes with an epistemic obligation to pay attention, even on those who disagree.[24]

This is not so with advising in ethics. Someone's moral recommendation has no force whatsoever for me, if its ethical foundation is one that I do not share. I am not somehow epistemically culpable if I reject the advice, if our disagreement about its underlying values is the reason I reject it. For the same reason, ethical advice does not have the role in settling disagreements that expert-based advice on factual matters may have. If you and I disagree about basic ethical values, then advice based on your values may have no force for me. Generally, ethical advice puts no epistemic pressure on dissenters to change their view, unless they can be assumed to share the values presupposed by the advice given.

Another very important difference between ethics advice and factual advice is the proper response to disagreements among providers of advice. Suppose one group of scientific experts advise the government to do one thing, based on their best scientific judgement, but another apparently equally qualified group of experts offers contrary advice. In such cases, there is a strong and often reasonable inclination to suspend judgement about who is right, even if practical considerations often require that deci-

[24] This holds for properly issued factual advice. However, it may be far from obvious when a piece of advice one receives is properly issued.

sions are made. Hence, with regard to factual advice, there will often be a strong reason to *suspend* judgement in the face of diverging factual advice.

With respect to advice in ethics, the situation is very different. When A and B offer contrary ethical advice, this does not provide us with an *additional* reason to believe that at least one of them must be wrong. Hence, the existence of a plurality of advice-givers that tend to disagree need not undermine the force of ethical advice as long as their disagreement is traceable to disagreement about basic values, and not to flawed thinking or lack of sincerity. As potential recipients of the advice, we need to decide whom to trust. You have reason to adopt A's ethical advice only when you share A's basic values. That B may come along and offer different ethical advice based on a different set of values makes no difference. Of course, the situation is very different if two persons provide incompatible advice about a particular question based on the *same* set of basic values. In that case, as potential recipients of the advice, we have a reason to suspend judgement about which advice to adopt.

## 3. The Place of NEABs in Liberal Democracy

I have now discussed the first of the two concerns raised concerning the function of NEABs, and presented a notion of trust-based advice in ethics. There is a respectable sense in which one can offer and accept advice in ethics. I now turn to the question of what legitimate role NEABs can have in liberal democracy.

### *3.1 Liberal democracy*

To address this question, we first need a working notion of liberal democracy. Obviously, this is a very large question which cannot possibly be dealt with adequately here. Therefore, I want to focus on one feature that I take to be crucial for understanding the role NEABs in liberal democracy.

A distinctive feature of liberal democracy is a particular division of cognitive and deliberative labour. Very roughly, different kinds of decision-making procedures are applied to questions of facts, questions of basic rights, political questions, and finally questions of individual

value.[25] Facts are decided by observation or some other form of truth-conducive inquiry. When, as is often the case in policy-making, the facts are not readily accessible, the task of establishing what the facts are is deferred to experts. If the facts are already plain, there is no reason to defer to experts.

Although liberal democracy considers parliamentary decision as, in one sense, the highest authority, questions of facts are *never* appropriately decided by political negotiations or majority vote in parliament. Neither are factual questions decided by individual value judgements, although of course everyone is entitled to his or her own view of the facts. There is a rationale behind this, of course. Truth matters for practical deliberation, and hence we want to rely on the most reliable methods for acquiring true belief about factual matters. Parliamentary discussion is not such a method, and neither may individual opining be.[26]

In liberal democracies, questions of basic rights are in some respects treated as a sort of factual question, although they may not really be. This is done by agreeing on a set of basic rights in a constitution, the content of which is not negotiable by ordinary parliamentary processes, and by delegating the competence to decide matters of interpretation to courts which are outside parliamentary control.

Political questions, on the other hand, concern a range of non-factual issues: what aims should we have in the society at large, or what policies or laws we should adopt, rather than what the facts are. A defining feature of liberal democracy is that political questions are ultimately decided by some sort of voting procedure, be it direct or indirect, possibly preceded by attempts to seek compromises or forge coalitions, or by some element of rational discussion. The rationale behind these decision procedures is egalitarian, not epistemological: parliamentary processes comprise a set of decision procedures that can be said to give each citizen equal power, an equal say, or pay each equal respect. Justice, not truth, is the prime virtue of a democratic decision procedure.[27]

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[25] For a similar outline of the place of expertise in liberal democracy to which I owe a lot, see (Turner 2003), see especially chapter 2.

[26] In some cases voting procedures may be very reliable, as made clear in Condorcet's Jury Theorem, see (Estlund 1994; List 2001). But the main point remains: when interested in a factual matter, we want decision procedures that are reliable. In certain cases, voting procedures may be very reliable, and in those cases, and for that reason, we should employ them.

[27] Cf. Rawls' famous remark in (Rawls 1972), p. 3.

Finally, in liberal democracies, an important space is left for a range of questions that are not apt for political decision-making, suitable for delegation to experts, or handled as constitutional questions. We can refer to this range of questions as individual value questions, and leave open what it exactly includes. At least it includes a vast range of life style decisions, as well as many questions of political observation and religious conviction. Many liberals would include some questions of sexual orientation, and a range of ethical questions, say questions concerning the morality of abortion and euthanasia into this category.

Again, a defining feature of liberal democracy is that the state should remain neutral on these questions of individual values (value neutrality), although liberals may disagree with one another about what value neutrality exactly should consist of, and its precise boundaries. The important point here, however, is that value neutrality precludes delegation to experts, just as it rules out non-neutral parliamentary decision-making about these matters.

Of course, the picture drawn is rough, and largely refrains from specifying which domains of questions are properly treated as factual, political, or as belonging to the realm of individual values. To do so would be beyond the scope of this paper, and moreover, there is hardly any non-controversial way of doing so. It is nonetheless a distinctive feature of liberal democracy that some version of this scheme of division of cognitive and deliberative labour is operative, though different liberal democracies, and different liberal thinkers, will surely want to draw the boundaries between the domains at different places.

In parliamentary deliberations about what policy to adopt, as well as in public debate, very often the relevant facts are not epistemically accessible. Hence, one must in one way or another delegate to experts. Sometimes this delegation has a procedural element, as in the judicial system, where judges are authorized to decide the correct interpretation of certain parts of the law. Here, the courts need not be thought of as bodies that have an epistemically privileged access to independent truth within some domain. Rather, they are accorded the privilege to decide what is to count as the correct interpretation of certain parts of the law. At other times, there is no similar procedural element, as when the state or political system merely decides to treat a particular body of experts as in possession of a privileged access to truth within some domain. Either way, the politi-

cal system can in this way formally decide to treat certain views as if they were known to be true. Very often, of course, delegation to experts comes about in much more informal and typically less transparent ways: public opinion and political views are informed by what is taken to be known by experts, hence known by everyone.

We can understand why parties to various disagreements may have a strong interest in whether questions are classified as factual questions, political questions, or as individual value questions. For the liberal democrat, the rules of the game are entirely different for each of these. To treat some disagreement as factual implies exempting it from negotiation, compromise and voting, and that expert views trump individual opinions. To treat some issue as an individual value question exempts it from parliamentary debate, and implies that individual opinions cannot be trumped by anything else.

### *3.2 The place of NEABs*

Let us now turn to the question of what kind of legitimate role NEABs can have in liberal democracy. The outline of liberal democracy is not meant to imply that ethical values do not matter for parliamentary processes. Of course, ethical values motivate politics, and political decisions often carry important ethical implications. But the decision procedure in parliamentary processes is quite different from what we normally accept for ethical questions. Parliamentary decisions are reached in a process of bargaining, compromising, and voting. Deciding what to think or believe about a question of ethics is entirely different. Consider a group of people that considers the view that stem cell research is morally wrong, because it involves the intrinsically wrongful act of destroying a human embryo. You cannot vote about this question, or entertain deals such as “if I agree with you on the question of the termination of life support, then you agree with me on the question of stem cells”. What we need to do, of course, is to produce reasons and arguments for ethical views or norms, to the extent that this is possible. Reasons for ethical views, whatever their exact nature, are very different from the trade-offs and deals involved in parliamentary decision-making. So, settling *bioethical* matters and settling *biopolitical* matters in liberal democracy require entirely different deliberative processes.

Ethical views, then, occupy two different roles in liberal democracy. Some ethical views are to be treated as concerning individual value questions, towards which state neutrality is the proper attitude. These questions should not be subject to parliamentary decision-making, except for decisions to make room for a diversity of views one might take. Apart from this, although the ethical views themselves are not subject to political negotiation, all ethical views may enter into the parliamentary processes as part of what motivates and justifies the political compromises that are forged. It may be that ethical views can be rationally discussed and rationally criticised, of course, but this is different from parliamentary deliberation, even if such discussions take place in parliament. The whole idea of a parliamentary process is to arrive at a legitimate common decision even when rational discussion based on ethical values does not lead to agreement. In parliamentary deliberation, the means of overcoming rational disagreement is not more rational discussion of basic ethical values, but trade-offs, compromises, and ultimately majority vote.

On this background, it is hard to see why biopolitical issues would be special compared to other political issues. The stance one wants to take on a biopolitical question partially depends on what one thinks about bioethical questions and basic ethical questions, but these are not subject to parliamentary decision-making. Precisely the same is true of many other areas of politics, however, including defence politics, environmental politics, welfare politics, and foreign aid. So, whatever the justification of the role assigned to NEABs, it cannot reside in biopolitics having a distinct relation to ethical values that is different from the way other political domains relate to ethical values.

Perhaps biopolitics is special in the regard that it is more often the case that biopolitics raises ethical questions that fall under what liberal democracy properly considers as individual value questions, regarding which the state should remain neutral. When biopolitics enters this domain, the proper response for the liberal democracy is to adopt a view on biopolitics that seeks to establish neutrality. Even if biopolitical questions are distinct in this respect, the contention that a bioethical issue qualifies as an individual value question is certainly not a compelling reason to appoint a NEAB to scrutinize the issue, although an important task of NEABs might be to point out that some bioethical questions should really be regarded as individual value questions.

So, clearly NEABs are *not* mandatory in liberal democracies, in the way that a system of courts and parliamentary institutions are. One could easily imagine a perfectly functioning liberal democracy without NEABS.

Are NEABs *impermissible*, then? Does the existence of NEABs somehow run counter to the basic tenet of liberal democracy? This is the very crucial question one sometimes senses is lurking in the debates about the legitimacy of NEABs. I think we can now firmly answer this question in the negative. NEABs may provide ethical advice to the general public and to policy-makers, but the uptake of this advice can be based on moral trust, not epistemic trust. In this way, the general public as well as policy-makers may adopt a particular ethical view based on NEAB advice on particular questions, and thereby arrive at what they take to be a better or a more qualified view. There is nothing in this that does not fit the general framework of liberal democracy.

Of course, one must uphold the distinction between biopolitical questions which are settled in a parliamentary process, and bioethical questions which are not. The idea of establishing a NEAB should not be to *replace* parliamentary negotiations of biopolitical questions with reflection on the corresponding bioethical questions as such, as if the latter were treated as akin to factual questions the resolution of which could be delegated to epistemic experts in NEABs. This would be to treat proper political questions as some kind of factual questions, the resolution of which can be delegated to experts.

Neither should the idea be to assign NEABs the role of promoting a common view on bioethical questions, or a shared set of bioethical values in domains that are really individual matters towards which the state should remain neutral. If NEABs were accorded the role of promoting non-neutrality in domains where neutrality is the proper attitude, this would indeed conflict with the basic tenet of liberal democracy.

But NEABs need not be assigned either of these two roles, and for the liberal democrat it would be a serious mistake to do so. Of course, NEABs or their individual members may disagree with the liberal democratic scheme of things, or they may insist that some question is treated as a non-individual question rather than as an individual question, even when others in the name of their preferred interpretation liberal democracy disagree. Such questions about the propriety of the liberal scheme of things – or the best interpretation of this scheme – when it comes to bio-

ethics and biopolitics, are common. Indeed, it is worth stating and noting the two questions just alluded to:

1. Should we accept the liberal scheme when it comes to bioethics, just as most people today have accepted it in domains such as religion and sexual orientation?
2. If we generally extend our liberal attitudes to cover bioethics, which questions should then be considered individual value questions, and which should be considered apt for a common (non-neutral) political decision-making?

In my view these two questions constitute a framework to understand the nature of the disputes that we are facing in bioethics in the western world. This is a framework that is much better than the one provided by the types of ethical theory such as consequentialism, Kantianism, common sense morality, virtue ethics, and various forms of phenomenological ethics.

Clearly, liberal democrats should welcome the existence of this sort of debate about the propriety and interpretation of liberal democracy, even when NEABs or others take what they regard as the wrong view. Of course, from the perspective of liberal democracy, it would be unfortunate if NEABs were skewed against the basic tenets of liberal democracy, not least if the advice provided on this basis is taken seriously by the general public and policy-makers. In extreme cases, NEABs may influence public opinion and policy-making in a non-liberal direction to such an extent that no genuine liberal could accept NEABs' continued existence. But surely that need not be the case, and one might just as well imagine that a NEAB serves to remind everyone of the basic values of liberal democracy.

### *3.3 Consensus and ethical advice*

We have now seen that NEABs are not generally required by liberal democracy. Nor are they impermissible, provided that ethics advice is regarded as based on moral trust, not epistemic trust, and given that NEABs do not conflict with the proper value neutrality of liberal democracy.

But do NEABs have a reasonable task to perform? I do not think there is a general answer to this question, and this is because the answer in particular cases will depend on the number and the quality of private think-tanks and individual contributors to public debate about bioethical issues. Essentially, if society contains a rich and varied public debate, in which virtually any view is represented and defended, it will generally be true that whatever your basic values, it will be easy to identify someone or somebody who applies these values to the relevant bioethical questions in a reflective way. When this is the case, there is no need to appoint a NEAB. Often, public debates are not this rich, I think, and in those cases NEABs do have a reasonable task to perform.[28]

Let me end with a policy-recommendation that relates to this last issue. Any important legitimate ethical view in society should be explicated and its implications for bioethical questions should be traced out, in order for those sharing a particular basic view to have a source of advice to turn to if they want. This has an important practical implication for NEABs. Rather than having one national ethics advisory board, there should in some cases be several, each rendering advice, just as several different institutions (private as well as public) offer guidance about, say, tax policy or environmental issues. If, however, only one ethics advisory board exists, it may serve its legitimate purpose in a liberal democracy much better by avoiding to seek consensus among its members. Consensus formation involves trade-offs, compromises and negotiations, and if such a process is applied to the level of basic values, something has gone seriously wrong. Of course, it may turn out that a specific policy recommendation is supported by a diversity of ethical perspectives not shared by the same people. When this is the case, it should be made clear, since this convergence may count decisively in favour of that particular policy. However, often such convergence is not forthcoming, and then it should be made transparent how different basic values lead to different policy recommendations. This is important to bear in mind, as NEABs may operate under a strong institutional incentive to seek consensus even on basic ethical values, since this may maximise political impact.[29]

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[28] Of course one should keep in mind the other roles that NEABs may have, see section 1.

[29] This paper is based on a presentation held at the Bioethics or Biopolitics meeting, Organised by the Nordic Comittee of Bioethics, Hanaholmen Culture Centre, Espoo, Finland, 11–12 June 2007. I would like to thank participants at the meeting for lively discussion and valuable comments, in particular Matthias Kaiser, Vilhjálmur Árnason, and Jan-Helge Solbakk. Also

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# Research Ethics Committees: Their Role, Opinion Formation and Justification

Professor *Veikko Launis*, Faculty of Medicine, University of Turku, Finland

## 1. Introduction: The Importance of Research Ethics Committees

It is not an exaggeration to say that the most important mechanism for dealing with ethical problems in scientific research today is the preview of research protocols by the ethics committee.[30] Research ethics committees (hereafter RECs) in their contemporary form emerged in the late 1970s and 1980s in response to the growing need for a formal and more unified means to address ethical issues in clinical and health care settings.[31] Until recently, European RECs have been dominantly (bio)medical research ethics committees. Only a few ethics committees are obliged to concentrate on non-medical (e.g. sociological) health re-

[30] The term *ethics committee* is capable of a wide range of connotations since literally any kind of ethical opinion formation body can be considered as an ethics committee. There is currently no single formula for organising and mandating RECs, although there is a movement toward harmonisation in this area. In this article, the term *REC* will be used in a restricted sense, referring solely to ethical bodies that use expertise power in evaluating research proposals.

[31] McGee, Glen, Caplan, Arthur L., Spanogle, Joshua P. and Asch, David A. (2001): 'A National Study of Ethics Committees', *American Journal of Bioethics* 1(4), 60–64. The need to regulate medical research involving human subjects already derives from the 1975 amended version of the Helsinki Declaration. The Declaration states that every experimental procedure involving human subjects should be approved by a research ethics committee. See World Medical Association: *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. Originally published in 1964. Amended in 1975, 1983, 1989, 1996 and 2000. Available at www.wma.net/e/policy/b3.htm

search, if the issues considered are not closely related to medical research.[32]

Scientific research and technology are nowadays progressing at an increasing rate and as a consequence, important ethical questions relating to research and policy-making, especially in the field of biomedicine and human genetics, are constantly being raised in the media and wider public debate. Such questions are of concern both to European and Nordic governments and the citizens throughout Europe. The way these ethical issues are resolved by RECs has important implications for the society as a whole, both today and in the future

The decisions and opinions of RECs make them visible and influential also within the scientific community. Although ethics committees have proved to be useful in many ways (for example, it has become standard for national human biobanks to submit their scientific protocols to ethical evaluation by a research ethics committee), they have been subject to criticism from researchers, civil society organizations and research sponsors. The identified problems include excessive workloads of committee members, the slowness of the evaluation process, disqualification of committee members, varying criteria used by different committees both in and between countries, lack of training of committee members, the secrecy surrounding decision-making, and extra costs and bureaucracy. The general concern seems to be that RECs will become an extra burden instead of an aid. RECs are thought to be doing many time-consuming tasks which do not suit them and prevent them from concentrating on the real ethical issues.[33]

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[32] Halila, Ritva (2003): 'The Role of National Ethics Commissions in Finland', *Bioethics* 17(4), 357–368; Mäkelä, Klaus and Stenius, Kerstin (2007): *Ethical Control of Social and Behavioral Research in Finland*. STAKES, Discussion papers 3/2007, Helsinki.

[33] See Launis, Veikko (2007): 'Tutkimuksen eettinen ennakkoarviointi – mitä se on? *Tieteessä Tapahtuu* 1/2007, 28–33; Hemminki, Elina (2005): 'Research Ethics Committees: Agents of Research Policy?' *Health Research Policy and Systems* 3:6; Edwards, Sarah J.L., Ashcroft, Richard and Kirchin, Simon (2004): 'Research Ethics Committees: Differences and Moral Judgement', *Bioethics* 18(5): 408–427; Ashcroft, Richard and Pfeffer, Naomi (2001): 'Ethics behind Closed Doors: Do Research Ethics Committees Need Secrecy?' *British Medical Journal* 322 (26 May): 1294–1296; Foster, Claire (1998): 'Research Ethics Committees'. In Chadwick, Ruth (ed.): *Encyclopedia of Applied Ethics*, vol. 3. Academic Press, San Diego, CA, pp. 845–852; Savulescu, Julian, Chalmers, Iain and Blunt, Jennifer (1996): 'Are Research Ethics Committees Behaving Unethically? Some Suggestions for Improving Performance and Accountability', *British Medical Journal* 313 (30 November): 1390–1393.

Despite the fact that most European countries have established RECs and in some countries (such as the UK) they have functioned over a very long time, there has so far been a lack of systematic analysis and empirical study in the field of research ethics including their role, function and opinion formation. In Finland and the other Nordic countries, this area is practically untouched, and relatively few such studies have been conducted in other European countries.[34] There seems therefore to be a recognisable need for a systematic evaluation of the aims and quality of RECs both at the European and Nordic level.

In this article, I will attempt to cover a very narrow slice of this issue. More particularly, I want to illustrate how philosophical argumentation analysis could be used in analysing the medical research ethics committee (henceforth MEREC) decision-making and opinion formation commonly referred to as "ethical evaluation". The analysis suggested is based not only on my own experience as a member of several MERECs but (more importantly) on a systematic review of the European REC opinion documents in a recent project commissioned by the European Commission Directorate-General for Research.[35] Although the analysis is only tentative and fairly limited in its scope, I believe that simply by starting to address these issues it should help to improve the ethics and quality of biomedical research and its relation to health care and society (and perhaps also to clarify the indefinite relationship between bioethics and biopolitics).

## 2. The Variety and Interplay of Issues in Research Ethics

The extent to which an ethical issue (raised by some particular research protocol) can usefully be discussed in MERECs depends, among other things, on the kind of issue it is.

For the purposes of the present analysis, four kinds of issues may be distinguished:

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[34] See, however, Beyleveld, Deryck, Townend, David and Wright, Jessica (eds) (2005): *Research Ethics Committees, Data Protection and Medical Research in European Countries*. Ashgate.

[35] Ahvenharju, Sanna, Halonen, Mikko, Uusitalo Susanne, Launis, Veikko and Hjelt, Mari (2006): *Comparative Analysis of Opinions Produced by National Ethics Councils*. Final Report. Contract No RTD–C3–2004–TOR1. Gaia Group, Helsinki. Available at http://ec.europa.eu/research/science-society/page_en.cfm?id=3164

1. empirical ethical issues,
2. ethical conflicts between principles,
3. interpretative ethical issues, and
4. ethico-legal issues.[36]

Firstly, some issues are controversial largely because relevant empirical facts are in dispute. These may be called *empirical research ethical issues*. A typical example of this category of issues is the question of whether a particular serious adverse event found in a drug trial gives the committee a sufficient moral reason to interrupt the study (given that this is within the scope of its authority). A more complicated example is this: if DNA analysis from a research biobank sample collection can be used for therapeutic purposes (or alternatively in criminal or paternity cases), how reliable should it be? What kind of and how severe are the risks involved? Opinion formation in these issues requires knowledge of the predictable advantageous and disadvantageous psychological, social, medical, political and economic consequences of the activities and policy options considered – for instance, whether or not to allow (or to forbid) the use of the results of DNA analysis for predictive genetic diagnosis or identification is likely to cause people serious psychological harm or considerable economic loss. Reasoned opinions on such issues may be called *consequentialist ethical arguments*. In theory, such assessments should not be too difficult to carry out. In practice, however, the situation is different. The consequences of novel technologies and scientific innovations are usually difficult to predict, and the actual consequences of using the results of genetic analysis for some specific purpose depend upon the social and political setting in which the application takes place. As the members of MERECs often hold different views concerning the structure and dynamics of social and political life, these members frequently disagree upon the consequences of using genetic data for this or that purpose.

Secondly, there are issues that may be characterised as *conflicts between ethical principles*. An example would be the question as to whether our moral duty to create more effective therapies and drugs to relieve

[36] See Launis, Veikko (2008): 'Introduction: The Scope and Importance of Genetic Democracy'. In Launis Veikko and Räikkä, Juha (eds), *Genetic Democracy: Philosophical Perspectives*. Springer, forthcoming in 2008.

human suffering overrides the embryo's assumed moral right to life in the case of stem cell and embryo research. Issues of this kind are genuine ethical problems in the sense that the moral conflict may remain even when the empirical facts are clear and accepted by all parties involved in the dispute. Since opinion formation in this context takes the form of establishing the moral status of certain scientific techniques and different stages of human life independently of the expected consequences of those activities, reasoned opinions on such issues may be called *categorical ethical arguments*.

Thirdly, there are issues that are most properly called *relevance or interpretation problems*. These are characteristically prompted by novel (bio)technologies and new (bio)scientific inventions. We may speak of a relevance problem when we are confronted with a new situation in which our traditional values and principles do not apply very well and we are unable to see what features of the situation are relevant to its moral appraisal. To take an example, whether some experiments in human reproductive cloning techniques should be permitted is largely a relevance problem, because we do not know what is, morally speaking, involved in the development of such techniques. Reasoned opinions concerning such issues may be called *interpretative ethical arguments*. This kind of reasoning aims to redefine or clarify the key concepts or ethical principles in order to solve an ethical problem or dispute.

Finally, there are ethical issues that may be characterized as *ethico-legal problems*. There is an ethico-legal problem when we consider a certain practice to be morally acceptable or unacceptable and are unable to specify on what medico-legal grounds, if any, it may be considered so, even though there is a clear demand for providing such a ground. To provide an example, whether biobank-based medical research should be understood as "medical research involving human subjects" or merely as "medical research on previously collected biological material and data" that can be conducted without a new informed consent (i.e. with a previously acquired "open" or "blind" consent) is largely an ethico-legal problem, because we (the MEREC) do not know what is, legally speaking, involved in the development and use of such human sample and data registries. Deeper analyses of ethico-legal issues often reveal important tensions and sometimes even conflicts between law (existing national

legislation) and morality. Reasoned or clarificatory opinions concerning such issues may be called *ethico-legal arguments*.

Ethical arguments typically include elements of many if not all of the above-mentioned categories. For example, besides posing the above-mentioned ethico-legal problem, biobank-based medical research poses an important relevance or interpretation problem and an equally important empirical problem. To begin with, it is not clear to us what, *morally* speaking, is involved in the development and use of human biological sample collections and data registries for completely new or medically different research purposes. Secondly, in order for the MEREC members to gain sufficient understanding of the concerns and expectations of the ordinary citizen (including the sample and data donors), empirical evidence is needed about public attitudes to human biobanks and genetic databases.

The four categories, then, are interconnected and may occur either simultaneously or in succession. It is important to observe that they often also compete with each other. One common – and ethically distorting – result of such a competition is reductionistic ethical argumentation in which genuine and very complex ethical issues are reduced to (i.e., discussed solely in terms of) what are considered to be more fundamental and – from the ethics committee members' point of view – more conceivable aspects of the issue, such as medico-legal or scientific or biopolitical aspects. In other words, opinion formation or decision-making of the MERECs may become ethically problematic when genuinely multidimensional research ethical issues are dealt with one-dimensionally. For example, considering human stem cell and embryo research merely an empirical (medical) or legal or political issue would distort the complex nature of the problem and create a serious justification problem for the ethics committee's decision-making.

## 3. Conclusion: We Need Value Pluralism

The analysis carried out above seems to confirm, firstly, that if there is such a thing as the truth or rightness about the subject matter of research ethics, there is no reason to expect it to be conceptually simple. That is to say, instead of using only one or two ethical concepts or values, such as moral duty (as characterised by Immanuel Kant) or good state of affairs (as defined by John Stuart Mill), we may need as many concepts and values to deal with research ethical issues as we find we need and no fewer. Secondly, the analysis seems to confirm that if complex research ethical issues are reduced to (what some ethics committee members regard to be) "more easily understandable or manageable" issues, and consequently addressed in fallacious or too simplistic terms, it is almost certain that there can be no such thing as the truth or rightness about the subject matter of biomedical research ethics.

In the past two or three decades, a mode of arguing commonly known as *principlism* or a principle-based approach has consolidated its position as the dominant approach in the field of biomedical ethics. In the form it has come to be known, principlism is usually characterised by adopting a limited number of *prima facie* binding ethical principles (protecting basic human and social values) which are then individually specified and balanced against each other when a specific moral problem is discussed. The derivation of the principles, their number, and the specification and balancing methods differ depending on the interpretation. The idea behind such a pluralistic approach is that these principles can, one way or another, provide the proper justificatory framework for bioethics and be used as a method for resolving ethical issues raised by new science and technology.[37]

It is interesting to observe that in the real world medical research ethics committees tend to follow the principlist approach quite literally by dividing their discussion and opinion formation process into several parts

[37] Principlism is most commonly characterised by citing four so-called mid-level principles – *respect for autonomy* (the obligation to respect and promote the decision-making capacities of autonomous individuals); *nonmaleficence* (the obligation to avoid the causation of harm); *beneficence* (the obligation to provide benefits and balance benefits against risks); and *justice* (obligations of fairness and non-discrimination in the distribution of benefits and risks). See e.g. Beauchamp, Tom. L. and Childress, James F. (1994): *Principles of Bioethics*, 4th edition. Oxford University Press, Oxford and New York.

according to the different values and principles involved. In the view I have just enumerated, this is of course most desirable, since as any ethical theory, the value pluralistic principlist theory can show its ultimate theoretical and practical adequacy only when it concerns itself with real research ethical disputes.

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# Governance and Ethics in Biosciences and Biotechnology

Professor *Stellan Welin*
Department of Medical and Health Sciences, Linköping University, Sweden

## Ethics and Politics

There is a traditional picture of the relationship between politics and ethics that still seems to play a certain role. According to the philosopher Karl Popper, there are two dimensions of political decision making (Popper 1966), both of which hold for the governance of bioscience and biotechnology as well. One is the factual question of what will happen if a certain decision is taken and implemented. Such a question, according to Popper, should be dealt with by experts. In principle, it can be decided by science and social science.

A completely different question has to do with the evaluation of the resulting situation. Is the result good or bad, right or wrong? According to Popper, who was a value relativist in ethics, there are no experts in ethics (Popper 1966). Everyone is equally qualified. Therefore, the appropriate decision-making model for questions of value is the democratic model of "one person, one vote". Furthermore, Popper insisted that if there really were experts in ethics and values (which he did not think), they should carry much more weight than ordinary citizens. This is a position that was taken by Plato, who advocated the rule of philosopher-kings (Plato 1974). Present day Iran is another example, where there is a special guardian council above the parliament and the president. The guardians are all high-level theologians and mullahs.

Most of us do not believe in philosopher-kings and are rather suspicious of guardian councils such as Iran's. On the other hand, not many of us want to go along with Popper and his rather extreme relativism in ethical issues. So we need to somehow find room for non-relativistic ethics in

democratic decision-making. That said, the democratic ideal is not fulfilled by the simple casting of a vote. There needs to be some sort of public discussion and deliberation also in the political realm. There have been some attempts to develop ethics for democratic politics. One can view Rawls's "overlapping consensus" and Habermas's ideas of a free, serious and non-coercive dialogue on value questions as such attempts (Rawls 1993; Habermas 1984). Also in the area of governance of science and biotechnology, consultative ideas have developed that involve the public and not just the experts, i.e. scientists.

It is, sometimes, not entirely clear why the public is or should be involved. Is the consultation part of a serious attempt to reach a widely acceptable decision? Or is it just a way to get the public to accede to whatever it is the scientists and decision-makers want them to accede to? The mere fact of consulting with the public requires scientists and decision-makers to argue their case. In an ideal world, there is a free and interested press discussing the issues and giving voice to different opinions.

In some controversial research areas, as for example human embryonic stem cell research, in particular the use of human embryos, it is very hard to find a universal consensus. This is also true in Europe where many projects have tried to find a common ground for European policy in these areas. This is an ethics exercise in finding principles and policies that are acceptable to persons with widely divergent value systems and ethical codes. It has some similarity to the "overlapping consensus" advocated by John Rawls. A successfully "harmonised ethics" would probably run into the same problem as "overlapping consensus" in many liberal democratic states. No one believes in harmonised ethics and no one is prepared to defend it. It is possible to defend ideas compatible with your convictions, but it is much more satisfying to actually defend one's own.

Ethics nowadays is increasingly popular and spreading into new areas. Medical ethics was an early starter. Research ethics has moved into the foreground along with animal ethics, environmental ethics, plant ethics and food ethics. Judging from the publications devoted to it, space ethics is on its way too (Williams 2003). Most professions are also developing ethical guidelines.

## Ethics Regulations in Science

The branch of science where the earliest ethical investigations took place was medicine. International regulations were put in place in response to the use of prisoners for medical research in Nazi Germany during World War II and other medical (mal)practice in Germany at that time. In the same way as the political and military German leadership was put on trial in Nuremberg for crimes against humanity, leading medical scientists and doctors were charged with having committed similar crimes in their research and practices. The court, consisting of judges from the four allied powers, convicted many of these medical scientists and physicians. The court set forth its arguments for the sentences it handed down, a document that later became known as the Nuremberg Code (Nuremberg 1949). Many of its points are recognisable in later codes on ethical research. Informed consent is important, the well-being and safety of the research subject are stressed and they include, albeit a rather weak, clause on the right to withdraw from an experiment. The Nuremberg Code also requires animal experimentation before moving on to humans. An interesting feature, which is still with us today, is the highly individualistic approach. The safeguards are for the individual, and it is the individual who is required to give their consent.

The Helsinki Declaration, which applies to all medical research on humans and was adopted by the medical associations of the world in 1964, was largely modelled on the Nuremberg principles (Declaration of Helsinki 2004). It stresses the individualistic character even further and endorses the subject's right to withdraw from research. In later versions of the Helsinki Declaration, a provision was added requiring an ethics review by an independent committee before research could commence. In addition, paragraphs were added to regulate research on donated human tissues and cells removed from the body. In many respects, the Helsinki principles apply the similar rules to research on donated (and removed) body parts as they do to research on the actual bodies themselves (persons).

Medical research ethics needed many scandals to develop and be implemented. The mass media played an important role. To give just one example, the Tuskegee Syphilis Study had gone on for many years when it was written about and brought to the public's attention in the 1970s

(Brand 1978). The study, which had been running since the 1930s, was of untreated syphilis; 399 infected black men were recruited in addition to a control group of 201. Treatment was withheld and the participants were deceived in various ways. They were not even treated when antibiotics became readily available (Jones 1981). The study, which was federally funded, violated a number of principles in the Helsinki Declaration. It has later been a leading example of a medical research scandal. After news of it broke in 1972, it was closed down and a presidential committee appointed to report on principles and rules in medical research and health care (The National Commission for the Protection of Human Subjects 1979).

Some of the commission's recommendations made it into federal regulations. One of them required all federally funded research to undergo an ethical review in accordance with the Helsinki Declaration. This was when the Swedish system of research ethics committees for such reviews came into being. The Karolinska Institutet enjoyed substantial funding from the American National Institutes of Health (NIH) back then. When the American funder threatened to terminate the funding if the Institute did not get an ethics committee, it did not take long for the Karolinska Institutet make the necessary arrangements.

From the Karolinska Institutet the system of ethics committees spread across the medical faculties of Sweden. For a long time, it was a completely voluntary system but legislation was introduced in 2003 (SFS 2003:460) stipulating the scope and nature of the committees. Each research ethics committee is an independent agency and has a judge as chairperson. They review in principle all research on humans, not just medical research. On the other hand, the Swedish law from 2003 only requires reviews of research on humans "intended to affect the research subject" and research involving sensitive personal information conducted without informed consent. Research involving the method of hidden observation need not be reviewed. There is also a central committee for appeal. At present, there is a Government bill to amend some aspects of the law (prop 2007/08:44).

## Universal or Local?

The principles of the Helsinki Declaration are formulated as universal principles even if they have been applied somewhat differently. When the principles were up for revision in 2000, strong voices called for more locally applicable rules. In particular, there was a debate about the paragraphs dealing with patients involved in medical research, as in the testing of a new medicinal product. According to the old universal standard, this substance under trial should be compared to the best available treatment. The patient should not be worse off from participating.

As is well known, health care is not equal around the world. Many poor countries never see treatments available in the affluent west. When conducting research in a poor country, should one adhere to local health care standards or to those of the affluent west? One highly controversial incident involved research on pregnant women with HIV. A drug aimed at preventing from the virus from moving from mother to child was tested in a third world country. The question was whether a lower dosage (compared to Western protocols) would be effective. The study was conducted as a blinded randomised study, that is, each infected pregnant women recruited to the study was randomly assigned to one of two groups: one group getting the drug and the other a placebo (Shaffer 1999). It could probably not have been done in a western country and when it became known, it was vehemently denounced. Defending the study, the scientists said that without their research, none of the women would have received any treatment at all. They were too poor to buy the medicine and it was not provided by the health care system (Resnik 1998).

The proposal to amend the Helsinki Declaration wanted new drugs to be compared to the best locally available drug, rather than the best globally. In the end, the universal character of the Helsinki Declaration prevailed and even strengthened by ruling out comparative trials with placebos. In notes added in 2004 to the 2000 version of Declaration of Helsinki some exceptions were made for the use of placebos.

I am sympathetic to the universal character of ethical principles on medical research, but there are some problems. One concerns public health issues (Buchanan & Miller 2006). Sometimes, the aim is not to get the best treatment (which may be affordable to just a few) but to find a treatment that can be widely used because it is affordable. But this afford-

able treatment must be tested against the best – and probably much more expensive – treatment. This is likely to result in the affordable treatment not comparing favourably to the current best treatment, making it difficult to introduce it. This is not just a third world problem; it is the same in Europe.

## Who Decides?

In 2000, two Swedish research groups got the approval of their local research ethics committees to derive human embryonic stem cells from donated human embryos. One group was based in Stockholm and the other in Gothenburg. Both consisted of researchers in basic biological science as well as physicians at fertility clinics. Actually, the connection to the fertility clinic was quite crucial as it was the source of donated embryos.

The Swedish stem cell discussion started the same year. It was largely initiated and orchestrated by Hans Bergström, editor-in-chief of the leading Swedish daily *Dagens Nyheter*. Bergström is a political scientist by training, and had just spent time in the USA studying the biomedical revolution. He wanted Sweden to be in the forefront of biomedicine and was especially keen on promoting stem cell research in Sweden. He asked the political parties to say where they stood in the debate on human embryonic stem cells. The parties complied and a number of articles on stem cell research by leading political figures ensued. Only one party, the Christian Democratic Party, voiced doubts about the use of human embryos in the derivation. The Conservative Party saw stem cell research as promising area for biomedical companies while the Green Party saw human embryonic stem cells as a possible alternative to animal experiments in medical research. Early in the debate, the Liberal Party published an article urging caution. However, after Bergström wrote "that the Liberal Party is worse than Bush" in an editorial (*Dagens Nyheter*, 11 August 2001), a more favourable article was produced.

The debate gained traction from the imminent general election in September 2002. Bergström and the opposition parties (Christian Democrats, Conservatives, Liberals and Centre Party) hoped to win. Last time they formed a government, the Christian Democrats fell out with the others on

a related ethical issue, pre-implantation genetic diagnostics (PGD). This time, Bergström seemed to think, it would be wise to get the stem cell ethics issue out of the way beforehand. In the end it was, but they did not win the election.

The controversy heated up in August 2001 when newly elected President George W. Bush tried to formulate a stem cell policy which satisfied the Christian right, the many patient organisations and the man in the street. He came up with a kind of compromise. Only stem cell research on already established human embryonic stem cell lines would be eligible to Federal funding (i.e. established at the time of the speech, August 9, 2001). The National Institutes of Health was asked to investigate how many such lines there were around the world. They found 64. Twenty-four of these supposed human embryonic stem cell lines were in Sweden, five at Karolinska Institutet and nineteen at Gothenburg.

In August 2001, there were two Swedish research groups deriving stem cell lines from surplus human embryos. As indicated above, their research protocols had been approved by the respective ethics committees. The Minister of Science and Education asked the newly established Swedish Research Council to issue guidelines on stem cell research. The Swedish Research Council was created in 2001 by fusing a number of independent research councils with expertise in various areas. The guidelines was the first major policy issue to be dealt with by the council. At the same time, another body, the Swedish National Council on Medical Ethics (SMER), was also asked to advise the government on stem cell matters.

As mentioned above, the derivation of stem cell lines was already going on, but the public got the impression that the whole issue of human embryonic stem cell research was about to be decided. All the parties in parliament – with some hesitation from the Christian Democrats – said they would wait for the Research Council to publish the guidelines. The Council had a small working group of people from the various parts of the Council, but dominated by medical scientists. The day before the guidelines should be issued, Alf Svensson, the leader of the Christian Democrats, endorsed derivation of human embryonic stem cells from human embryos in an article in *Dagens Nyheter*. Svensson also mentioned that it might be possible some day to derive human embryonic

stem cells without damaging the embryos, but he did not elaborate on how.

On December 3, the Research Council issued their guidelines in a well directed TV show. They endorsed everything already going on and were open to the possibility of therapeutic cloning. It would require a change in the law, however. Quite soon the Social Democratic Minister of Education and Research and the Minister for Health and Social Affairs endorsed the guidelines in *Dagens Nyheter*, and declaring that a parliamentary committee looking into legislation on genetic integrity should also look into therapeutic cloning. One and a half months after the Research Council's publication of its guidelines, SMER came forward with theirs. The public did not even notice this event.

The conclusion to be drawn from this particular event in Sweden is that the Research Council and leading scientists are arbiters of important ethical issues in biomedicine. Parliament and the rest simply follow. In the case of stem cells only the Christian Democrats voiced concern; all the other parties were enthusiastic. An earlier controversial issue, namely xenotransplantation, was treated differently. That question was delegated to a parliamentary commission which recommended moving forward, but the field collapsed globally due to the perceived risk of infections and some other problems. At present there is some recovery.

Another interesting feature of the work on the stem cell guidelines was the dissenting voice of Madelaine Leijonhufvud at the very board meeting where the guidelines were finally approved. Madelaine Leijonhufvud had actually chaired the Research Council's working group, and was the deputy leader of the Council and Professor of Law. None of this was reported by the press, and it only emerged much later. What Leijonhufvud and certain other dissenters in the Council objected to was that weighty decisions like that on the guidelines should have been taken by parliament. (For details on the media debate and discussion in Sweden on the guidelines, see Persson & Welin, forthcoming.)

## Scientific Integrity

After this example of the supremacy of science it may be interesting to look at scientific integrity. Various initiatives are currently doing the rounds in the European Commission in this area. They, of course, are a response to some rather high-profile cases of scientific misconduct in nanophysics and human embryonic stem cell research. It was not a case of nervous PhD students desperately needing another publication who cut corners but of well-established, already famous scientists. In the South Korean case of Hwang Woo-suk, the researcher was a national hero with government backing (Gottweis & Trindl 2006).

Why did they do it? It is hard to know. But my guess is that funding priority and fame are important factors. There are probably other explanations more related to personal traits. A troubling question is why leading journals published the articles and why it took so long to find out. My personal view puts the blame on the present craze for impact factors and the commercial character of the leading journals. If a journal publishes a surprising and interesting result – even if it turns out to be wrong – it will be much discussed and debated. It will give more citations, raise the impact factor and be generally good for business. It is hard for a reviewer to find out that fabricated data is wrong – if it has been fabricated by an expert scientist!

There is one thing that could be done at a European level to combat scientific misconduct. It happens again and again that someone – mostly younger scientists but senior researchers are not immune – is caught plagiarizing, fabricating or falsifying data. What happens often is a hushed up dismissal from the department after which they find work somewhere else – and the same thing happens again. In the US there is a federal system in place. It is far from perfect. In Europe, where there also is free movement of scientists, we should set up a European agency to keep track of fraudulent scientists.

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# Mechanisms of Power in Biopolitics

Dr.polit *Jill Loga*
The Rokkan Centre for Social studies, University of Bergen, Norway

As the 20th century came to an end and we turned towards a new millennium, the Norwegian Government set up three ambitious, high-profile inquiries: one was about freedom of speech (The Commission on Freedom of Speech), one was about our values (the Human Values Commission) and one was about the question of power and democracy (the Norwegian Study of Power and Democracy). The Commission on Freedom of Speech was launched by the social democratic Jagland Government in 1996.[38] When Prime Minister Bondevik and his coalition government of centre parties took over in 1997, he fronted the Human Values Commission as his most important political issue.[39] Only three months later Prime Minister Bondevik then appointed a research group of five professors[40] to lead a research programme on power similar to the widely respected study of 20 years back under Professor Gudmund Hernes and Professor Johan P. Olsen's leadership. Neither the mandate nor the political guidance for these three different inquiries were alike. However, the question of colliding values and freedom of speech touches upon difficult aspects concerning the question of power and democracy in contemporary international politics. The political situation after 9/11 and, e.g. the conflict over the Muhammad caricatures, may need new research perspectives to establish where power exists and who possesses it.

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[38] The Commission on Freedom of Speech delivered its final report in 1999: "NOU 1999: 27 «*Ytringsfrihed bør finde Sted*». *Forslag til ny Grunnlov § 100*. Utredning fra en kommisjon oppnevnt ved kongelig resolusjon 26. august 1996."

[39] The Value Commission was launched January 30th 1998 (Kongelig resolusjon: *"Oppnevning av Verdikommisjonen"*, saksnr. 97004412 av 30. jan. 1998). The Commission delivered its final report on Mars 29th 2001.

[40] The five professors were Øyvind Østerud (political science, Univ. of Oslo), Hege Skjeie (political science, Univ. of Oslo), Fredrik Engelstad (sociology, Univ. of Oslo), Per Selle (political science, Univ. of Bergen) and Siri Meyer (culture studies, Univ. of Bergen).

In this paper, I will focus on the question of power in politics along the moral dimension, which also was the focus of the Commission of Freedom of Speech and the Human Values Commission. It is a focus on what I shall call the field of biopolitics, where the dilemmas concern colliding values and how we shall live our lives.[41] As an example and prism for discussion, I have chosen the Norwegian Human Values Commission. I will view this commission as a value-political experiment, which might inform the question of power in biopolitics. The paper is organized around two dichotomies and their relations. The first dichotomy is the analytical distinction I attempt to make between interest politics and value politics. The second dichotomy touches on the concept of power developed by the first Norwegian research programme on power in the 1970s and the debate on "what is power?" which arose in the second research group on power in Norway.[42] This latter issue I intend to discuss in terms of a differentiation between an institutional perspective on power and a "rational man" model, on one hand, and on the other, a concept of power focused on values and the moral dimension.

## 1. Freedom of Speech, Value Conflicts and the Question of Power

The two professors leading the research into power in the seventies operated with a certain concept of power. Sociologist Gudmund Hernes adopted the "rational man" model which sees societal power in terms of calculating, strategic and conscious action.[43] The institutional perspective, represented by Johan P. Olsen – a political scientist – focused exclusively on the formal state apparatus.[44] Questions concerning freedom of

[41] The concept of biopolitics refers to a scholarly tradition focusing on what Niklas Rose (2006) calls "the politics on life itself". Investigating the governmentalities surrounding these political issues, this tradition is inspired by the argument of Michel Foucault in *History of Sexuality* (1976) that Western societies are characterized as being in a 'biopolitical age'. "Politics now address the vital processes of human existence: the size and quality of the population; the reproduction and human sexuality; conjugal, parental and familial relations; health and disease; birth and death." (Rose 2006:1).

[42] Engelstad 2005, Meyer 2003, NOU: *Makt og demokrati. Sluttrapport fra Makt- og demokratiutredningen*, Statens forvaltningstjeneste, Oslo 2003.

[43] Hernes 1975.

[44] Olsen 1978.

speech and the dilemmas arising from different values in society are aspects of power that exist outside and beyond both the formal institutions and the theoretical perspective of "rational man". When the Norwegian government appointed the research group to deliver a report on power in 1998,[45] the normative dimension was prominent in politics, the media and in the mind of the national and international public. Issues concerning multiculturalism, the authority of science as purveyor of truth, secularism, postmodernism and the loss of meaning, new religious movements and religious controversies etc. – all were aspects related to the normative dimension. Therefore, one might say society looked different by the 1990s, only 20 years later, first of all because the perspective was different. If we are interested in understanding *why* stem cell research, gender equality, masculinity, abortion and gay rights are political dilemmas and struggles today, the argument of this paper is that we need to develop new concepts of power which include the moral dimension on the level of meaning and operate across the state–society divide.

## 2. The Human Values Commission

The Human Values Commission was asked to "contribute to establish a broad mobilisation on ethics and values in order to strengthen the positive values and the responsibility to environment and community".[46] Nevertheless, when the Commission was presented to the Norwegian public in 1997, it was rapidly dismissed as a total failure by the media before it had even got down to work. This was in great contrast to its massive and spectacular launch by the new Bondevik government. Although the media widely reported the Commission, headlines characterised the project as totally unimportant. Instead of promoting a debate on values, the public wanted to know why the Commission was needed at all. Indeed, it was quickly considered such a great flop that Norwegians burst into laughter whenever it was mentioned. But before this, the Commission provoked widespread public frustration and anger. There were concerns about the Government's appointment of an official body to report on moral decay

[45] This research on the general state of power in society was done parallel in both Sweden and Denmark.

[46] Kongelig resolusjon: *"Oppnevning av Verdikommisjonen"*, saksnr. 97004412 av 30. Jan. 1998.

in society, a misuse of its powers to govern morality. The Human Values Commission was called a moral tribunal, appointed by a Prime Minister who in fact is an ordained priest.

## 3. Moral Decay

Both the Human Values Commission's and the 1998 Power Commission's mandates[47] were informed by widespread concern for the health of the leading social institutions such as politics, law, idealistic organizations and the family. None of them seemed to carry as much authority as they had done. In the mandate of the research programme on power, the government requested an *investigation* into this negative development, but in the mandate of the Human Values Commission, the wish was to *reverse* this tendency. When Prime Minister Bondevik presented the idea of the Human Values Commission to Parliament, he was met with support and enthusiasm across different political parties. The parliamentary debate that followed uncovered a deeply felt worry concerning the spread of violence, materialism and a culture of greed, the declining respect of youngsters for parents and teachers, the loneliness of the elderly, family breakdown, the impairment of democracy etc. The politicians in Parliament saw in the Human Values Commission, a means of reversing the negative moral development in Norwegian society.

## 4. Ambiguities in the Mandate of the Human Values Commission

However, the Human Values Commission's mandate was unclear as to whether the problem affected politics as such or society and the people. Was this initiative to be seen as an attempt to strengthen the bond between politics and citizens by consulting with the citizens and listening to their wishes, needs and possibly new values? Or did the negative moral diagnosis implicate rather the citizens and society as a whole?

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[47] Kongelig resolusjon: *"Oppnevning av Verdikommisjonen"*, saksnr. 97004412 av 30. Jan. 1998. Østerud, Engelstad, Selle, Meyer, Skjeie (1999): Mot en ny Maktutredning. Oslo: Gyldendal.

Another ambiguity in the mandate, which caused problems for the Human Values Commission, was the role the Commission was expected to play in the public debate on values. Was it meant to stimulate public debate and help a new value debate get off the ground? Or should the 50–strong Commission conduct the debate internally? Naturally, it was this latter interpretation that led to sense of scepticism. What right did these 50 government-appointed officials have to conduct a value debate on behalf of the citizens? Had the conservative Christian Prime Minister established a value-political organ, and handpicked its members, to substitute for political debate in Parliament? And, in that case, what were his criteria when he picked his distinguished citizens to debate the fundamental values of society?

A third ambiguity in the mandate may be illustrated by the two metaphors to which Prime Minister Bondevik referred on presenting the idea of a human values commission to Parliament. Discussing what was missing in society, he talked of Jerusalem and Athens. However, when Bondevik — as a priest — spoke of the need of Jerusalem, it evoked certain ideas in the mind of the people, such as blaming secularism for the current moral decay. The Human Values Commission was considered to be the tool of an ecclesiastic Prime Minister intent on re-building and strengthening "*the valuable*", that is, the Christian code of ethics. On the other hand, Athens as a metaphor pointed in another direction, towards the philosophers who had collaborated with the government in forming the idea of a value commission. The reference to the political practice of ancient Greece is interesting and not without relevance to the case of the Human Values Commission. Often held up as a democratic ideal for democracy, the politics of ancient Greece is known for its focus on values, in contrast to modern politics, where the question of money and redistribution of material goods among different interest groups are more in focus.[48] The political debate of ancient Greece is idealized precisely as a continual and fundamental value debate on existential questions such as what kind of human qualities do we want to value in our society, what is the good way of living and what is the best society? These kinds of political questions on life itself are similar to the agenda of the Human Values Commission. In this respect the debates led by the Human Values Commission differed distinctively from ordinary party politics, where the

[48] Strauss 1953, Arendt 1996.

distribution of resources among interest groups is more in focus. In light of the metaphor of Athens the Human Values Commission could be seen as a contribution to fill the lack of an existential dimension in current Norwegian politics.

The members of the Human Values Commission were shocked by the emotional intensity of the reaction in the media. First of all, they were shocked by the enormous attention they got, and the media hype that recalled the launch of a new government and interest in newly appointed ministers. In the months before the launch of the Commission, it was clear from the media coverage that membership of the Human Values Commission was considered an honour. Well-known intellectuals stepped up as candidates and wrote about values, the need for ethics and the state of society, and the Prime Minister's Office received thousands of applications from individuals. The media speculated for weeks over likely nominees. When the names were finally announced, the journalists gathered outside their homes, inspected their tax records, they mapped out their holdings and properties, and even rifled through their garbage looking for evidence of immoral behaviour in their personal lifestyle. The next surprise for the members was the amount of anger they provoked: what had they done wrong and why this aggression?

There is a parallel here to the conflict surrounding the government inquiry into power in 1998. The Human Values Commission had no *formal* powers. It was not part of the official state apparatus, it had no legal authority and could make no decisions on behalf of the government. It had only a mandate to debate and to create debates on values. Unlike the first research group's conceptualisation of power 20 years before, the Human Values Commission was totally irrelevant to studies of power and authority in society. Nevertheless, the Human Values Commission generated huge interest, great enthusiasm and great frustration and anger. To go by the emotional response, the Commission was not at all considered totally irrelevant or without influence, as the intense headlines in media paradoxically claimed.

## 5. Power Struggle in the Research Group on Power

The high public profile of the new research programme on power and democracy was related to the high prestige of the project. This had to to with the former research programme of the 1970s, which was viewed as a paradigmatic scholarly standard by central parts of social science in Norway in the coming two decades. As already mentioned, the 1998 research group on power ended in a very public spat. When the research group was to deliver the final report in 2003, two of its five members left and refused to sign the final report. These two female professors represented perspectives that had not been addressed by the first research group on power. One was the perspective on gender and the other a humanistic perspective of culture and language. They claimed that the final report ignored their contributions, and instead rehearsed the same perspectives and conceptualisations of power as the report of the 1970s. Their signature would have been pointless. The three remaining male members were seasoned social scientists and had worked closely with professors Hernes and Olson during their careers.

A common aspect with the two perspectives these two women represented is that power in their definition exists not only in the formal state apparatus. It is a kind of power that is not necessarily performed as a conscious or calculated act. It exists at the level of meaning, they said, in the mechanisms producing and defining our truths, mentalities and normality, the mechanisms operating in our conventions that are performed, managed and produced by all of us whether we are conscious of it or not. As power mechanisms they are not necessarily recognised as such because they operate at an unconscious level, rather as a lack of freedom, resentment, something diffuse that produces anger or frustration. This is power that produces the kind of feelings that were visibly expressed by Norwegian journalists on being introduced to the Human Values Commission.

## 6. Interests versus values

I want to return to the Athens metaphor in order to discuss an analytical distinction between interest and value politics. At the same time we should bear in mind a concept of power which holds interests as given, and an alternative concept of power focused on changes in basic values and production of meaning at this informal level of society.

The Human Values Commission met mixed expectations. The hopes and expectations were for something new and refreshing, something to be opened up. The value-politics launched by the Prime Minister contrasted with mundane party politics in two ways. The first difference was its relationship to materialism. Politics had become too materialistic, too absorbed in the redistribution of resources. Instead, the government wanted to look beyond questions of money and law and concentrate on what really mattered, the immaterial values of life and existence. Second, mundane politics had lost touch with the foundations of politics. There was a need to consider in depth and evaluate the very foundations of society, including the foundations on which redistributive politics was built. The invitation from the government promised a renewal and opening up of a rigid political landscape. It made contemporary politics look outdated and based on yesterday's requirements on how we should live our lives. Politics seemed in need of a fundamental revision to get in touch with the current values of society and then also the engagement of people. Thus, a general invitation went out to citizens to participate in the great value debate and to help improve and refashion politics. Value politics was defined in opposition to interest politics. Value politics was about immaterial values, interest politics material values. The invitation to debate the foundations of society placed value politics in a dynamic light, in contrast to rigid, mundane politics. This latter aspect must be taken into account if we want to understand the hopes and expectations of the Human Values Commission. Politicians had their hopes as well, those with a feeling of being set aside. They seemed to express a loss of power and control and being subjected to other, more central forces.

If we return to the value political or biopolitical ideal, as we are wont to associate with ancient Greece, it is interesting to note the difference between the public/private distinction inherent in this political ideal and

in modern politics.[49] Unlike today, economic questions were considered to be a private, not a public, matter. The public questions dealt with the ideal life and the ideal way of organising the society. Politics dealt with the ideal personal qualities society should choose as a model of living for citizens. These are questions which today can be characterised as more of a private than public matter.[50] Another difference to today's politics was that value debates in ancient Greece were not pursued by ordinary representatives of the people. On the contrary, elected representatives whose job it was to identify the positive values on behalf of the citizens, were exemplary citizens, the most morally distinguished and respected. Through their personal behaviour, their habitus, these exemplary role models who led the value debates presented a moral-political message of the fundamental values of society.

Hannah Arendt and Leo Strauss were two high profile political theorists whose ideas are still in circulation and continue to exert influence in the US, although in different contexts. Strauss was used as a central philosophical thinker by the Republican administration of George W. Bush, and Hannah Arendt has received new actuality in light of the religious climate in politics after 9/11. Both shared an enthusiasm for the ancient political ideals, an emphasis on value politics, a use of the moral dichotomy in politics, a focus on religion versus politics and an acknowledgment of the role of philosophy in shaping the moral persona.[51] A possible explanation for the resurgence of interest in these exile Jewish thinkers of the 1950s, might point to their knowledge on the workings of power in contemporary politics. Leo Strauss advocates a return to the ancient value-political model, because – and here his arguments resemble those of the Human Values Commission —value politics promotes interest in and support for politics and brings back its ancient glory and authority insofar as value politics is addressed at an existential level in the lives of the citizens.[52] Thus, arguing for what I refer to as the politics of life itself, or biopolitics, is also an argument for awaking the engagement of the citizens so they can help improve democracy's health through their participation.

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[49] Strauss 1953.

[50] Arendt 1996.

[51] Arendt 1996, Strauss 1953, Norton 2004, Kielmansegg, Mewes, Glaser-Schmidt (ed.) 1995.

[52] Strauss 1953.

## 7. Moral superiority

In a value-political or biopolitical landscape, where the debate and disputes concern a way of life, the distinction between politics and religion becomes vague. In the past, religions have offered the answers to the existential questions, such as what it means to be a human being, how we as men and women should live our lives, and what we should value as noble and morally superior. When politics becomes a question of values, it impinges on the field of religion and makes religious truths subject to value-political debates. This may, of course, become a delicate matter, because one asks questions about deeply rooted conventions, our normality and established truths, which we normally take for granted. In value-politics one might ask, for example, whether natural births and natural deaths are necessarily better than assisted or artificial ones? Are same-sex-relationships a better choice than traditional marriage? When the value system is set in motion, when we start to question the fundamental building blocks of society, everything risks being made a subject of debate. Therefore, there is a distinct difference between the two metaphors used by the Prime Minister to describe the work of the Human Values Commission. The reference to Athens connoted an ambition to question the fundamental values and make possibly every normative aspect of society a subject of open-ended debate. The reference to Jerusalem could be viewed as an invitation to put religious values under debate. Having said that, the descriptions of moral decay point in the opposite direction. It rather seemed like he was deploring the lack of support for a specific Christian value system, e.g. the family, where relationships between men and women were causing the moral decay. The high expectations invested in the Human Values Commission to open up a new way and renew politics were turned into disappointment by the use of the Jerusalem metaphor.

## 8. Mechanisms of power in biopolitics

Mechanisms of power are different in politics about values and politics involving bargaining among interest groups. When investigating mechanisms of power in the value system verbal expressions become important. I want briefly to discuss two examples. First, in a value-political land-

scape, moral authority becomes an important mechanism of power. A linguistic mechanism which confers moral authority is the distinction between good and evil. The moral dichotomy, good versus evil, is implicit in the concept of values across different cultures, which is why the moral code is easily translated between e.g. Christian, Muslim and Hindu cosmologies. In the language of American Republican politics, in which Leo Strauss has been influential, we recognize the explicit use of this moral dichotomy in the concept of "the axis of evil".[53] By defining your political enemy in terms of malignity, you implicitly identify yourself with the good and with moral superiority. Something that has been established and defined as goodness cannot be criticized without a possible risk of seeming cynical, egoistic or potentially evil oneself. You may therefore become immune to criticism if you manage to occupy the subject position of the good. Immunity and the subject position of the moral superior is part of the concept for which I call "the power of goodness".[54] The dichotomy of good and evil will necessarily inform the dialogues of religious leaders, because the authority of religious leaders is based on moral superiority. By pitting two moral authorities against each other, one arranges a meeting between two manifestations of the good. The morally good is something beyond negotiation and compromise, because if you are willing to compromise on the good you will reduce it into something lower and less pure. The dichotomy of good versus evil makes dialog between religious leaders very difficult, because it actualises mechanisms of power. Similarly, in value politics or biopolitics, linguistic mechanisms concerning the moral dichotomy can become a strong force in the formation of meaning. Debating ways of living, whom and what society is to recognise as noble and morally superior etc. actualises the good versus evil scenario, with its implicit mechanisms of power functioning at an informal level.

Opposed to moral superiority as a kind of authority in politics is the undermining mechanism of irony and humour. The anger and aggression provoked by the Human Values Commission was gradually replaced by laughter. The tone of the media was becoming increasingly ironic, with the Commission's members portrayed as comically pompous figures, not

[53] Norton 2004.

[54] For further discussion, see my dissertation "The power of Goodness. The Norwegian Human Values Commission – Between Politics and Morals (Loga 2005).

to be taken seriously. Irony and humour are effective techniques to undermine moral authority. The fact that the Human Values Commission was subject to irony to such a degree may in itself indicate a fear, of both the press and the people, of the moral authority and power the Commission might have exercised.

## 9. Conclusion

It is actually ironic that a research group tasked with reveal the source of power in Norwegian society omitted to investigate biopower, when it is a kind of power Norway is known to possess and might confer political authority internationally in the biopolitical field. International operations like the Norwegian peace missions in the Middle East, e.g. work on the Oslo Agreement in the 1990s, the strong support for and engagement with the United Nations, and possibly most importantly, the annual Nobel Peace Prize are all of enormous importance to the moral authority of Norwegian foreign policy. The five-strong Nobel Peace Prize Committee, comprising mainly former academics and retired politicians, decide which moral criteria to apply to investigations of the most valuable contribution to mankind. From the perspective of moral governmentality in biopolitics, the philosophy behind this prize is not very different from that of the Human Values Commission. While the 50 members of the Human Values Commission were appointed as distinguished citizens or moral role models in Norwegian society, the Nobel Committee rewards the most distinguished man or woman worldwide each year. If all the now living Nobel Peace laureates were collectively sent into the political arena to discuss values, they might be viewed as a council inspired by the politics of ancient Greece, a council of morally extraordinary world citizens who conveyed a political message through their personal charisma. They could have become a Human Values Commission on a global level.

It is possible that the Norwegian press was right when it passed judgement on the experiment of the Human Values Commission as an embarrassing failure. In light of the moral struggles affecting contemporary international politics, one could also ask whether the Human Values Commission was actually ahead of its time. In that case, this pure value-political experiment might teach us something important about mecha-

nisms of power, as this experiment revealed both the potentials and the challenges concerning the "the power of goodness".

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# Dolly in the Public Sphere

## Expectations and Fear in a Decade of Overselling

*Torben Hviid Nielsen*
Department of Sociology and Human Geography, University of Oslo, Norway

Dolly, the cloned sheep, was a biotechnological breakthrough –living proof, and a powerful symbol, that it is possible to clone mammals by merging an empty egg with the genetic material from an adult cell. The press and "the biotech complex" did, however, both overrate and oversell the practical feasibility of the new technique, and thus contributed to higher expectations than justified as well as graver fears than necessary. Furthermore, Dolly was the only success in 430 attempts, and was put down at the age of six and a half. It is no coincidence that the pioneering technique has since found its main application in stem cell research, to grow tissues and develop organs, but not to create babies.

## The Birth of Dolly: Living proof of a Principle

Dolly the cloned sheep was conceived in the secrecy of a laboratory and born in the anonymity of a stable. Only a select few had any idea of the vital implications of the seemingly normal birth of Dolly, on the morning of 5 July 1996. Professor Ian Wilmut and his team at the Roslin Institute had fused a genetically empty ovum with a six-year-old cell nucleus in a Petri dish. The ovum was later implanted into the womb of a surrogate mother sheep. But it was not until the following winter – after the Institute had applied for patents on its cloning technique and Dolly had appeared to develop quite "normally" – that the time was ripe to reveal to the public the news of the long-kept secret. The prestigious journal *Nature* had accepted a four-page article for publication Thursday 27 Febru-

ary 1997.[55] The week before, a press briefing was released under embargo, but *The Observer*, which also had its own independent source, broke the news in its weekend edition – swiftly followed by the rest of the world press.

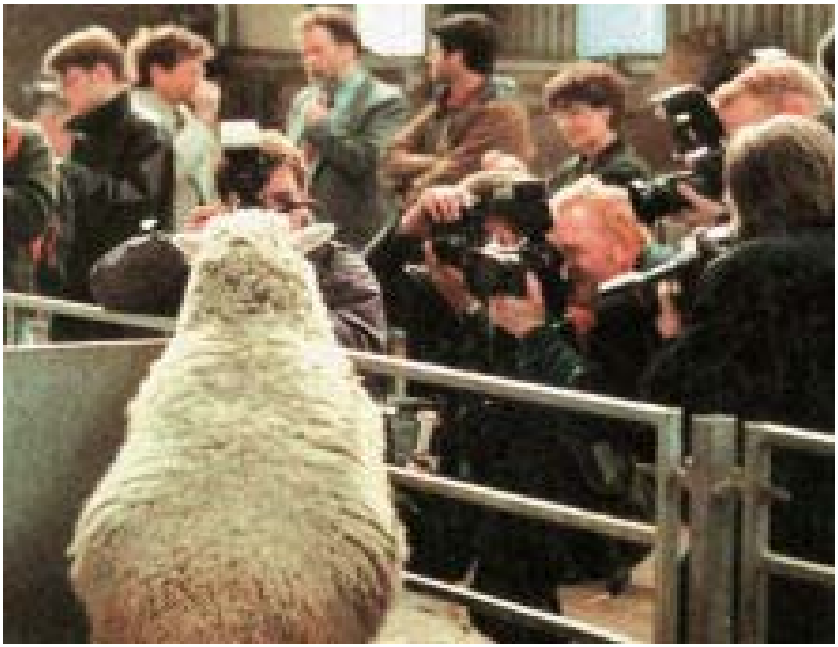

*Fig.1. Dolly Meets the World Press. Associated Press.*

One of the most reproduced photos of Dolly depicts her in front of the assembled world press on one of those hectic days after she became a celebrity (Fig 1). The theme is the staging of an event. The camera angle reveals backstage, from underneath and from behind. The focus is on Dolly as the focus of the world press – not on Dolly herself. And the photo session had great documentary value. Despite the spectacular way she had been created, she seemed fairly normal. The very existence of Dolly was living proof of a principle: What was considered a "biological impossibility" had turned out to be a "practical reality". Anyone could see that no one could see the difference between the clone and a normal (or

[55] Wilmut, I. et al. Viable offspring derived from fetal and adult mammalian cells. *Nature*. Volume 385. February 27. 1997: 810–813.

natural) sheep.[56] The living clone was more persuasive than the technical article in the scientific periodical reporting "fertilization", methodology, failed attempts and birth.

Dolly "spoke" to the microphones at the press session, but she was unable to control or dictate the message. Consequently the press reports came in two quite different framings: as an epoch-making scientific breakthrough and as a new moral challenge, requiring political action. She would soon symbolize both. Behind the two main framings, as scientific breakthrough and moral challenge, lay five modalities of thought or "arguments", clipped together as an ideal-typical collage of newspaper headlines in Norway (see Table 1). [57]

The breakthrough was first reported as a statement of scientific "fact", transferred by analogy as a possibility of cloning humans, and finally generalized as the approaching inevitability of human cloning. Together, these successive steps turned the scientific breakthrough into a moral challenge, first voiced as fear of the consequences and later as a call on politicians to regulate or even ban the technology.

**Table 1 From Scientific Breakthrough via Moral Concern to Political Ban, Norwegian Newspapers, end of Feb. 97**

| Headline | "Argument" |
|---|---|
| "Cloned sheep a breakthrough for scientists" | Statement of a scientific "fact" |
| "Human cloning possible" | Possibility by analogy |
| "Human cloning ahead" | Generalisation to necessity |
| "afraid of Dolly" | Expression of concern and fear |
| Norwegian ban on cloning sought | Demand for political ban |

[56] Cf. Edna Einsiedel, et al. 2002. Brave new Sheep – The Clone named Dolly. In Martin W. Bauer & George Gaskell (eds.): *Biotechnology. The Making of a Global Controversy*. Cambridge University Press. 313–347.

[57] All Norwegian newspaper quotes are from the week beginning February 22, 1997. For the Norwegian wording and day of publication cf. Torben Hviid Nielsen. "Dolly. 10 år i pressen". *Prosa. Faglitterært Tidsskrift*. 03/06. 12. årgang. 6–11.

## A Scientific Breakthrough: Overselling Expectations

The press framed the story as an apparently straightforward "scientific" fact. A decade earlier, *Nature*'s American counterpart *Science* had asserted that "cloning mammals by single nuclear transplantation" was "biologically impossible".[58] Now, suddenly, a "biological impossibility" had become a "practical reality". Yet although the technique was simple, it was not easy to explain. Newspapers therefore helped their readers along with explanatory graphics, like cookbooks or do-it-yourself manuals, where the arrows apparently indicate causality with each new step succeeding the last, provided the instructions are followed (Fig. 2).

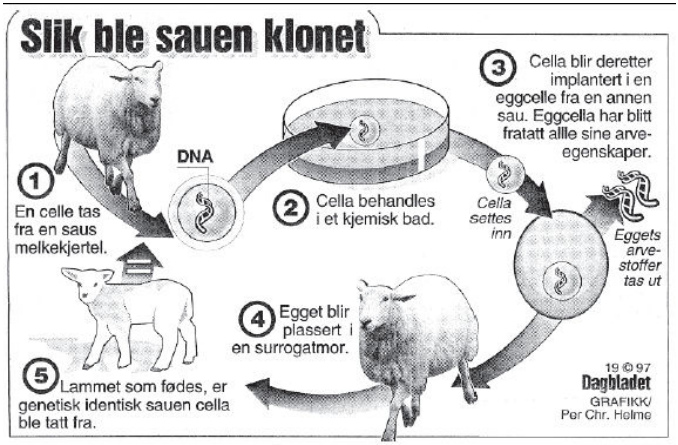


*Fig. 2 The Cookbook. How to Clone a Sheep. Dagbladet, 22 February, 1997*

Dolly was, however, not only the first but also the only success – the only live birth of 430 attempts. A tiny success rate. The team had attempted to remove the DNA from an isolated ovum and replace it with an adult cell nucleus from Dolly's "mum". Of the 430 isolated ova used in these attempts, they were successful in 277. Twenty-nine of the 277 ova developed to the blastocyst stage. Six of those matured enough to be implanted in surrogate mothers. And Dolly was the only of born lamb to survive longer than a few days.[59] Although it would have been simple, the many

[58] Cf. Gina Kolata. 1997. *Clone. The Road to Dolly and the Path Ahead.* Allen Lane. The Penguin Press. New York and London, p. 103.

[59] Cf. note 1.

failed attempts demonstrated the practical limitations of the process, but were hardly ever mentioned in the newspaper articles.

The press soon turned from the novelty of the event to its possible consequences, *from statement to analogy*. Because it is possible to clone sheep, it should also be possible to clone other mammals, including humans! Even "Norwegian researchers could do it". As a professor at the Norwegian School of Veterinary Science explained, "if you can create genetically identical animals, you can copy people too".

The third step was a fatalistic *generalization by which the possibility* of cloning humans *became a necessity or inevitability*. A simple technique such as "cloning á la Dolly" could "be used all over the world". Stopping it from spreading in a globalized world would not be easy. A professor of genetic technology at the Norwegian College of Agriculture thus confirmed, "it is only a matter of time before humans will be cloned....and she believes this will happen soon".

## A Political Challenge: Overselling Moral Concern

It is often overlooked or neglected, but ironically cloning sheep was not the original purpose of the research at Roslin Institute. They wanted instead to modify domestic animals' genetic make-up so they could serve as living medicine factories. The new understanding of the function of DNA before and soon after fertilization was only a prerequisite for this.[60] Had the scientists applied for funds to clone a sheep by cell transplantation, they would almost certainly have been turned down!

The likely, yet unforeseen and often barely perceived, consequences of creating Dolly were often illuminated better by cartoons and explanatory figures than words and graphs. Virtually all of the many cartoons that were published take the possibility of cloning humans for granted and use it as the starting point to illustrate its possible consequences. And in order to accentuate the historical impact, the illustrators often allude to ancient myths of the western world.

On January 13 1998, *Le Monde* depicted the erstwhile Creator ruminating in impotence over the new wonder Ref. Even the omniscient God

[60] Cf. Ian Wilmut, Keith Campbell and Colin Tudge. 2000. *The second creation: Dolly and the age of biological control*. Harvard University Press; Gina Kolata. 1997.

finds it difficult to ascribe the right status to the new creation, and situate it relative to the trinity of the Father, Son and Holy Spirit (Fig. 3).


*Fig.3 A New Wonder? Le Monde. Jan. 13 1998.*

*Gazeta Wyborcza* resorted to the Faustian covenant, evoking limitless duplication as a kind of eternal repetition in the era of reproduction Ref. The homunculus, originally created by Mephistopheles, is now a sheep which creates a copy of itself, which creates as copy of itself, which cr eates a copy of itself – all proceeding as if they were their own original (Fig. 4).

*Fig. 4 The Faustian Covenant – forever! Gazeta Wyborcza.*

And on March 3 1997, the front page of *Der Spiegel* highlighted the possible abuse of the technique, the mass production of beauties as Claudia Schiffers, geniuses as Albert Einsteins and beasts or politicians as Adolf Hitlers (Fig. 5).

A few days after the news broke, the possibility and likelihood of human clones was the main story. Headlines such as "Afraid of Dolly" transformed scientific hope into moral challenge. And ethical concerns soon became an agenda-setting political problem. Even professor Wilmut believed the "anxiety about this being abused as well-founded". And *Der Spiegel* quoted him saying: "Using our technique [we] can produce genetic copies of people. Only strict legislation can stop abuse".[61]

[61] *Der Spiegel*. No 10. 3 March 1997.

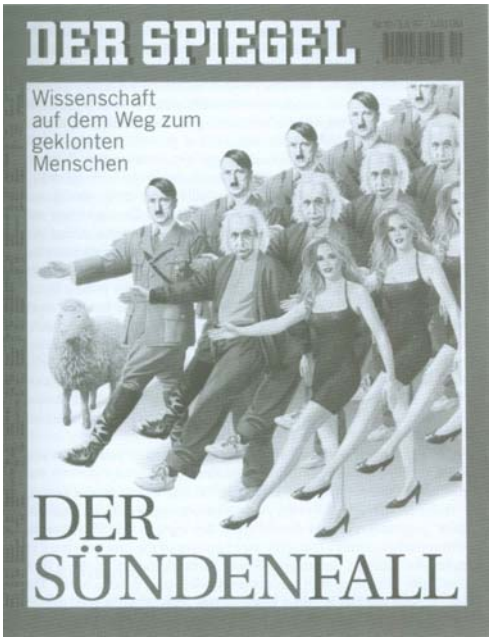


*Fig. 5 Cloning for What? The Beauty, the Genius and the Beast. Der Spiegel. March 3, 1997.*

The moral concerns were acute, but seldom specific. The undertone was often just that a taboo had been broken – and this suggestive hint was often argument enough: as master of the cloning technique, mankind had wrested the power of creation from God's omnipotence and Nature's fickleness. Allusions to Greek hubris and the Christian Fall were made and seemed obvious. The eternal and natural was no longer a norm.[62] The mere capacity to clone animals and people – rather than its impact on individuals and society – constituted the ethical threat.

The key argument for setting limits on use of the new technology was now ethical. Ethics was supposed to "reverse" or undo what had been learned, to prevent the technology from becoming a practical option. But

[62] The German philosopher Jürgen Habermas characterized the new biological technologies as freedom gradually encircling and encroaching on the necessity and chance of earlier times. "What Kant reckoned as the 'realm of necessity' was from the point of view of evolution theory transformed into the 'realm of chance'. The gene technique is now displacing the boundary between this unusable natural/instinctual basis and the 'realm of freedom'." *Die Zukunft der menschlichen Natur. Auf dem Weg zu einer liberalen Eugenik?* Frankfurt am Main. Surhkamp. 2001: 53. The grandiose statement might, however, interpret and contextualize the intended program more than it describes its feasibility or reality.

the numerous national bans and international guidelines were unable to stop expectations and rumors. According to reports in the press, science proceeded in the margins. The picture of the respected researcher was replaced by the mad scientist, the Frankensteins and Strangeloves, working on ships in international waters or laboratories in banana republics. Three small headlines over short reports from the Norwegian News Agency expressed the dual sense of hope and fear in the Norwegian press in late 2002 (Fig. 6).[63]

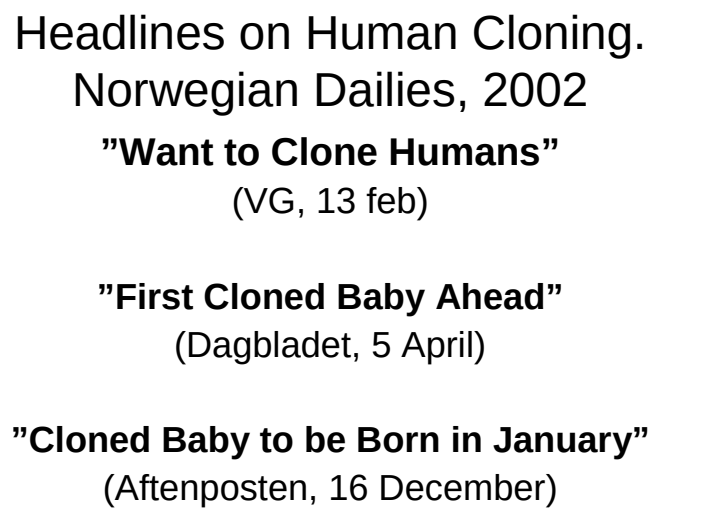


*Fig. 6 Headlines on Human cloning. Norwegian newspapers, 2002.*

In a mutually -reinforcing spiral the Norwegian press put the issue onto the political agenda and the politicians complained about the press coverage. The newspapers used ethicists and politicians to make news – whereas politicians and ethicists, in turn, used the newspapers to make politics. The chairman of the Parliamentary Committee on Social Affairs was alleged to have said, “cloning is fiddling with the Creation and therefore repulsive”,and the following day a headline stated that Norwegian politicians “want a ban on cloning”. Only two weeks after the first reports about Dolly, the Norwegian Parliament passed a resolution requiring the

[63] *Verdens Gang*, February 13, *Dagbladet*, April 5, and *Aftenposten*, December 16, all 2002.

Labour Government – against its own votes – to propose a bill banning cloning of all "higher organisms".

The revised Norwegian Biotechnology Law[64] was one of the most restrictive in Europe, and Eurobarometer surveys between 1993 to 2002 indicated that the Norwegian public was more skeptical than most Europeans to biotechnology.[65] During this period a Norwegian "biotech complex"[66] repeatedly complained about the Norwegian press's handling of the story, and its negative impact on public opinion. It was unjustifiably skeptical and the picture it painted of biotechnology downright negative.

The biotech complex's understanding of the press was, however, misplaced. A collating of all substantial articles about biotechnology in the two most circulated daily newspapers *Aftenposten* and *Verdens Gang* in the years 1993 to 2003 found almost twice as many positive as negative articles in both, and during this vital period the proportion of positive articles increased in both newspapers (Table 2).[67]

**Table 2 Valuation of biotech in the Norwegian Press, 1993–2002.**

| | Aftenposten | VG |
|---|---|---|
| Positive valuation | 43% | 30% |
| Balanced/neutral | 33% | 53% |
| Negative valuation | 24% | 17% |

N= 570

More than half of the articles in *Verdens Gang* and a third in *Aftenposten* were "neutral" or "balanced", in the sense that they reported both positive and negative assessments and valuations. Typically, they quoted or paraphrased two "experts": a scientist or businessman who supported biotechnology and an ethicist or politician expressing concern. In a double over-

[64] Act No. 56 of 5 August 1994 *Relating to the Application of Biotechnology in Medicine (Biotechnology Act)* with later changes and additions. Cf. Torben Hviid Nielsen, Trond Haug, Siv Berg and Arve Monsen. 2002. "Norway: biotechnology and sustainability" in Gaskell, G. and M. Bauer (eds): *Biotechnology 1996–2000. The Years of Controversy*. Science Museum. London. 237–250.

[65] Torben Hviid Nielsen. "Flere ser mere positivt på bioteknologi", "Et spørgsmål om viden?" and "Genterapi, genmad og genpolitik". *Samfunnsspeilet.* Statistics Norway. 1/2007: 8–21.

[66] Cf. Martin Kenney. 1986. *Biotechnology. The University-Industrial Complex.* Yale University Press. New Haven and London.

[67] Trond Haug recorded, selected and coded the articles. Cf. Torben Hviid Nielsen, Ørnulf Seippel and Trond Haug. 2003. "Hva mener og vet nordmenn om bioteknologi? Noen resultater fra Eurobarometer 58.0 (2002)". *TIK arbeidsnotat, nr. 20/2003*. Oslo University.

sell, the ("scientific") proponents and the ("ethical") opponents were referred to as if they disagreed solely about the acceptability, and not the feasibility of the technique. The press thus appeared to be "neutral" or "balanced" by serving as mouthpieces for the optimists who oversold the hopes, as well as the critics who oversold the (im)possible consequences. Their assessments differed, but proponents and opponents both seemed to confirm the technique's feasibility and practicability.

## Dolly Euthanized. The Death of an Oversell

Let us go back to Dolly and the prospects of cloning humans. Hope turned into disappointment and fear into relief when the Roslin Institute on 14 February 2003 announced that Dolly had been "euthanized", i.e. was helped to die a worthy death, at the age of six and a half Ref. Ethics as limitation had had an inferior role in Dolly's conception and birth, but was now destined to become the key justification for her death.

For a while there had been rumors and speculations about Dolly's health and of other cloned animals'. Since the fall of 2001 she had been lame due to an arthritic left hind leg. Earlier that month the first Australian cloned sheep had died at the age of 2 years and 10 months. In the spring of 2002 an article in the Norwegian Biotechnology Advisory Board periodical *GENialt* noted predicted "no end" to

> the illnesses which could affect cloned animals. Enlarged tongue, deformed head, poor kidneys, defective immune system, diabetes, unnatural posture.… So far sheep, mice, goats, turkeys, cats and rabbits have been cloned. For each photogenic and seemingly well-formed animal, many have died as embryos or a short time after birth due to serious deformities.[68]

"Euthanasia" was an unusual expression to use for the death of a sheep whose life was lived as an experimental domestic animal. "Euthanasia" belongs in the realm of human or medical ethics, not animal ethics. Experimental animals are created as experiments or to have experiments performed on them – often until they die. And in the normal language of modern agriculture, farm animals are "slaughtered" or "killed" when they

[68] Ole Johan Borge. Helse hos klonede dyr. *GenIalt*. 2/2002. 6–8.

no longer serve their purpose. Describing the death of Dolly as "euthanasia", the Roslin Institute endowed her with a sense of dignity and afforded her a form of care otherwise reserved for humans. Dolly was, of course, unable to give her consent. And as an active form of intervention to shorten her lifespan, two other key elements of legitimate and legal euthanasia were ignored.[69]

In Norway, *Dagbladet* printed at the bottom of page six NTB's brief report of Dolly's death, February 15 2002. The rather grandiose foreign word "euthanized" was translated into the more straightforward "put down", and the reason given was that "she had a serious lung infection".

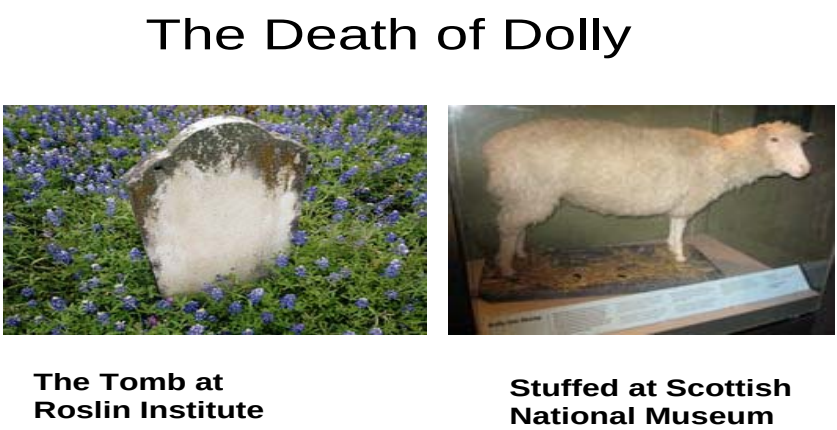


*Fig. 7 The Death of Dolly*

The international press gave Dolly's death a more prominent place and asked more questions about it. But the actual cause was explained on a poster – *Dolly: A Final Report* – presented in the relatively modest setting of the International Embryo Transfer Society, in Portland, Oregon in January 2004[70] (Fig. 10).

It had been written by six employees of the Roslin Institute who downplayed the possibility and likelihood of any connection between Dolly's early death and her status as a clone. Most of the text is in the

[69] See Knut Erik Tranøy. *Medisinsk etikk i vår tid*. 4th edition. Oslo. 2005.
[70] Rhind, S. et al. *Dolly: A final Report*. Poster. 2004. www.roslin.ac.uk/public

form of bullet points, not full prose. All indications are reported as if they were of equal significance, but only a few are interpreted. Statistical correlations are not calculated. Occasionally the line of argument is broken without explanation. The poster resembles an autopsy report more than a scientific article, and its spirit is an acquittal by law more than a discussion of causes and risks.

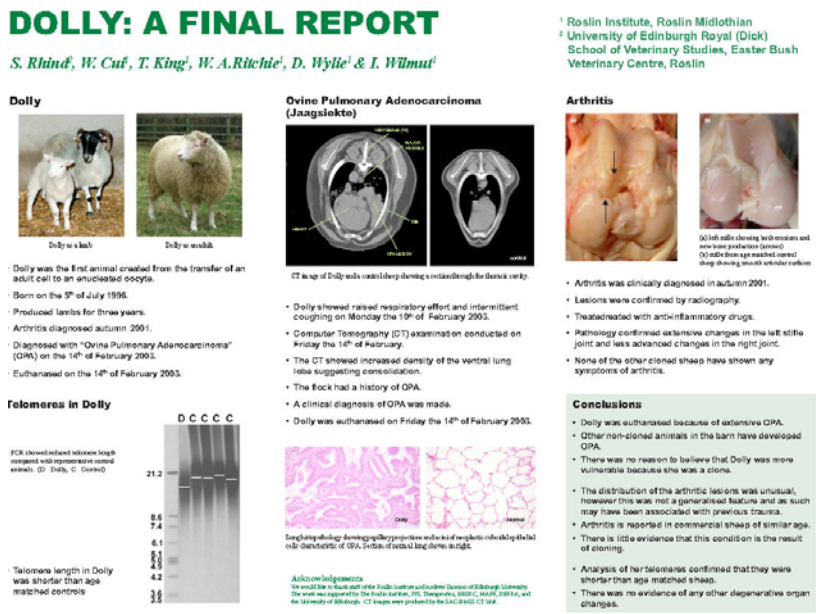


*Fig 8. Dolly: A Final Report.*

Back in 2000 Professor Wilmut interpreted the first signs of Dolly's premature ageing as an indication that the cloning technique might have been "ineffective".[71] Photographs reveal that Dolly's telomeres, (the small pieces of DNA at the end of the chromosomes, which are shortened by each cell division) were "shorter than in normal sheep of the same age". But referring to the fact that the same symptoms may arise in ordinary sheep of the same age, the final report says there are "few indications" that the premature ageing was caused by the cloning .

Despite the overselling of hope and fear, the primary aim of cloning research since Dolly has been "the possibility to grow tissue and organs,

[71] Cf. note 6.

not make babies" Ref . Shortly after Dolly's birth Richard Lewontin thus diagnosed the greatest obstacle to cloning was the unavoidable risk and uncertainty since clones would often lack or have a surplus of chromosomes.[72] And on the tenth anniversary of the publication in *Nature* of the original research, the journal acknowledged in an editorial that the focus of subsequent research had been "on the transfer of nuclei of somatic cells in the context of stem cells".[73]

[72] Richard Lewontin. "The Confusion over Cloning". It Ain't Necessarily So. The Dream of the Human Genome and Other Illusions. *New York Review of Books*. 2000 (1997). 281–312.

[73] Editorial. "Dolly's legacy". *Nature.* Vol. 445. Issue no. 7130. 22 February 2002: 795.

# Media Power? – Influencing Public Opinion Formation about Stem Cell Research in Denmark[74]

*Maja Horst*, Associate professor
Department of Management, Politics and Philosophy
Copenhagen Business School, Denmark

Questions about the power and influence of the media over political decision making have been central to mass media research throughout the twentieth century.[75] Opinions have varied. Some see the media as crucial in determining policy objectives, others present the media as little more than superficial commentary. Here I will adopt a perspective known as agenda-setting theory, which argues that the media do indeed play a significant, if indirect, role in policy processes, because the media agenda has a crucial influence in shaping the attention structure of policy makers.[76]

According to agenda-setting theory, the mass media affect the policy agenda both in terms of issue selection and framing. The influence of *selection* stems from the fact that attention is a limited resource and that the media, by covering certain issues, can divert attention away from other issues. The agenda of the news media is therefore thought to influence the agenda of issues that citizens and politicians regard as important in terms of political action. As media sociology has amply demonstrated,[77] however, the media possess particular preference structures and will tend to favour stories that are high on salience, controversy and

[74] This chapter is partly based on my paper "The laboratory of public debate: understanding the acceptability of stem cell research" published in *Science and Public Policy* vol 35, April 2008.

[75] McQuail, D.(1994): *Mass communication theory*. London: Sage Publications.

[76] McCombs, M.(2004): Setting the Agenda – the mass media and public opinion. Cambridge: Policy Press.

[77] Berkowitz, D.(1997): *Social meanings of news*. Sage Publications.

reader identification. The resulting media agenda might therefore not accord completely with the agenda considered to be crucial by politicians or the public conception of the crucial issues.

The agenda-setting influence of *framing* is based on the observation that media have pre-defined interpretative frames, story-lines and rituals which journalists employ when they try to make sense of a story. An issue is always presented with a number of attributes, some of which will prevail in a particular case, encouraging readers to associate a certain issue with certain attributes. For instance, media coverage can have an important effect by making some viewpoints in a controversy seem more legitimate or relevant by representing them in a positive and less critical fashion. Media can also play a crucial role in defining the *problem* in a controversy, because different definitions of problems often lead to different types of possible solutions.

I will here explore the Danish media coverage of stem cell research in order to discuss the agenda-setting role of the media with regard to the governance of biotechnology. The analysis is based on quantitative and qualitative studies of the media coverage of stem cells. Rather than trying to prove the agenda-setting role of the media, it is taken as the starting–point of the analysis. The ambition of the article is therefore not to *prove* the influence of media coverage on the Danish regulation of stem cell research, but rather to examine it and point to its possible influence on policy-making. The analysis is divided into two sections. The first section is a quantitative overview of Danish media coverage, i.e., how often the issue appears and how it is framed as a newsworthy issue. This analysis demonstrates that stem cell research has received a lot of attention in Danish mass media and that coverage has tended to portray stem cell research positively, but also as an issue with social and ethical dimensions.

In the second section, I shall use one example to explore the framing influence of the media in greater depth. This concerns the policy process by which embryonic stem cell research became legal in Denmark. It began in 2002, with an expert committee report identifying stem cell research as a very promising scientific field, and recommending a lifting of the ban on experiments with embryos.[78] Before 2002, the government

[78] The Gene Technology Committee (2002), Biotechnologies of the future – possibilities and *risks (Fremtidens bioteknologier – muligheder og risici)* (Ministry for Science, Technology and

had been reluctant to permit embryonic stem cell research as the status of the human embryo remained a highly contentious issue. The analysis will argue that the media coverage helped create a situation in which Danish policy makers found it possible to legalise embryonic stem cell research. In the original description of the controversy in policy documents, the political issue was presented as a conflict between two fundamental principles. During the policy process, and particularly in the media, however, it became framed as a conflict between different actors pursuing specific and conflicting interests. This change in the framing allowed for a compromise to be reached, and can therefore be seen as enabling the policy decision to permit stem cell research.

## Media Coverage of Stem Cell Research

The empirical material comprises every article in eight national Danish newspapers[79] which contains the letter combination "stem cell" ("stamcelle" in Danish) between 1 December 1990 and 1 June 2005. This amounts to a total of 997 articles, of which almost 40 per cent dealt with stem cell research/innovation as the main story. Based on these figures it is obvious that stem cells have received a great deal of attention in the Danish media. 44 per cent of the articles frame stem cell research positively, and only 10 per cent in negative terms. The newspapers differ widely however, in their presentations. The business paper, *Børsen*, had 20 times as many positive articles as negative, whereas the intellectually-oriented *Information* "only" printed two positive articles for every negative one.

It is also interesting to examine how the media portray the timeline and progress of stem cell research. New research results are in focus in 44 per cent of the articles, while 20 per cent look at routine use and 34 per cent at public regulation. It is remarkable that less than half of the articles focus on research, since stem cell innovation cannot be said to have moved beyond basic research as yet. It is perhaps particularly noticeable that every fifth article presents routine use of stem cell technology. These

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Innovation, Copenhagen).

[79] Politiken, Berlingske Tidende, Jyllandsposten, Weekendavisen, Information, Børsen, Ekstra Bladet, B.T.

articles present stem cell research as if it had already led to routine uses, or describe a future in which stem cell therapy is routine. The geographical focus is primarily Danish (62 per cent). Danish oriented articles focus relatively more on routine use, while news stories originating from EU and USA relatively often focus on public regulation.

More than half of the articles also refer to other forms of biotechnology including cloning (30 per cent) and animal experimentation (22 per cent). This frequent association with other technologies suggests an understanding of stem cell research as part of a wider biotechnological innovation complex. It is, however, surprising to see cloning mentioned so often, as this has been regarded as very problematic among the Danish public. So why is the relatively positive treatment of stem cell research linked to the cloning issue which is so widely considered negatively? Analysed in closer detail, it appears that stem cell research is precisely described as something fundamentally different from cloning. Whereas cloning is problematic, stem cell research is portrayed as a very beneficial technology. On this basis it can be suggested that stem cell research has become the technology of hope previously represented by gene therapy.[80] A qualitative examination of the articles confirms this reading of stem cell research as a powerful focus for hopes of a better future in which medical science will be able to cure serious diseases, manufacture "spare parts" and repair damaged ones with biological building materials.

The longer the articles, the more complex they are, measured by how many different biotechnological applications they mention and how many sources they include. Researchers and health professionals are the most commonly used sources (59 per cent), but politicians (31 per cent) and organisations (26 per cent) are also frequently used. Citizens with or without a certain professional training are sources in 19 per cent of the articles and patients, their families and patient organisations are used as sources in 10 per cent of the articles. It appears that many different sources are able to speak about stem cell research in the Danish newspapers, although researchers and health care professionals do receive most attention. The business paper Børsen has a very high degree of business sources (56 per cent) and the two tabloids, Ekstra Bladet and B.T. give

[80] Horst, M. (2007): Public expectations of gene therapy: scientific futures and their performative effects on scientific citizenship. In *Science, Technology & Human Values.* 32 (2) 150–171.

much attention to patients (both 26 per cent). At the same time these three papers use researchers and health professionals relatively less than the other papers (on average 38 per cent).

A previous examination of the media coverage of biotechnology in Denmark identified four dominant framings of stem cell research.[81] They can be understood as overarching story-lines used routinely by the media to ascribe meaning to a particular phenomenon.

- *New knowledge*: stories about scientific progress, new discoveries and invention of new technologies. This framing was employed in 26 per cent of the articles.
- *Economy and usability*: stories about economic prospects and growth, business opportunities and innovation (18 per cent ).
- *Societal consequences*: stories concerning social, cultural and ethical aspects of biotechnology (46 per cent)
- *Human interes:t* stories about patients and their experience of the technology (10 per cent)

It should be noted that the "new knowledge" frame is only employed by a quarter of the articles, much less than "societal consequences". Given these figures, we can only conclude that stem cell research is viewed less in terms of new discoveries and economic growth, and primarily in terms of its cultural and ethical implications for society. Stem cell research should therefore be understood as embracing much more than questions relating to a narrow technical focus. It is primarily seen as a political issue with far-reaching implications for society. As such it relates to general and political discussions concerning the relationship between science and society. This particular framing of the issue is also an example of mediated discourse about science as a central activity with implications for social dynamics in society.

[81] Horst, M.(2003): Controversy and Collectivity – Articulations of social and natural order in mass mediated representations of biotechnology. Copenhagen Business School, Doctoral School on knowledge and management:

## Framing Effects: from Incommensurable Principles to a Compromise between Interests

In October 2002, the Gene Technology Committee, set up by the Danish government, published a report on the future prospects of genetic technology.[78] Stem cell research was a particularly promising field, argued the committee, and legal restrictions on embryonic stem cell research ought to be lifted. This report led to parliamentary calls for a "broad public debate" to serve as a basis for policy decisions. The Danish Board of Technology was consequently commissioned to arrange a one-day hearing in January 2003. After another round of public hearings, the first bill was introduced in April 2003 and passed into law in May. The Act made stem cell research on "spare" embryos after fertility treatment legal as of 1 September 2003. During this process, representations of the conflict and its opposing parties were transformed, and it seems that the mass media played an important role in this transformation

### *A Conflict between Principles*

In the expert committee's report from 2002, the conflict is described as a tension between on the one hand science and economic development, which offers hopes for the future, and on the other hand ethics, which urges caution[82]. Subsequently, the report translated this tension into a conflict between two ethical principles – one that values the potential benefits higher than the wish to protect the human embryo, and one that puts the necessity of protecting human life above everything else. Following these two principles, the report states that: "For many people a subscription to one or the other of these overarching positions will determine their opinion on the use of embryonic stem cells for research."[83]

Throughout the report, research and industrial aspects are portrayed as part of the economic system, which unconditionally represents a reason to permit stem cell research. It is therefore solely the ethical considerations

[82] The Gene Technology Committee (2002), *Biotechnologies of the future – possibilities and risks (Fremtidens bioteknologier – muligheder og risici)* (Ministry for Science, Technology and Innovation, Copenhagen). Page 38.

[83] The Gene Technology Committee (2002), *Biotechnologies of the future - possibilities and risks (Fremtidens bioteknologier – muligheder og risici)* (Ministry for Science, Technology and Innovation, Copenhagen). Page 43.

which create the societal dilemma of choosing between two abstract principles and their moral consequences. The report concludes that "Decision-making regarding embryonic stem cell research represents an ethical conflict, which presents society with a choice between two possibilities, which both have some unavoidable moral consequences and costs. In such circumstances there is a need for a continuous, broad and open public debate and for political decision-making."[84]

Similar formulations can be found in a report published by the Council of Ethics in 2003[85] and in the parliamentary debate about regulation of stem cell research which took place in November 2002. According to articulations like this, the conflict is a stable and universal disagreement between two different sets of arguments guided by two different ethical principles. Regulation is then made by deciding which of these two principles should have supremacy over the other. The central positions in the controversy are therefore framed as "principles" or "overarching ethical positions", which are incommensurably juxtaposed. When deciding on the regulation of stem cell research it is these basic principles that are presented as being necessary to "take into account". The controversy, however, thrives on the fact that they cannot both be seen as indispensable at the same time, since they are mutually exclusive. The role of the politicians in this part of the debate is therefore presented as a responsibility to assume the function of central judges over what principle should be considered supreme.

### *A conflict between interests*

The second form of framing the conflict emerged in the media in 2002. In spring 2003 it became dominant as the public discussion of general principles seemed to be transformed into a consideration of actual people – as in a debate contribution from three medical doctors:

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[84] The Gene Technology Committee (2002), *Biotechnologies of the future – possibilities and risks (Fremtidens bioteknologier – muligheder og risici)* (Ministry for Science, Technology and Innovation, Copenhagen). Page 56.

[85] The Danish Council of Ethics (2003), The beginning of human life and the moral status of the embryos (Menneskeligt livs begyndelse og fosteranlægs etiske status) (The Council of Ethics, Copenhagen).

> There is a lot of talk about respect of human life. The human embryo should of course be respected at all levels, but we find the respect for, and consideration of, the difficult life of ill people much more imperative.[86]

Instead of two opposing principles we have an attempt at balancing opposing considerations. But the media coverage also here extends the conflict beyond the needs of the ill:

> The ministers of this country probably cannot avoid taking into account the fact that one of the heavy industrial players in Denmark, Novo Nordisk, says that "the train is about to leave the platform" and that we shouldn't let this chance pass us by. (…) Much is pointing in the direction of stem cells as the next revolution within medicine – but nobody knows. If it works we should let the consideration of the already living and the suffering weigh heavier than a moral consideration of a very diminutive collection of cells, which barely can be seen and which mostly resemble the snot from cold noses.[87]

An important relationship is posited here between private and public sector stem cell researchers, portrayed as holding the key to future cures (if they would only be permitted to use it), while patients suffering from serious diseases are portrayed as having legitimate and sustainable expectations of future cures. One of the patients highlighted by the media is a six-year-old boy, Anders, whose parents' plea was presented several times in the regulation debate:

> Injections will never be able to compete with healthy beta cells' ability to administer precisely the right amount of insulin to process the blood sugar. It would therefore be optimal if Anders could have some new beta cells, without his immune system killing them off again. It is precisely this biotechnological hook Finn Kristensen [the father] is now hanging his hopes on. The building block of hope is called stem cells.[88]

The strong relationship between stem cell researchers and patients is linked to a notion of the "spare" embryo as a lump of cells, which would otherwise be thrown away. It is presented as a form of actor, but one to which it is relatively easy to give low priority in a contest between oppos-

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[86] *Politiken* (2003a): "To the Stem Cell Laboratory (Til stamcellelaboratoriet!)". 2 January 2003

[87] *Information* (2003): "Once more for... (En gang til for...)". 23 January 2003.

[88] *Berlingske Tidende* (2003a): "The building blocks of hope (Haabets byggesten)". 17 April 2003.

ing interests. When the government finally issued the bill, it extrapolated from this association, arguing that since research on embryos is already allowed in some circumstances the changes to the legislation would therefore be minor:

> Health minister Lars Løkke Rasmussen (Liberal Party) thinks that the government has made a sober balancing between the considerations of the embryo on one hand and the possibility of curing serious diseases on the other hand: "Research on embryos is already allowed when the purpose is to improve methods of in vitro fertilisation. In light of the new possibilities for treating serious diseases we expand the law a little bit so medical research will be permitted. You have to remember that the alternative to research on spare embryos is that they will be thrown in the waste basket," says Lars Løkke Rasmussen.[89]

Opposing this view are the Christian Democrats and a minority of the Council of Ethics, both of whom stress the right of human embryos to life. In contrast to the earlier representations of ethical principles, however, these actors come across with a particular and personal set of ethical preferences:

> Not everyone is delighted with the law. A minority in The Council of Ethics is against using the fertilised eggs for research, and also the Christian Democrats are against utilising the eggs for other means than what they were created for: to create little new people.[90]

The important point about quotes like this is that the principled argument against stem cell research has been substituted with a reference to certain individuals who are against the law. It is their personal preferences which they are representing, not a general ethical principle commonly accepted in society. In this context it is interesting that almost all the media articles written by journalists are positive towards stem cell research. Many of the articles, as in the previous quote, mention resistance to legislative change, but it is usually kept for the last part of the article and rarely takes up more than a quarter of the space. In general, the mass media coverage suggests two networks of representation, as summarised in figure 1.

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[89] *Berlingske Tidende* (2003b): "Biotechnology: yes to research on embryos (Bioteknologi: ja til forskning på fostre)". 18 March 2003.

[90] *Politiken* (2003b): "Political yes to stem cell research (Politisk ja til stamcelleforskning)". 2 April 2003.

The figure demonstrates how the network in favour of legalising embryonic stem cell research on the left hand side is presented as a stronger alliance than the right hand network. In the end it seems that opposition to stem cell research is only supported by a network consisting of the individual moral preferences of the (very small) party of the Christian Democrats, a minority in The Council of Ethics and the notion of a right to life on behalf of some un-specified un-born foetuses. In contrast, the network in favour of permitting stem cells represents a much stronger alliance including industry (representing a profound impact on national prosperity) and stem cell researchers articulated as holding the key to future cures of serious diseases.

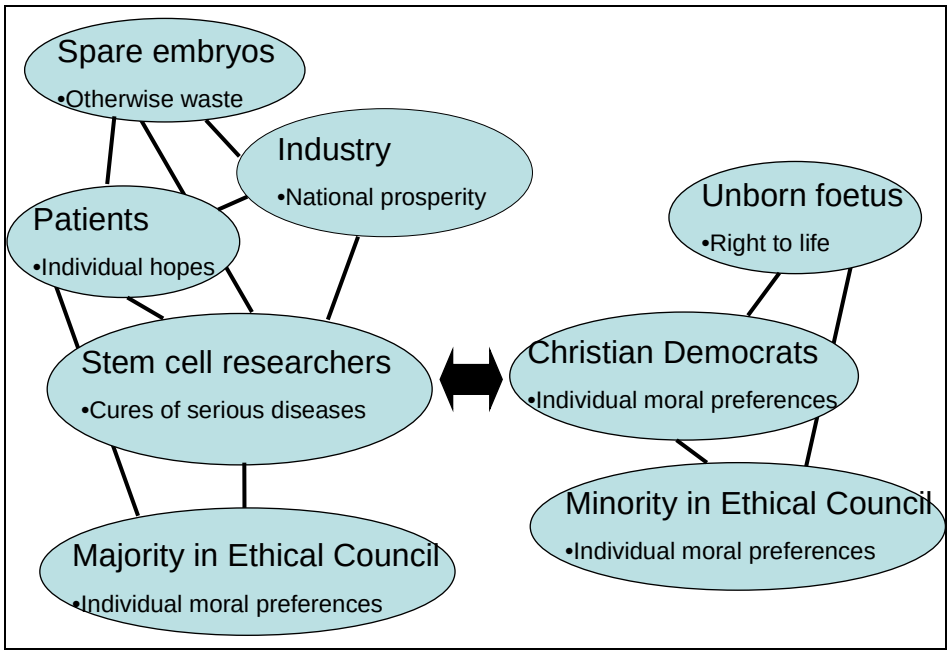


*Figure 1 Two representation networks in mass media coverage*

The task of policy-making in this framing of the controversy concerns mediation in a conflict between actors with particular interests. Whereas the early policy formulations of the problem framed the policy question as one of deciding between two mutually exclusive principles, the frame employed by the media represents politicians as mediators, who are supposed to balance the interest of the various actors in order to find a work-

ing compromise. In this context the difference in strength of the two networks becomes crucial. The actors who oppose legalisation seem like a much weaker alliance than the actors in favour. Presented in this way, it seems like an obvious decision to legalise stem cell research on spare embryos.

## Biopolitics and the Role of the Media

The previous section illustrated how the framing of the policy issue evolved from a conflict between two incommensurable principles to one between different alliances with different interests. The effect of this discursive change can be illustrated by considering how the inherent models of problem solving in the two framings differ substantially. In the first, the policy issue is framed as finding the right decision in the face of two contradictory ethical principles: Which of them should have precedence and inform the regulatory changes? Against this, the second frames the policy issue as a question of mediating between different interests and reaching the best possible compromise. The shift between these two framings can be viewed as a simplification of the policy process, because it makes compromise possible. As long as the issue remained a choice between two incommensurable principles the situation was locked. The shift to representations of interests, however, made compromise possible.

It would be wrong to conclude that the mass media were the main arbiters in this change of framing. Journalists do not normally use frames for which they cannot find support among sources. Furthermore, the change in framing also happened outside the realms of the mass media, such as parliamentary debates. But there is reason to believe that the media's tendency to personalise conflicts as well as focus on specific problems of actual people has played a role in the general change in framing of the policy question. As first-year students of journalism learn, abstract problems should be made specific, tangible and personal. To a journalist it will therefore be second nature to repackage the abstract ethical norms deliberated upon by the Gene Technology Committee as the opinion of a certain person or group – for example a majority and a minority of the Ethical Council.

On a more general note, the coverage appears overall to have given readers a very positive picture of stem cell research in terms of its potential to cure illnesses and instil hope for the future. In this context, it is important to remember the effect of people's expectations. Social scientists have tended to dismiss people's expectations of biotechnology as "hype". Recently, however, Brown and colleagues argued that we ought to expand the study of expectations.[91] Rather than focus on the possible justification for expectations of the future, we should look at their performativity in the present. The generation of expectations might be integral to any new innovation area, since it is the basis for funding, attraction of qualified personnel and the creation of markets. In this regard, the mass media undoubtedly play a significant role.

We can conclude that in the case of Danish media coverage of stem cell research, several influences can be identified. Firstly, the coverage is generally very positive and likely to generate expectations in the Danish population, which in turn facilitate the allocation of resources. Secondly, it has a strong focus on the cultural and ethical impacts on society, which probably will reinforce these issues within the policy process and in the minds of the Danish public. And thirdly, the media coverage has been an engine of change in the framing of the policy issue. What started as a conflict of incommensurable ethical principles evolved into a conflict between groups of individuals with personal interests, making a compromise possible.

[91] Brown, N., Rappert, B., & Webster, A. (2000): *Introducing contested futures: from Looking into the future to looking at the future.* In Brown, N. et al: 'Contested Futures: A sociology of prospective techno-science'. Aldershot: Ashgate.

# Who has the Power in GMO Issues?

*Helena von Troil*, science communicator, Archeon Ltd

Knowledge is power, it is often said. To exercise power it is useful, and often necessary, to be well informed. But access to power platforms is also important. Such platforms can be the media, various political platforms or a position in a powerful lobbying organisation.

The public GMO debate can be traced back as far as to the late 1980s when the first reports of novel applications of this new technology were reported in the media. It has continued ever since , becoming especially intense in 1996 after the first shipload of GM soybean arrived in Europe in the face of vehement protests from the environmental lobby. Lately the debate has become less intense and also relocated in part from the daily media to other arenas, such as the Internet. But the issues remain divisive and controversial. The consumers have been said to resist this new technology and in the Nordic countries we still have very few GMO products on the market.

To identify who has the power in GMO issues we need to look at the history of genetic modification, the regulatory environment and public perceptions.

## History

The first scientific article reporting that genes can be isolated and transferred from one organism to another was published in 1973.[92] The scientists Stanley Cohen and Herbert Boyer had succeeded in modifying the genes of the common and well-known gut bacterium *Escheria coli*.

Very soon the first warnings appeared about the possible risks involved in this new technology. – A few scientists questioned the new

[92] Cohen & al. Construction of Biologically Functional Bacterial Plasmids In Vitro. Proc. of National Academy of Science, Nov 1973, 70: 3240–3244. 1973

methods at a scientific conference in Asilomar, USA, in 1974. They were worried that the technology could be used to produce harmful new bacteria and urged the scientific community to discuss risk evaluation, preventive measures and common guidelines.

This debate, conducted mainly within scientific circles, lead to the publication of the first official guidelines on work with recombinant DNA technology, or what we now call genetic modification, by the National Institutes of Health (NIH) in the US in 1976.[93] Ten years later, in 1986, OECD published its guidelines called Recombinant DNA Safety Considerations.[94]

The European Union soon started the process of regulating work involving the new gene technology in the late 1980s and the first two EU directives on contained use and deliberate release of GMOs came into force in 1991. They covered not only the application and production of new products using gene technology, but also the use of these technologies in laboratories for purely scientific purposes.

Three years later, in 1994, the first commercial GMO products were approved for marketing. The so called Flavr Savr™ tomato in the US and a pesticide-resistant transgenic tobacco in France. The tomato was sold for a few years in the US and a tomato paste was also marketed for some time in the UK by the supermarket chains Safeway and Sainsbury's.

But the event that really triggered the GMO debate in Europe was, however, the arrival of a shipment of GM soy beans in Rotterdam in 1996. This was the first time a large amount of a genetically modified product had been imported to Europe. The environmental organisations launched protest actions and a heated public debate began on the pros and cons of GM technology.

Today, more than ten years later, while the debate has somewhat ebbed away, GM crops are still not cultivated in the Nordic countries, nor are there GMO products on the supermarket shelves.

[93] http://www4.od.nih.gov/oba/IBC/IBCnihguidelines.htm
[94] http://www.oecd.org/LongAbstract/0,3425,en_2649_201185_1943774_1_1_1_1,00.html

## Regulation

As mentioned above, the first attempts to regulate the use of gene modification techniques, or recombinant DNA techniques as they were called, were made by the US National Institutes of Health. Today, gene technology is regulated in all Nordic countries as well as in most other industrialized countries, many countries in transition and developing countries. There are, however, some fundamental differences in the approach to regulation between the US and Europe. The controversy has also created problems for companies active in the field.

In the US, regulation is based on the view that only the consequences of the genetic modification – that is, the characteristics of the genetically modified organism or the product derived from it – are important. Thus regulations, risk evaluation and management are based on product characteristics. Also in the US, several GM crops have been approved for cultivation with increasingly larger areas allocated for cultivation since 1996. The consumer products derived from them are considered to be similar to those derived from traditionally bred crops.

In Europe, on the other hand, it is felt that there is something inherent in the GM technology that requires specific regulation. The regulation is based on the process, not the product, and the aim is to protect human health and the environment. Because the technology itself is very controversial, risk evaluation is not considered sufficiently robust as a regulating mechanism. In the European Union, the first two directives, both of which came into force in 1992, were based on risk evaluation.[95,96] As the controversy persisted, newer regulating instruments include paragraphs about the ethically acceptable use of GM technology. While these regulatory mechanisms were under development, a trend emerged in Europe to establish various advisory ethics committees, i.e., special bodies to which issues can be referred for ethical evaluation.

At the same time, the role of the consumer remained high on the political agenda, with growing awareness of consumers' right to know what they buy and how the products are produced. This has increasingly led to calls for information targeting the public in general and consumers in particular e.g. by improving the product labelling. Current EU legislation

[95] Directive 90/219/EEC, OJ L 117 of 8.5.1990, p 1
[96] Directive 90/220/EEC, OJ L 117 of 8.5.1990, p 15

also allows for informing and consulting with the public in matters related to the cultivation and eventual marketing of GMO products.[97]

Although the legislation has been amended many times already and extended to cover many different areas of production, the conflict between advocates and opponents of this technology persists.

## Public Perceptions

Public perceptions of GM technology have been the focus of discussion and a vast number of opinion surveys during the last two decades. One of the first surveys was conducted by the Office of Technology Assessment in USA in 1987.[98] The Eurobarometer surveys have measured European perceptions of gene technology since 1991.[99, 100, 101] The degree to which the public has accepted the technology, or rather rejected it, has also been discussed by experts in the social sciences and genetic engineering and several reports have been published.[102] Since its inception, the GMO debate has gone through six different phases.

### *Knowledge*

In the beginning, that is, late 1980s and early 1990s, whenever the lack of public support for the new technology was discussed, scientific illiteracy was usually blamed. If only the public knew more about basic biology and genetic engineering, the experts said, especially those in the field of modern biotechnology, they would be more likely to accept the technology. By this reasoning the remedy was easy: educate the public, and acceptance ratings would improve.

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[97] Directive 2001/18/EC, OJ L 106 of 17.4.2001, p 1

[98] Public Perception of Biotechnology, 1987. Office of Technology Assessment. US Government Printing Office, Washington, USA

[99] Eurobarometer 35.1. European Commission, 1991

[100] Eurobarometer 39.1. Biotechnology and Genetic Engineering: What Europeans think about it in 1993, INRA European Coordination Office, 1993.

[101] Eurobarometer 46.1, The Europeans and modern biotechnology, European Commission, DG XII, 1996

[102] Gaskell G, Bauer M, Biotechnology 1996–2000 The years of controversy, Science Museum, 2001

*Information*

As a consequence, the debate now centred on information and the need to produce information material for the public. This lead to much activity in the Nordic countries. The Danish Board of Technology (Teknologinaevnet) received 23 million DKK for technology assessment and information regarding genetic engineering during the years 1987–1992 and financed 71 larger and smaller projects. Among these were the first so-called "Consensus Conferences" with more than 600 local discussion events in which more than 40 000 persons participated. In Norway, the first open meeting about the deliberate release of GM organisms was arranged by the Advisory Board for Biotechnology (Bioteknologinemnda) in 1992. Also in Sweden, the new technology was discussed and information material produced early on. The Swedish Council for Planning and Coordination of Research (Forskningsrådsnämnden), the Delegation for hybrid DNA issues (Delegationen för hybrid-DNA frågor) and the Institute for Futures Studies (Institutet för framtidsstudier) were some of the organisations funding the production of information material.[103]

In Finland the debate had not yet started in the early 1990s, but the need of informing the public about gene technology had been recognised by at least some experts. As an example, it can be mentioned that the Science Centre Heureka introduced gene technology in its permanent exhibition. The new exhibits that dealt with e.g. gene mapping, transgenic animals and ethical issues in human genome research were widely reported by the media after opening to the public in January 1993.

*Trust*

People were beginning to realise that even widespread public information campaigns were failing to shift the public mood in favour of genetic engineering. On the contrary, there were signs by the mid 1990s of deteriorating sentiment, instead of improvements, from the technology advocate's point of view. Once again, the problem was discussed by various experts and the explanation put forward was that no matter what the information to the lay public is, people tend to put their trust in different information sources depending on their personal views and preferences.

[103] von Troil, Helena. Bio– ja geenitekniikan tiedotustarve Suomessa (Eng: The need for information about bio– and gene technology in Finland, Ministry of the Environment, 1994

For example, people who are concerned about the state of the environment tend to trust environmental organisations and persons who are positive to science usually trust scientific information. The conclusion was that an individual will trust information from sources that she or he considers trustworthy. Communication is not only about giving information. For the message to be understood and accepted, the communicator of the message should be considered reliable. Reliability perceptions are often connected to expertise, which in this context depends on whether the communicator is perceived to know the truth and can tell right from wrong.[104]

*Ethics*

The second half of the 1990s was the "years of controversy", a period at which the public debate over GMOs was most intense. Knowledge, information and trust were not enough in themselves. People were still very critical of gene technology. The ethical issues began to seep into the debate which until then had been about the technology as such and its possible affect on human health and the environment. Now, the ethics of using the technology became the issue. It was felt that even if measures were taken to ensure the safety for environment and the health of consumers, the technology was still problematic. Indeed, using GM technology was deemed "unethical". The increasingly negative attitude toward gene technology, which policy leaders and decision-makers to took seriously, resulted in the establishment of ethics committees in many countries the aim of which was to discuss the ethical issues related to genetic engineering. Often these ethics committees were also tasked with advising the authorities and other decision makers in matters regarding research and application of gene technology. The European Group on Ethics in Science and New Technology, an advisory organisation to the European Commission, was established in 1998.[105]

[104] Turner G, Wynne B. Risk Communication. Biotechnology in Public ed. Durant J. Science Museum, 1992

[105] http://ec.europa.eu/european_group_ethics/archive/index_en.htm

*Public participation*

By the early 1990s, genetically modified crops had been cultivated and marketed in the US and other non-European countries already for five years, but none in Europe. The industry was very concerned about the American dominance in the field. In the EU, work started on amending the two GM directives from the beginning of the 1990s. The aim was to implement EU-wide legislation that would ensure the safety of the GMOs and thus resolve the deadlocked situation in the market. Consumer acceptance was a particular concern to the legislators. Because the ethical advice of the advisory bodies had apparently failed to reassure consumers enough to persuade them to embrace GM technology, it was felt that something more was needed to open the European market. Public participation in decision-making was suggested as part of the solution. The legislative work resulted in 2001 in the new Directive 2001/18/EC on the release of genetically modified organisms.[106] The directive strengthens the legislative framework on the deliberate release of GMOs into the environment and the placing of GMOs on the market. In particular, the directive improves the efficiency and transparency of the authorisation procedures, establishes a common methodology for risk assessment and a safety mechanism. It also introduces mandatory public consultation and GMO labelling. According to the directive (articles 9 and 24), member states shall consult with the public on the proposed field trials and the Commission shall inform the public about planned marketing permits and provide the public with the opportunity to express its opinion on the matter.

*Precautionary principle and co-existence*

At the Earth Summit meeting in Rio de Janeiro in 1992, world leaders adopted Agenda 21, which advocated the widespread application of the precautionary principle in the following terms:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall

[106] http://europa.eu/scadplus/leg/en/lvb/l28130.htm

> not be used as a reason for postponing cost-effective measures to prevent environmental degradation. (Principle 15)[107]

Since then the precautionary principle has been endorsed internationally, and has featured as one of the main arguments against GMOs during the first half of the current decade. It is frequently invoked in arguments in favour of a continued restrictive policy on the cultivation of GM crops.

At the same time, members of the farming community and industry are lobbying for permission to perform field trials and commercially cultivate new GM varieties in Europe. To make this possible, the legislators and public authorities have introduced the concept of co-existence. Co-existence refers to the ability of farmers to make a practical choice between conventional, organic and GM crop production, in compliance with the legal obligations for labelling and/or purity criteria. The possibility of adventitious presence of GM crops in non-GM crops cannot be dismissed, and may have commercial implications for the farmers whose crops are affected. Consequently, suitable measures during cultivation, harvest, transport, storage, and processing may be necessary to ensure co-existence.[108]

This has led to EU guidelines on the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming.[109] These guidelines are intended to help member states to develop workable measures for co-existence in conformity with EU legislation.

## Power

Who has the power in GMO issues?

The answer is that the power lies with different groups at different times. When widespread ignorance was considered to be the main problem, the scientists, of course, had the expertise and ability to assess the risks of the new technology and the power to decide on both scientific and risk issues.

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[107] http://www.jncc.gov.uk/page–1575

[108] http://ec.europa.eu/agriculture/coexistence/index_en.htm

[109] http://ec.europa.eu/agriculture/publi/reports/coexistence2/index_en.htm

Information for the public came next and here too the scientists were in a key position as they held the information. However, scientists are generally not good at communicating with the public, so journalists and the media were needed to channel the information. At this juncture, power lay with the scientists and the media.

The third trend, as mentioned above, came about when the authorities began to realise that people tend to believe information from sources perceived to be reliable or trustworthy. The mid 1990s saw many non-governmental organisations – environmental organisations and consumer organisations – take up positions vis-à-vis GMOs. Some became very influential.

The first EU directives on GMOs came into force in 1992. With the exception of Denmark, which in 1986 was the first country to regulate the use of genetic modification, [110] all member states worked to incorporate the directives into domestic legislation during the 1990s. It could thus be claimed that the power, at the time, lay with policy makers and parliamentarians. This would not be completely true, however, as the directives did not leave much of the decision making to the national legislators; the important decisions had already been taken at EU level.

During the latter half of the 1990s, many advisory ethics committees were set up, to which questions of a more or less ethical nature regarding the use of genetic modification were increasingly referred, even to the extent of making decision making virtually impossible without first consulting with an ethics committee. Without doubt these committees had a lot of power in the decision-making process.

The citizens were handed power in the GMO debate only when information designed for lay persons was produced and disseminated and even more so when the EU GMO directives were amended in the beginning of this decade. Provisions were made in the regulatory framework for the public to access information and procedures were set up for the public to feed opinions into the decision making process before permissions for field trials of GMOs and marketing permits were granted.

The latest in the series of trends and power configurations is the emergence of the precautionary principle and co-existence. The legislators have accepted both and amended legislation in that light. However, for the lay person, these concepts are not easy to understand. The procedures

[110] https://www.retsinformation.dk/Forms/R0710.aspx?id=113305

are complicated and bureaucratic, which increases the power of the public authorities.

There are two key groups missing from the list of groups exercising or having exercised power in the GMO issues. They are the farmers on the one hand and the food industry and retailers on the other. Especially in the Nordic countries, the farmers seem not to have been very interested in these issues. Partly this may be due to the fact that developing GM crops suitable for cultivation at our latitudes has not been an industry priority, and partly because of the increasing interest in organic farming where GMOs are banned.

The situation may, however, change as the land allotted to GM crop cultivation increases in the European Union member states. In 2007 GM maize was the only commercially cultivated crop in Europe. Eight EU states (Czech Republic, France, Germany, Poland, Portugal, Romania, Slovakia and Spain) had allocated a total area of about 100 000 hectares.[111]

There are signs that consumer resistance towards GMO crops and products is waning in Europe. This combined with the fact that prices for certified non-GM varieties are rising, may lead food manufacturers to change their policy and include such ingredients in the production of foodstuffs.

[111] http://www.isaaa.org/resources/publications/briefs/37/executivesummary/default.html

# Transparency and Openness – Pros and Cons

*Ulla Järvi*, medical journalist, Finland

To communicate is to share – but do we all share the opinion that good and relevant mass communication is important?

Science produces new knowledge as the outcome of interaction, common perceptions and understanding. The media produces news about scientific research, politics, economy, etc. – for information and for entertainment. We often hear claims like: "The media are the link between citizens and politicians" or "Scientists have the duty to inform the public about their research". At least we journalists want to believe in these kinds of claim, which sound somewhat old fashioned in the Internet era.

Popularizing science is not the paramount aim of all scientists in academic communities. But should it be?

As a science journalist I strongly believe that the mass media have two ultimate tasks. The media can make science available to society by reporting and explaining academic research achievements. Second, communicating science through media is the only way to make science part of our public debate. Of course, sometimes it could be easier for scientists to act the "outsider" and avoid this debate. Sometimes researchers find out things that are difficult to explain to the public. And sometimes public opinion turns against scientists and their work.

In Finland we have a saying: "In science we trust!" A public opinion survey, the Finnish Science Barometer 2007,[112] shows that 63 per cent of Finns are interested in science. 71 per cent trust universities, with medical research coming out as the most popular, and the most reliable, field of

[112] Finnish Science Barometer, 2007. Finnish Society for Scientific Information. www.sci.fi/~yhdys/tb3/tiedebaro3.htm .

science. Finns are optimistic even about genetic and biotechnological research. The situation in Finland differs radically from many other EU countries, where the public tend to trust scientists and scientific aims less.

Again according to the Science Barometer, the most popular information source on scientific issues is the mass media, especially television, newspapers and Internet. As much as three-quarters of Finns want the media to provide more information on science. Information is sought much more frequently on the Internet and information networks than it the beginning of this decade.

It is obvious that mass media workers, journalists, have a remarkable opportunity to fashion the public image of science and scientists. Professor Esa Väliverronen shows in his studies, that when reporting about biotechnology Finnish mass media use the format of storytelling.[113] The media tell stories about famous Finnish scientists working abroad or about new medical advances of crucial benefit to mankind. Prof. Väliverronen also noticed that biotechnological inventions, like new drugs, represented "good biotechnology". However other inventions, like genetically modified plants, were "bad technology" to the mass media. Good biotechnology creates hope and bad biotechnology creates fear.[114]

We also have to remember that journalism and the media operate under different kinds of mechanisms than science and science policy. 1) In media science, biotechnology and bioethics are two issues among many others. Science news has to be very remarkable to reach the front page. For journalists, "bad news" is also good news. 2) Modern media love personalities, charismatic and articulate. In the academic world such characteristics are not so important. 3) The media want numbers and exact results – and often find them in scientific papers. At the same time the media often "forget" to mention that results are still very preliminary. 4) And lastly, science avoids generalizations; journalism feeds on generalizations. From stem cell research it's only a short step to cloning, isn't it?

Because of these differences, journalists and scientists often clash. Each has his or her own "culture of communication". They also have different kinds of opinions on the need to popularize science. The British

[113] Väliverronen, Esa (2004): Stories of the "medicine cow": representations of future promises in media discourse. Public Understanding of Science. 13:363–377.

[114] Väliverronen, Esa (2007): Geenipuheen lupaus. Viestinnän julkaisuja. University of Helsinki. Vaajakoski 2007.

Royal Society launched in June 2006 its report about British scientists.[115] According to this report in the past 12 months,

- 75% of British scientists said they had written neither articles nor books (for the general public)
- 77% had not been interviewed by newspaper journalists
- 80% had not taken part in a public event about science (debates)
- 10% said that the relation with general journalists is really important
- 12% announced that communication with the general public is truly relevant
- 95% said that communication with policy-makers is important or very important.

These figures are always important to remember. Publicity is a difficult thing for many scientists. We have scientists who want publicity more than anything else. But we also have scientists who prefer discussions with other scientists or even with national policy-makers rather than journalists.

## Journalists have Rights and Duties

It's been said that the mass media have no rules and reporters make news in whatever way they want. But journalists have duties as well as rights. Some are encoded in the laws of the land, others are agreed codes of conduct, like the "Guidelines for Journalists" issued by the Union of Journalists in Finland.[116] Journalistic ethics and laws are very similar in all of the Nordic countries. A journalist is authorised to write about difficult or unpleasant things in the name of freedom of speech. But a journalist has to check the information to try and ensure it is reliable. A journalist can not promote goods or issues: she has to be independent.

Science journalists do not yet have their own international ethics code. But a basis for an ethical code in science journalism is the preamble of

[115] Survey of factors affecting science communication by scientists and engineers. Rapport of The Royal Society. June 2006. www.royalsoc.ac.uk

[116] Guidelines for journalists. Union of Journalists in Finland. 2005. www.journalistiliitto.fi/Resource.phx/sivut/sivut-journalistiliitto/union/inbrief/guidelines.htx

the World Federation of Science Journalists´ (WFSJ) Constitution, which states:

> Science journalists must be thoughtful critics and commentators, linking the world of science and technology to the daily life of ordinary persons, clarifying the processes of research and discovery, and making the public aware of the social, economic and political context of science and technology, and its impact on society. [117]

In many countries science and, not least, medical journalists have their own guidelines. Often they will have been written together with scientists or doctors. For example, the Finnish Union of Journalists and Finnish Medical Association have adopted a common set of guidelines.[118] The first guidelines were issued already 45 years ago. In Great Britain guidelines on science and health communication are prepared by the Social Issues Research Centre in partnership with the Royal Society and the Royal Institution of Great Britain.[119] They were formulated in response to concern expressed within the health and science communities about the ways in which some issues were covered in the media. "Some issues" included, for example, the British debate on the risks of vaccination and false hopes of new cancer treatments.

From the historical perspective scientists and journalists have always worked closely together. Scientists have produced interesting items for newsrooms. Sometimes this link has been even too close. The German science journalist Wolfgang C. Goede opened this chapter in the discussion about ethics when he spoke about the history of the oldest German science journalists´ organisation (TELI) during the Nazi era. Goede demonstrated that scientists went along with the Nazi regime as a means of enhancing their careers. During Nazi years German newspapers ran headlines and stories like: "The Fuhrer promotes technology". Science journalists wrote the news and authored comments like: "The engineers are at the front, every German is a soldier". The climate between scientists and

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[117] World federation of Science Journalists, Constitution. www.wfsj.org/about/page.php?id=27

[118] Suomen Lääkäriliitto (Finnish Medical Association) & Suomen Journalistiliitto (Union of Journalists in Finland ): Lääkärien ja toimittajien tiedotussuositus (Guidelines for communication between physicians and journalists). 2003.

[119] Guidelines on science and health communication. Prepared by the Social Issues Research Centrein partnership with the Royal Society and the Royal Institution of Great Britain. November 2001. ISBN 0 85403 570 2. www.sirc.org/publik/revised_guidelines.shtml

journalists in the Thirties expressed a common purpose: "together we create the new and powerful Germany". TELI is investigating its own history and will present a detailed study to its eightieth anniversary in 2009.[120]

Today we have the same kind of discussion. How close can scientists and journalists – and information officers – come before they are too close? It is a well-known fact that journalists and politicians do not always agree on the way politics is reported. Why should scientists and reporters agree about how science should be presented? Is it easier to work as a journalist when you share the aims and opinions of the scientists and press officers at universities?

Holger Wormer is a German science editor and professor of science journalism at the University of Dortmund. Writing in the *Journal of Science Communication* on the relationship between science communicators and science journalists, he posed a question: "Is all this science communication helpful because there are scientists and science communicators coming up with better explanations and helpful material? Or is there an increasing danger of business-oriented science communicators selling science to the media in a cheap soap selling style?" [121]

## Science can make us Confused

In our complex world the ordinary citizen accesses information about science – and also about ethical problems – via the media. Science produces new information every day. At the same time the rapid changes in science make us confused. Who can I trust when scientists disagree about the facts and their interpretation?

I believe that openness is the best way to avoid scientific fraud and other inappropriate behaviour. But we have to accept that openness and independent journalism also mean problems. Publicity often prefers a manageable number of "stars", and in this climate there is not much space for many scientists. Who knows if they are good or bad role models?

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[120] Goede, Wolfgang: Ethics in Science. To whom are science journalists accountable? EUSJA News. Summer 2007.

[121] Wormer, Holger: Selling science in a soap selling style? Journal of Science Communication 5 (3) September 2006. International School for Advanced Studies.

It is very important that we journalists avoid exaggerating our admiration. Sometimes the media can help build a sense of national pride by hailing domestic research advances. But do we journalist close our eyes for example in the name of patriotism? Do we sometimes want good news so much that we forget normal journalistic criticism? We have had issues of this kind before in the history of scientific and commercial media.

Transparency and openness have their good sides, and their bad. The media can make genetic research understandable, enabling the public to comprehend the issues associated with genetically modified plants, drugs development, genome projects, etc. But we, the public, also need to discuss ethical issues in biosciences. These ethical problems aren't the stuff of big and simple headlines, and the media should accept this. Publicity is necessary when we try to promote a discussion between citizens and scientists.

# Commercial Interests Versus Common Goods

*Peter C. Gøtzsche*, Director, Nordic Cochrane Centre, Denmark

## Where do our Best Drugs come from?

In USA, the share of biomedical research that is financed by the industry went up from one to two thirds in just 20 years, from 1980 to 2000 (1). Industry propaganda has made people believe that innovative new drugs are invented by the industry, but this is not correct (2). Basic research that leads to breakthroughs is usually publicly funded, and public funding of research was instrumental in the development of 15 of 21 drugs introduced between 1965 and 1992 that were considered to have had the highest impact on society (3). For example, the first drugs against cancer and AIDS were invented by researchers who were publicly funded (2).

Such breakthroughs may be less common in the future when more and more research is financed by an industry whose main research output is "me-too" drugs, i.e. molecular analogues that rarely represent anything of value although they are often very expensive.

## Pervasive Conflicts of Interest

There are many conflicts of interest in health care research, and many researchers have many conflicts of interest. As any journal editor will know, researchers sometimes do not reveal their financial conflicts of interest, and sometimes they describe so many that it is overwhelming. Some researchers argue that since they work for so many companies they are not influenced by any one of them. But that, of course, is not true.

Recently, a randomised trial in patients with multiple sclerosis was published in the *New England Journal of Medicine* (4) by authors with numerous conflicts of interest. For example, the first author listed 22 medical companies. The ubiquitous conflicts of interest are a problem for the credibility of health care research. The *New England Journal of Medicine* has detailed instructions to authors on types of conflicts that should be revealed in articles, and the journal is aware that reviews and editorials are particularly vulnerable to statements that might be influenced by such conflicts. The journal therefore introduced a policy that authors of such articles could not have any financial interest in a company (or its competitor) that makes a product discussed in the article. Unfortunately, this didn't work. The journal later stated:

> In the past two years we have been able to solicit and publish only one Drug Therapy article on a novel form of treatment. Certainly, if we publish nothing on a given subject we run no risk of promulgating a biased opinion, but our silence does not serve our readers (5).

The journal then announced that it expects that authors of such articles will not have any *significant* financial interest in a company (or its competitor) that makes a product discussed in the article.

But what is a significant financial interest? It seems it can be anything. Research has shown that people are inclined to return a favour, whatever its size (6,7). A doctor who gets a pizza from a drug salesperson will be inclined to use his new expensive drug, as this is the only way he can reciprocate the kindness.

## Why the Industry uses much More Money on Marketing than on Research

How can patients and other consumers of health care services get unbiased information about the treatments? No one would buy a washing machine that is 5–10 times as expensive as other machines just because the producer has compared it with the cheaper ones and found that his was the best one. Nonetheless, this is what we allow to happen in health care. There are two main reasons for this absurd behaviour. First, the doctor is not personally accountable for writing prescriptions of expen-

sive medicines, as it will cost him nothing. Second, the intensive marketing by the pharmaceutical industry is extremely effective. In USA, it amounts to between $8,000 and $15,000 per physician, and there is one salesperson per five office-based physicians (8). Furthermore, 12 per cent of a random sample of physicians received financial incentives to participate in clinical trials (8). Many of these trials are not really trials at all, but marketing ploys disguised as science. In some instances, for example, general practitioners are given free samples and a piece of paper on which to record their "experiences". For the effort they receive a monetary reward (9). Such manoeuvres are effective in hooking physicians up onto new, expensive drugs that are no better than their cheap counterparts. In essence, it's bribery.

There are many recent examples of corporate crime and other misdeeds. In one case, Pfizer agreed to pay $430 million to settle criminal and civil charges for paying doctors (please use original text, as it was not Pfizer, but another company that Pfizer later bought that paid these doctors) to prescribe an epilepsy drug, Neurontin, for non-approved ailments (10). This fine may seem large, but is small compared to the returns on the illegal activities. Sales reached $2,700 million in 2003 alone, and more than 90% was for off-label use (11). Imagine what taxpayers would be likely to do in a similar situation. If taxpayers were fined only a small proportion of what they gained from tax fraud, there would be little incentive to fill in tax returns honestly. Crime will continue for as long as crime pays. Although the industry is the prime player here, one should not forget that it takes two to tango. The doctors involved are also to blame, as is the system, which at times seems to protect drugs and sales better than it protects patients.

## Flawed Research

Systematic reviews of industry-sponsored drug trials have showed that the design and data analysis are often flawed, that there is often selective reporting whereby what is published does not reflect what the trial protocol stated should be published, and that the conclusions are often flawed (12–18). A positive conclusion in a prestigious journal can be worth millions of dollars, even when it contradicts the data that are presented in the

main text. It should be noted that selective reporting is also a big problem in academic-led trials (16) making it essential to ensure access to all trial protocols and all data originating from trials, not just what investigators and sponsors care to publish. The patients, without whom we could not do trials, deserve nothing less than this. The increasing incidence of financial conflicts of interest related to trials is a problem because, as stated by Abramson in his book "Overdo$ed America" (19), either a study is designed to maximise sales or it is designed to determine the best way to prevent or treat a particular health problem. As Abramson also notes, we have witnessed during the last 20 years a transformation of medical science from public good, the purpose of which is to improve health, to commodity whose primary function is to maximise financial returns. (the two "a's" that have been deleted, should they not be there? A public good and a commodity)

## An Example in Schizophrenia

An analysis of 2,000 trials in schizophrenia showed than many of them were of limited quality, duration and clinical utility (20). One of the newer drugs, olanzapine (no, it is not a brand name, but a generic name and should not be in capitals), costs 7 times more than haloperidol, an old drug, but in Denmark, sale of olanzapine was nevertheless 54 times that of haloperidol in 2002, although a systematic review in the BMJ concluded that the new drugs had no unequivocal advantages for first line use (21). In many trials financed by drug companies, the dose of haloperidol has been much too high, resulting in many adverse effects and a claim that the new drugs were better tolerated (14). A Swedish trial that was to be run independently of industry with haloperidol at a low dose unfortunately had to be scrapped for lack of funding.

After I had described these issues in *Ugeskrift for Læger* (*Journal of the Danish Medical Association*) (22), I was taken to task by two persons working for (please retain the two persons, as it was not an official report on behalf of the Agency)the Danish Drug Agency who wrote in a correspondence that I got it completely wrong with olanzapine (23). Modern antipsychotics, they contended, were for the treatment of chronic conditions. It worries me when people working for the Drug Agency use the

same kind of empty arguments as the drug industry they are supposed to oversee. The word "modern" means nothing else than one drug being newer than another. According to a big trial sponsored by the National Institute of Mental Health in USA a few months after this dispute, olanzapine was not found to be better than an old cheap drug, perphenazine, in the treatment of schizophrenia (24). Another recent article had the amusing title: "Why olanzapine beats risperidone, risperidone beats quetiapine, and quetiapine beats olanzapine: An exploratory analysis of head-to-head comparison studies of second-generation antipsychotics" (25). Logically, this should not be possible, and is therefore yet another example of misleading conclusions in industry-sponsored trials.

## What should be Changed?

Trials in schizophrenia are not exceptions. Similarly absurd examples abound in all therapeutic areas. We clearly need fair comparisons with old cheap drugs. We also need comparisons with non-drug interventions. It is remarkable that when a trial showed that a drug, metformin, could decrease the incidence of type 2 diabetes by 31 per cent (26), it was the focus of a Wall Street Journal article (27), although the same trial also showed that exercise and a small weight loss could reduce the incidence by 56 per cent. But in a health care system dominated by commercial thinking, who cares? Jogging in the forest cannot be patented.

Not so long ago, academic researchers were key players in the design, patient recruitment and data interpretation in clinical trials, also when they were sponsored by industry. Nowadays researchers have little or no input on anything, including the writing of the manuscript, although they put their names to it (28,29). We looked at 88 industry-initiated trial protocols and found that in more than half of them it was stated that the sponsor owns the data or needs to approve the manuscript (28) (which is almost never written by the researchers anyway); none of this information was contained in the published trial reports. We also found that the sponsor had access to accumulating data – although this should not be allowed – in 16 out of 44 trials, and that an additional 18 protocols stated that the sponsor could stop the trial for any reason.

The tight sponsor control over randomised trials should be changed to ensure research integrity and transparency in reporting should be improved. Trial protocols, researchers' agreements, other relevant documents, and all the data should be publicly available and, last but not least, trials should be a public enterprise for the public good. Industry could provide funds and comments on protocols but should not be otherwise involved. For some years, I have suggested the establishment of a fund in Denmark of about 35 million Euros for independent clinical research and have argued that it could easily more than pay for itself rather than costing the taxpayer anything , as we are wasting so much money on expensive drugs that in reality are no better than cheaper ones. The Danish Medical Association is very positive to the idea, but we have not convinced our current government to establish such a fund. In Italy, a 5 per cent tax on drug advertisements has been introduced and created a rather large fund for independent clinical research (30). We should consider something similar here in the Nordic countries, too. The drug market is not a free market and patients do not decide whether they want to buy prescription drugs or not; they either need them or they do not. The market is heavily subsidised and protected, and the drug industry is the most profitable of all industries (2). Taxing the drug industry is therefore only right and proper.

Buying influential doctors is one of the industry's main marketing strategies, and, unfortunately, most doctors are all too willing to be bought (31). This is depressing, but perhaps the main fault lies with the system. Why have we created a system that stimulates corporate crime, fraud and bribery, all of which have been abundantly documented? (2,9,10,19,32–37). A system that invites immoral behaviour that is profitable for everyone involved, apart that is from the taxpayers and the patients, who sometimes pay with their lives in the tens of thousands (38,39,40), needs a radical overhaul.

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# Bioethics at Novo Nordisk A/S

*Lise Holst*, M.D. Ph.D. Director of Bioethics Bioethics Management
Novo Nordisk A/S

## Why Bioethics?

At Novo Nordisk we define bioethics as "all ethical issues related to the use of life science technologies for the discovery, development and production of pharmaceutical products"[122]. The type of bioethical issues we need to address are mainly confined to the medical, animal and environmental aspects of our work.

Bioethical dilemmas are part and parcel of any attempt to develop new medicines. The testing of new formulas on animals, patients and healthy volunteers throws up bioethical issues that are relatively well known and will always remain a concern. Advances in modern biotechnology have dramatically changed our ability to alter the natural world. Rapid technological progress creates new opportunities but also new ethical dilemmas, and our relationship with other living creatures and the environment is debated in all quarters of society. Two of the recent ones are the use of human embryos for research purposes and the genetic modification of cells and living organisms (GMOs) – and new ones will certainly appear as a result of further scientific breakthroughs.

In 2007 Novo Nordisk used 54,675 animals in research and development out of which 95 per cent was mice and rats. Every year we initiate clinical trials involving thousands of people. We have done explorative research on mouse embryonal stem cells for many years, but recently extended our research capacity to human embryonic stem cells as well. We use human tissue in our laboratories. In the production of modern insulin we employ confined use of GMOs.

We are not isolated from society – and must conduct our business in a responsible way.

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[122] http://www.novonordisk.com/science/bioethics/default.asp

We are accountable to our customers, shareholders, stakeholders, the wider environment and future generations. We believe we have a responsibility to ensure that what do will be of benefit, not only to ourselves in terms of the financial bottom line but to patients and society. To ensure that we act in a morally responsible manner we work on the basis of what we call the "Triple Bottom Line" and our "Bioethics Policy".

## Triple Bottom Line and Bioethics Policy

The Triple Bottom Line was adopted as Novo Nordisk's business principle. It entails a commitment to sustainable development and balanced growth and is built into the corporate governance structures, management tools and individual performance assessments. It ensures that decision-making balances financial growth with corporate responsibility, short-term gains with long-term profitability and shareholder return with stakeholder interests. In the same way as we have financial targets, accounts and external reviews of them, we have social and environmental targets, accounting and reviews. How we perform is published in our annual reports.

The triple bottom line rests on a set of values and policies, including our Bioethics Policy, a visionary guide to our bioethical engagements.

## The Bioethics Policy

At Novo Nordisk we strive continuously improve our bioethical performance.

This means that we

- Promote bioethical awareness throughout the company
- Establish and ensure high ethical standards for
    - Experiments on living animals
    - Clinical trials and use of human material
    - Gene technology
    - Our external partners, contract research organisations and suppliers and monitor their performance

  - Engage in stakeholder dialogue and partnerships, and report on our performance
- Live up to the spirit, values, principles and content of relevant conventions, laws and requirements.

The policy provides the skeleton for all important activities and is a guide to how we should act and perform in relation to external partners, stakeholders and society at large, including regulations and regulatory initiatives.

## Implementing the Bioethics Policy

Novo Nordisk was one of the first pharmaceutical companies to establish a comprehensive bioethics governance system to ensure the companies business activities are ethically sound. A dedicated department, Bioethics Management, and a virtual cross functional bioethical set-up are responsible for the implementation of the Bioethics Policy. The set-up, which employs approximately 60 employees directly involved in dealing with bioethical questions, includes the *Environment & Bioethics and Occupational Health Committee*, the company's highest authority on bioethics, The *R&D Bioethics Board*, an *Ethical Review Committee* that reviews all experiments on living animals performed at or on behalf of Novo Nordisk, and several *Focus Groups* established ad hoc, to address specific issues that need special attention.

The bioethical work, to constantly improve our bioethical performance, includes proactive identification and management of bioethical issues related to drug development. We follow regulatory initiatives and provide input to public hearings and debates. We ensure that R&D lives up to the spirit and values of relevant conventions and regulations by formulating internal policies, positions and guiding principles. We assess and report on our bioethical performance and have both internal and external audits and reviews.

Another important part of our work is to promote greater awareness of bioethics within the company, e.g. by improving information and extending training opportunities.

Externally, we engage with stakeholders through dialogue and partnerships. We have established partnerships with, e.g., animal welfare organisations and universities. We acknowledge that society decides the framework within which we can operate, which means that we take the concerns of the public into account. We learn from the dialogue, and that improves our performance.

Our bioethical efforts tend to result in two main types of outcome: those that can be seen and measured and those that are less tangible, both of which help us ensure that we conduct our business in a way that is acceptable to society, while building and maintaining stakeholders' trust and confidence.

## Animal Ethics

Two of our major achievements are the significant reduction in the number of animals used and the improved welfare of our laboratory animals. In 1999, we started collaborating with the *Danish Animal Welfare Society* with a view to reaching a common understanding of animal welfare and identify areas for improvements. Together with external specialists in animal behaviour we established new standards for housing and living conditions. All animals housed at Novo Nordisk now have more space and a more stimulating environment by taking their natural behaviour into account.

We have developed training programmes for staff and animals to further reduce the animals' distress. The work of the internal Ethical Review Committee is based on the 3R principles: Reduction, Refinement and Replacement of experimental animals. We screen contract research organisations in advance and monitor performance continually to ensure compliance with the highest ethical standards of animal use in research and development[123]. The 3R principles are now embedded in the mindset of all research and development staff and our efforts have resulted in a 70 per cent reduction in of the total number of animals used by Novo Nordisk over the last decade.

[123] Appendix A of the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Cons 123 (2006) 3

## The Company

Novo Nordisk A/S is a pharmaceutical company focusing on diabetes care. The company has the broadest diabetes product portfolio in the industry, including the most advanced products in the area of insulin delivery systems. In addition, Novo Nordisk has a leading position within areas such as haemostasis management, growth hormone therapy and hormone replacement therapy. With headquarters in Denmark, Novo Nordisk employs 22,460 people in 79 countries and markets its products in 179 countries.

# Private Public Partnership and Potential Conflicts of Interest

*Boo Edgar*, Dr Med Sci, MedCoast Scandinavia, Sweden

Biotechnological research in general and biomedical research in particular annually attract billions of dollars in public funding, research grants and private investments. Early biomedicine is an area where the global potential to change the world is huge. So why should the health care system and industry, private and public funding not make the verification of early results possible? In spite of all the scientific breakthroughs, we are still waiting for the large economic successes: indeed, nearly all the funding organisations promote anticipated returns as a major objective for their grants/funding. (1) This increases the pressure on researchers to succeed, especially in academia, but at the same time one should remember that researchers have multiple roles and expectations in today's society. A structured and open process of public funding of precompetitive research is therefore needed, and has been set up both in the US and in Europe.but is in principle not implemented. (1,2) In principle, private-public partnership (PPP) refers to the contractual agreements between a public agency and private sector entity which includes a university that allows for greater private sector participation in the delivery of projects. (1,2)

It is therefore essential to understand the different kinds of partnership and how they can affect the outcome of the research. More important, though, is the question of how one should relate to these partnerships. What are the rules of engagement in these partnerships? Are they partnerships networks for further contacts, fundraising agents, additional support of the university research or research supporters without obligations ? The wide range of possible roles, makes it harder to get a conceptual handle on PPPs. What do they give researchers? What are the drawbacks from the researchers' point of view? What can be owned by the organisation or researcher and what by the partnership? How will the contracts be formulated? Will they constrain academia in terms of publicising work and commercialisation further down the road? The questions for the re-

searcher are plenty, maybe more than the available answers, and there is a need for a detailed contractual relation or the information that the PPP claim no ownership. University managements will need answers to questions of similar importance as those of the researcher. One observation is however obvious. Public and private partners are moving quickly to promote innovation commercialisation and there is mounting pressure on universities in Europe to manage their innovations.

The ownership situation for university researchers in Europe varies. In Sweden and Italy researchers keep their teacher's exemption while the rest of Europe has officially adopted a split ownership model for research results. Of similar importance though is whether these partnerships will affect the research as such, the ethics, the scientific hypothesis tested, and of course how the results are disseminated, published and protected. And an issue that is not so often discussed is how the research organisation will benefit from the research, i.e., channel the generated knowledge into further research and value creation. Finally, some are asking whether the partnership will cramp research, violate academic freedom, (3) and harm in the process possible commercialisation of the ideas.

The discussion on academic freedom set in motion by the association of University Professors 1940 (4), stated that the "Institutions of higher education are conducted for the common good…upon the search for truth and its free exposition". The additional funding and cooperation that could restrict the research would, by the sharing of data and increase of funds, have a beneficial effect on the academic research (3). Partnership funding may have as a consequence greater reticence on the part of other sources of funding, both private and public (tax). This would be another effect of these PPPs.

The Swedish law that governs the universities (5) differentiates surprisingly between freedom of research, the right to choose the issue, the free development of research methods and publication of the research on one side and the extraction of value/utilisation and exploitation on the other (6). The teacher's exemption clause, i.e. the right of teachers at universities to patent and own their innovations, is further debated. The laws and guidelines on research and its exploitation differ within Europe as well as globally.(6) The EU has no plans for harmonisation of the rights of university employees to their innovations, but the Commission did encourage European universities to embrace their research results,

especially those that could lead to innovations (7,8). A recent public inquiry (SoU 2005:95), recommended that Swedish universities should enhance the extraction of value from research within the university.(6) This could include validating, developing, selling and licensing the innovation, commercialising it or putting it to practical use. But it could also include disseminating findings and publishing for a wider readership (6). All forms of utilisation of the intrinsic values are expected to stimulate growth, employment and the common good. They would further underpin research platforms and open knowledge sources. The question remains however how to create the incentives for the researchers involved.(6)

## The Right to Utilisation

What one needs to know it seems is who has the right to utilise the results created by the sponsored research and who is in charge In a global economy where business, in this case bio-business, and society rely increasingly on new research and knowledge development, the more important the university management teams will become. (6 ) The end result will be that academia and business will be working together in partnerships, sharing the management of the supported project. A corollary of this is that the universities will have to govern and manage new knowledge and be accountable for how the results may be disseminated and utilised. (8,10)

What is seen, is the development in part of the knowledge economy, where the traditional research and development systems, based on national or local collaborations, are forced to be more national but also more aligned towards the EU in the competition for more funding, more licensed value, more publications and, in the end, an improved university value. (7, 10) Therefore, the governance of intellectual wealth could be seen as an entrepreneurial agenda in need of a structural transformation of knowledge ownership and management(9) The first step in the preparation for the PPPs is to consider how to claim the intellectual property rights, and how their ownership should be managed within the different partnerships.

In biomedicine the traditional knowledge creation network has to be adjusted to allow for patient information. The graph below illustrates the likely roles in such a revised network

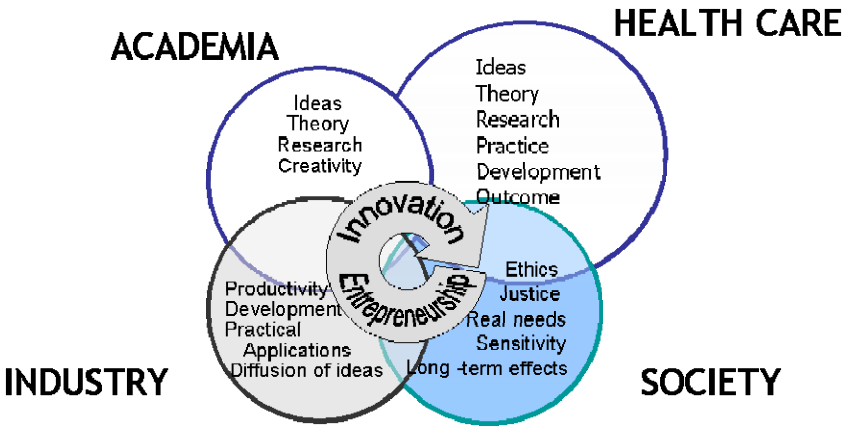


*Figure 1: The biomedical creative network and roles*

These parties have worked together for many years, but with increasing dependencies between industry, academia and the health care sector, where all participants are structured differently, the roles have to be redefined. Without it, the PPPs will be doomed. Private-public partnerships should also seek to claim the outcome of natural science, technical development, processes etc., i.e., to privatize the outcome of the knowledge process.(9) There is a need for improved management, tools and understanding for this in all parts of the partnerships. In the universities there is a need for radical change to integrate all parts of their activity; education, research, verification and utilisation, without which they will be unable to fully benefit from these partnerships.

The value description and vision of the partners are important in building the partnership. A strong commercial partner will of course have a mission as will a venture fund. The questions to answer before applying to or entering the partnership are:

- Is there a potential to adopt the same business ethics/aim
- Could the partnership be based on an agreed platform on how to behave, given the differences?
- Can one adjust for the duration of the grant?

## Different Partnership – Different Demands

The table below is a summary of different private-public partnerships and their potential impact on the right to the utilisation of the research results based on information in the public domain.

A network organisation like MedCoast Scandinavia will support the research projects to do_higher quality research, but will not own any of the research results as such, as the funding is for the networking process and not for the research. But MedCoast and other similar regional networks will increase their knowledge of the process, which will increase their brand value. The same will apply in general terms to Biomedical Development in Western Sweden. The network cannot own the results, but will own the process for supporting different projects within the research areas they support. In one of the areas, however, biomaterial and cell therapy, the results and the knowledge will be owned by the partners and the formed institute.(IBCT=institute for biomaterial and cell therapy)

The larger the research funding the more the funding partners will want to influence the rules for utilisation of the results. The private-public funding organisations are usually not entitled to ownership, but they require rules for commercialisation to be in place before entering the programme and making the funds available.

The PPPs will change the role of the universities throughout Europe, where the management of innovations will be even higher on the agenda than today. The competencies necessary for this have to be shared between the industry, public organisations and universities.

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# Business and Bioethics – the Way Forward

*Salla Lötjönen*[124], Adjunct Professor, University of Helsinki, Finland
Lecturer in Health Care Ethics and Law, University of Manchester, United Kingdom

## The Interests Involved

In the partnership of a private biotechnology enterprise and the academic research organisation, there are more parties involved than just the industry and the academic scientist. It seems that there is a triangle of three main stakeholders: in the two bottom corners there is on the one hand industry with its interest in maximising its financial return and maintaining a viable business, and on the other hand there is the academic research organisation represented by an investigator whose interest lies in maintaining her academic freedom and who is accountable for any publications bearing her name. In the upper corner is the state, monitoring and controlling research and the applications of biotechnology. In the middle of this triangle we have the individual, who is pulled in different directions: his services are wanted by the industry, by academic researchers and by the state.

Often the aim of the state coincides with that of the bioethicist – both strive for the common good, although the state interest is bound to be a mixture of views on what that entails, and hence its goals are much more politically tainted. While the state's interest is manifold, at least two opposing interests can be distinguished: on the one hand, the state is re-

[124] Salla Lötjönen works full-time as the Secretary General for the National Advisory Board on Research Ethics in Finland, although this paper has not been written in that capacity. She does not own stocks or hold managerial positions in biotechnology companies. Her only direct involvement with biotechnology industry is that she serves as a member of an ethics committee for an EU-funded ADIT-project, which is a project that involves mainly academic research centres, but is led by a private company called Siena Biotech (http://www.aditproject.org/). For her involvement, she is remunerated a small fee from the project funding.

quired to take sides with the industry in commercialisation of research results thereby furthering the state economy and possibilities of maintaining research competence and infrastructure. However, it is also the responsibility of the state to protect research subjects against abuse by research projects and maintain the public trust in academic research.

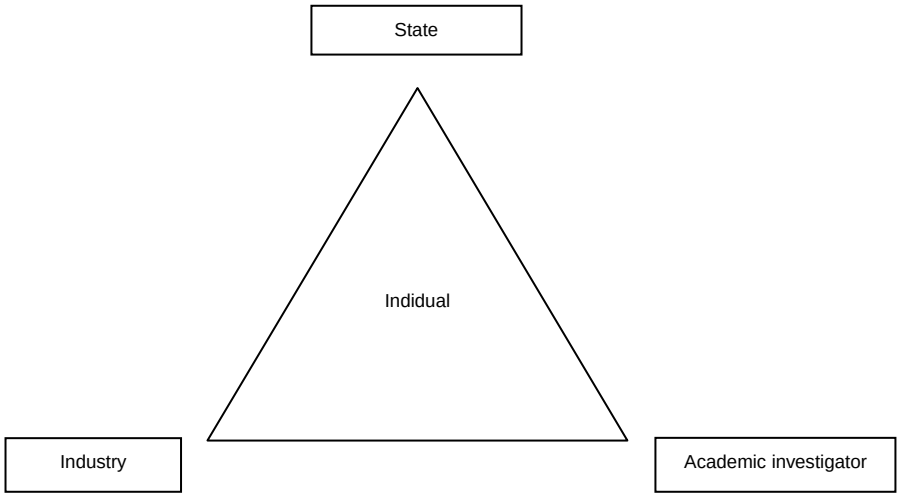


*Figure 1: Stakeholders involved in the partnership between the industry and the academic investigator*

Whenever the discussion turns to the almost inevitable conflicts of interest arising from the relationship between biotechnological industry and academic research, the views of the individual in the middle of the triangle are sometimes forgotten amidst the hectic debate amongst the experts. However, we all represent not only the different interests in this imaginary triangle, but also our views as individuals, as family members and friends. It should not be that hard for each and every one of us to put ourselves in the place of that individual and keep in mind the golden rule that is nowadays often missing in the various research ethics guidelines: whatever we do, we should be able to imagine being done to ourselves or our nearest and dearest.[125] We should not design or approve research

[125] M.H. Pappworth, *Human Guinea Pigs*, Routledge & Kegan Paul, London 1967, p. 189.

projects or products that we would not want ourselves, or our families and friends, to take part in or buy.

## Living with the Interest Conflict

This approach will not, however, make conflicts of interest disappear. We may still have different opinions on how we would like ourselves or other people to be treated. How should conflicts of interest be dealt with then? First of all, we need to declare openly and honestly our own interests, making sure that they are efficiently communicated to the parties of the debate. Many scientific journals now require contributors to declare their interests, and the rest should follow. This should be made an automatic standard rather than an awkward and apologetic procedure. The second step is to make a genuine attempt to understand each other's point of view. This does not mean that we need to achieve or even aim for complete consensus on all issues, which I believe is neither a realistic nor even a desirable goal. We can agree to disagree on some matters and still live with the fact that there are conflicts of interest in this area. However, if we do think there is a useful role for the biotechnology industry – and I think even the most critical voices would agree that there is – we need to find out whether there is a compromise position with which all parties can live. This third step can only been touched upon in this brief article.

## Suggested Compromises

I am grouping my preliminary suggestions for compromises on the management of conflicts of interest into four categories: 1) choice of research topic; 2) method and conduct of research; 3) publication of research results; and 4) research applications and patenting.

### *1. Choice of Research Topic*

The choice of research topic is always bound by external factors as long as external funding is required. This factor is independent of whether the funding comes from the public or private purse, although the extent of

control varies among different funding sources. Sometimes the freedom of research is persuaded to adopt recommendable goals by the dual application of sticks and carrots, as in the case of so-called orphan medicinal products.[126] However, bad or misleading science should not be encouraged, and even less so, if the research project involves animal or human experimentation. The responsibility for ensuring that the study is conducted for justifiable reasons lies primarily with the persons or organisations who initiate the research project, but the responsibility for rooting out e.g. research conducted merely for marketing purposes is shared by the ethics committees and investigators who are approached to take part in these projects. The likely loss of goodwill to the industry – if caught – should also act as an incentive to refrain from engaging in this kind of activity.

### *2. Method and Conduct of Research*

How the research is conducted is another point to consider. Much of the existing regulation at all levels is concentrated in this area. The protection of animals in animal experiments, the protection of humans in clinical trials, and the protection of the environment when handling genetically modified organisms are highly regulated. Some would say that the regulations are too extensive for small biotechnology companies and academic researchers with limited resources for the bureaucracy involved.[127] The regulation of method and conduct of research not only involves the effects of research. It affects the integrity of the science and requires the research to be conducted according to the validated methodologies of scientific inquiry. Both the rules governing the effects of research, not least on research subjects, and scientific integrity, must of course be adhered to with vigilance, with no leeway attached to the source of funding, i.e. public or private.

[126] Regulation (EC) No 141/2000 adopted on 16 December 1999 (OJ No L 19, 22.1.2000) on orphan medicinal products and Regulation (EC) No 1901/2006 adopted on 12 December 2006 (OJ No L 378, 27.12.2006) on medicinal products for paediatric use.

[127] A Hemminki and P Kellokumpu-Lehtinen, 'Harmful impact of EU clinical trials directive', *BMJ* 2006;332:501–2.

*3. Publication of Research*

Many publications mentioned in the article by Peter C. Gøtzsche earlier in this volume, deal with conflicts of interest in the publication of research. I tend to agree with those that say that only the ignorant are entirely interest free. To some extent, objective scientific publishing requires us to refrain from obvious and intimate connections with the industry, such as when our income is directly dependent on how the product does in the market. However, if conflicts of interest are openly declared in connection with the publication, can we not leave it to the readers to make their own judgement on how much value they are prepared to give to it? On the other hand, if the author has any qualms with being honest about declaring her affiliations and connections, one might also wonder whether she should be writing that article as a scientific article at all.

The nature of the publication – if it is presented as an objective scientific article rather than a commercial advertisement – is also the reason why the industry should not tamper with its substance when perusing the report prior to publication. Delaying the publication in order to protect a commercial interest – such as securing the patent for an innovation before releasing the science – would seem to be a reasonable compromise in this area. If the results are negative or neutral, they should still be published to avoid repeating the same exercise and wasting time and resources of both the public and private sector, in addition to causing harm to any research participants or experimental animals.

The problem remains what to do if the scientific journals do not accept articles whose findings are negative or neutral for publication. Scientific journals are also commercial businesses that need to think of their readers and what appeals to them. A partial solution to this problem could be to promote Internet publishing, where the printing costs can be brought down, and the cost of editing the article and managing the site could be covered by the authors themselves. An alternative or parallel solution is to expand capacity of the publicly maintained registries of clinical trials. At present, the only European-wide registry of clinical trials is only accessible to the authorities on medicinal products, which is of little help to either the industry or the academic researcher, both of whom may be wasting resources and creating unnecessary risks for research subjects by duplicating efforts when trying to find their niche in this highly competitive area.

*4. Applications and Patenting*

Research applications and patenting issues are the last item to be addressed in terms of potential compromises. This is connected to the area that concerns the industry the most – after all, the investment in research is pointless to the commercially motivated industry, if the fruits of the exercise cannot be harvested and sold on. One way of commercialising the results of research is by patenting new products and farming out through licensing agreements. It has been suggested that the universities or the public sector should include social clauses in licensing agreements, to make the products freely available or at a lower price to certain groups or causes. By not doing so, the universities carry a direct social responsibility for the outcome. Another issue is whether the licensing companies would eventually agree to this kind of contract, as broad social clauses would limit their markets and thereby reduce the profit margins of the marketed product.

## Conclusion

Overall, most people agree on the fact that the present system of public and private partnerships in the area of biotechnology is not functioning in an optimal way. This is an important message to the developers of national research and development policies. The Nordic countries have already made a considerable commitment to public-private partnerships and collaborative ventures, but obviously more work is required. The discussion should continue from here with the aim of developing practical problem-solving mechanisms of use in conflicts of interest and to improve co-operation between the private and the public sector.