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Summary

Legitimate Strategies of Dissent Management. A Comparison of Law-Making in the Field of Biomedicine in Japan and Great Britain

The main problem of ethical decision-making in modern pluralistic societies is that consensus is hard to establish. Most of the relevant questions in the field of biomedicine, such as stem cell research, embryology, euthanasia and transplantation medicine, are highly controversial. At the same time, legal certainty often requires legislative action. Thus, the legislator appears obliged to act, but there are neither generally accepted moral rules that can be relied upon, nor can all-encompassing consensus be reached.

This thesis deals with the question how, in the field of biomedicine, dissent can be coped with when legislation appears to be necessary. It investigates which – presumably new – procedures have been or are being established in Great Britain and Japan in order to deal with this problem. As a result of the comparison of different ways of coping with dissent the thesis tries to develop a new strategy of dissent management that is democratically legitimate.

Part 1 of the thesis sets out the theoretical background. It outlines the notions of "dissent" and "democratic legitimacy", the latter both in particular form for the two countries to be compared and in a conceptional way for the overarching analysis. It also shows that and why dissent poses a dilemma to the legislator of pluralistic democracies (I.).

Part 2 is dedicated to the comparison of biomedical legislation in Japan and Great Britain (II.). The method used is to line out higher-level criteria suited for comparison. These criteria, called "legislative strategies" are methodized as substantial and procedural strategies. Substantial strategies concern the present legal situation in the two countries and the particularities of the existing biolaw (1.). In contrast, procedural strategies focus on the method of legislating. This section on procedural strategies evaluates specific procedures applied in the legislative process or specifically created by the norms that concern biomedicine (2.).

Finally, part 3 deals with strategies of dissent management that neither Japan nor Britain has applied so far in order to find out whether any important method of dealing with dissent is still missing (III.). These additional strategies include the formation of a national ethics committee, the inclusion of elements of direct democracy in biomedical legislation and the enactment of a comprehensive law on biomedicine. Part 3 also briefly deals with existing theoretical strategies of dissent management. The thesis closes by depicting its own strategy of dissent management derived from the results of the research.

A. Theoretical background

I. Dissent

The notion of dissent as understood in this thesis describes a persistent intersubjective disagreement. As a starting point, it includes all sorts of disagreement, even mere conflicts of interests. However, coming to the question of how to cope with a diagnosed dissent, several types of disagreement have to be distinguished in order to identify a suitable strategy.

For the purpose of this thesis, nine types of dissent are to be discerned. Relating to the source of dissent, there are conceptual dissents as well as dissents regarding specific issues. The latter are subdivided in the categories of conflict of interests, empirical and normative dissent. Further differentiations are necessary between solvable versus unsolvable dissent as well as between open versus concealed dissent or pseudo-consent.

While disagreement as such is a phenomenon of pluralistic societies and should not *per se* be judged as negative, it can also harbor a dilemma, the dissent-dilemma. This dilemma originates in the fact that biomedical issues often touch upon ethical questions that lie at the core of the common concept of man that is essential to any given community. Thus, on the one hand, legislation appears to be necessary in order to keep the state together as a unity. It is also a demand of legal certainty that certain biomedical questions are legislated upon so that there are equal legal standards within one state. In addition, the state has to observe certain duties to protect its citizens from harms that might be induced by the unregulated application of biomedical techniques. On the other hand, pluralistic democracies are committed to neutrality in religious matters and should only constrain the liberties of their citizens if

justified by important reasons. The dissent-dilemma thus lies in the conflict between legal certainty, the unity of the nation and duties to protect the citizens from harm on the one hand and the principles of neutrality, liberty of the individual and the ideal of promoting an open, pluralistic society.

II. Democratic legitimacy

In order to apply an effective strategy of dissent management in a democracy this strategy also needs to be democratically legitimate. Accordingly, the various strategies outlined in the thesis are also evaluated with the criterion of legitimacy. Three different concepts of legitimacy are put forward, one each for the two countries examined, which naturally need to be empirical concepts, and one normative concept for being able to evaluate the results of the comparison on an abstract and universal level.

The empirical concepts are deduced by applying the concept of David Beetham (The Legitimation of Power, 1991). Beetham distinguishes three preconditions for an act of state to be legitimate: the legality of the act, its justification by the shared values embodied in the legal system of the state and an act of approval expressed by the citizens in elections and ballots.

The Japanese concept of democracy is characterized by far-reaching restraint of the Parliament resulting in the dominance of norm-setting by ministerial guidelines. Accordingly, the civil servants producing these guidelines have a lot of impact on the legal system as important regulative decisions are often delegated to them. These expertocratic structures have only recently been antagonized by reforms such as the enactment of an Information Disclosure Act and the introduction of the Public Comment Procedure into administrative law. However, the Japanese concept of democratic legitimacy remains focused on output-legitimacy.

The British democracy has only recently undergone major reforms, changing from a mainly political to a legal constitution. The concept of democracy is based on two criteria: political equality through elections as an element of input-legitimacy, and accountability of the elected as element of output-legitimacy. In addition, procedures of participation and responsiveness have recently been added, though not on a legally binding basis. These increase the focus on output-legitimacy that characterizes the British concept which focuses on control by the unelected

House of Lords and the public and on the expertise assembled in numerous *Quangos* (quasi-autonomous non-governmental organizations) that are designed to be effective and independent.

Requirements for the normative concept of democratic legitimacy include democratic decision-making in a predetermined procedure, as a legislative process following fixed rules is attributed acceptability irrespective of its contents. In addition, the concept requires a functioning representative system providing self-determination, equality and accountability. It distinguishes between co-determination by citizens in the decision-making process (input-legitimacy) and mechanisms of controlling the legislator (output-legitimacy). Each strategy of dissent-management is examined for the respective amount of input- and output-legitimacy. Depending on the relevance of the law in question for the rights of the individual, a certain level of overall legitimacy has to be obtained.

B. Comparison of existing strategies of dissent management in Japan and Britain

Both in Japan and Britain exists a normative dissent over biomedical issues such as the status of the embryo, reproductive medicine and, especially in Japan, the criterion of brain death in relation to organ donation. However, the dissent is widely discussed in British media, while there is little coverage of bioethical issues in the Japanese media. In fact, most Japanese, being aware of the ethical dilemmas, still tend to think of biomedical issues as rather technical problems that should be regulated by ministerial expert-committees.

I. Substantial strategies

As substantial strategies of dissent-management, the thesis distinguishes between those relating to the level of regulation, those concerning the density of regulation, those regarding the point in time of regulation and, finally, those regarding the contents of regulation.

1. Level of regulation

As for the level of regulation, strategies range from regulation by comprehensive acts of parliament, acts of parliament that delegate legislative

powers to other subjects, regulation by non-parliamentary norms and by soft law.

While neither Japan nor Britain has any constitutional regulation of biomedical issues, both have regulated these questions by comprehensive acts as well as by acts that delegate legislative powers. The Japanese Motherhood Protection Act (botai hogo hô) of 1996, regulating abortion and sterilization, the Japanese Organ Transplant Act of 1997, reformed 2009 (Zôki no ishoku ni kansuru hôritsu), the British Abortion Act 1967 and the Surrogacy Arrangements Act 1985 belong to the former category. All these laws originate from a relatively early period of biomedical legislation. The strategy of comprehensive legislation has not been applied by the two countries lately. Only the Japanese Motherhood Protection Act has achieved a settlement of the situation and ended controversies on the issue of abortion. In contrast, organ transplantation in Japan and surrogacy in Britain remain highly controversial. Accordingly, the strategy of comprehensive acts does not function as a means of effective dissent management.

Japan has one act delegating legislative powers: the "Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques" (Hito ni kansuru kurôn gijutsu tô no kisei ni kansuru hôritsu) of 2001 (Cloning Act). In Britain there exist the Human Fertilization and Embryology Act (HFE Act) of 1990, reformed in 2008, and the Human Tissue Act (HT Act) of 2004. Sanctioning reproductive cloning, the Japanese Cloning Act only regulates a small and uncontroversial field of the cloning issue while regulation of therapeutic cloning is being delegated to the ministry of science. The techniques of artificial reproduction and stem cell research are not mentioned at all in the act. The act has been criticized as overly technical and complicated and has not achieved any dissent management. The British acts comprehensively regulate their respective subject by fixing the general rules of application of certain procedures and by establishing regulatory authorities that ought to regulate the details and watch over the respective biomedical issues in their area of responsibility. These legislative efforts have been publicly discussed in the legislative process and are being regarded as effective means of dissent management. The respective delegated legislation are the cloning guideline (tokuteihai no toriatsukai ni kansuru shishin) of the Japanese ministry of science of 2001 and various British regulations further outlining the regulatory responsibilities of the agencies created by the HFE Act and the HT Act. The Japanese guideline can be changed quickly and flexibly and has already been adapted to technological advancement in 2009 without any involvement

of parliament or the public. Some of the British regulations have been issued as envisaged by the acts in order to specify the general provisions of the acts. This method is a democratically legitimate means of dissent management. On the contrary, adjusting legislation to technological advances by mere regulation without involvement of parliament lacks legitimacy as new ethical issues could be regulated upon by ministries avoiding public notice or necessary discussion.

Soft Law is an important tool of regulating bioethical issues in Japan. There are three ministerial guidelines covering stem cell research, genome research and gene therapy. In Britain, the regulatory agencies regularly issue codes of practice that specify the modalities for obtaining licenses in the fields of artificial reproduction, embryology and transplantation medicine. Accordingly, while in Britain soft law is used to further specify statutory provisions, some biomedical issues in Japan are solely covered by soft law. This Japanese strategy lacks democratic legitimacy and evades rather than copes with existing dissents.

2. Density of regulation

As for the density of regulation, there are the strategies of all-encompassing regulation, of selective regulation and of deliberate regulatory gap. Compared to Japan, Britain has the higher density of regulation. Parliament is outlining the framework that is further developed by the agencies specializing in the respective issues. Regulatory gaps only happen when technological development outruns legislative efforts. Such gaps are mostly compensated for by selective legislation but, as the reform of the HFE Act has shown, a complete revision appears to be necessary in the long run. Surprisingly, the British courts do not play an important role in biomedical rule-making. This might be explained by the unforeseen issues raised in the field of biomedicine, where the application of existing legislative standards and case law is difficult.

In Japan, the strategy of deliberate regulatory gaps appears to be dominant. The gaps are normally filled by guidelines of professional associations that do not have the degree of compulsion necessary to achieve compliance.. All-encompassing regulation has only been obtained in a few areas of importance to researchers such as genome research and gene therapy, while practical issues such as reproductive medicine are not regarded to be in need of regulation at all. The resulting legal uncertainty and lack of democratic legitimacy are grave obstacles to successful dissent management.

It is obvious that the strategy of all-encompassing regulation is better suited for coping with dissent and has higher democratic legitimacy. Only the comprehensive debate of biomedical issues in their respective context can lead to general awareness and discussion of the underlying ethical dilemmas being a precondition for effective dissent management. All-encompassing regulation generally has a higher level of output-legitimacy than selective or missing regulation.

3. Point in time of regulation

Strategies regarding the time of regulation are the quick legislative reaction to arising legislative needs, the late or lacking reaction to this and the strategy of preliminary legislation that has to be revised at a certain point in time. The strategy of quick reaction can be further classified into preventive and reactive regulation. Reactive action means that legislation takes place as a reaction to scandals or controversies. Preventive action in contrast avoids controversies by legislating before an issue is widely conceived as problematic by the public. When applying the strategy of preliminary regulation, the legislator is putting a time limit to the norms so that they will be revised on a regular basis, taking into account the development of new research methods and changes in the public debate.

As for the quick legislative strategy, opposed approaches can be observed in the two countries. While Britain is often reacting to scandals by legislating in a case-related way, as can be seen in the Surrogacy Arrangements Act and the Human Tissue Act, Japan tends to legislate in a preventive way before the issue is being discussed in the public as can be observed with all existing guidelines as well as with the legislation on cloning. Problems with the British approach include the sometimes too quick action that leads to premature and badly thought-out solutions, while the Japanese approach, pretending that agreement has been sought and found, prevents even the start of discussions that could eventually lead to effective dissent management. As for democratic legitimacy, the British approach lacks output-legitimacy regarding the quality of regulation but this is compensated for by a great amount of input-legislation as parliament in these cases acts in order to obey the will of the people. The Japanese strategy has little legitimacy as parliament and the public are left out in the legislation process. However, as this is a situation caused by the passivity of the Japanese parliament itself, the approach is not in effect violating the principles of democratic legitimacy.

The strategy of preliminary legislation has so far only been practiced in Japan where most regulatory instruments include a clause on the preliminary nature of their content, sometimes even a concrete date of envisaged revision. However, these clauses have mostly had only symbolic character as revisions have mainly taken place on the soft law level, seldom on the parliamentary level. Regarding the fast changing nature of biomedical issues it seems nonetheless advisable to include revision clauses in biomedical legislation more often to provide sustainable dissent management.

4. Contents of regulation

Strategies relating to the contents of regulation include the strategy of minimum consensus, of compromise, of extreme position and of pragmatic solutions in avoidance of value-driven debate. In both countries, legislation often leads to compromises while minimum consensus seldom is the outcome. An extreme position in terms of "anything is allowed" can only be found in the areas that lack regulation in Japan. Both countries show a corresponding relation between legislation of compromises and a pragmatic approach to biomedical issues. The almost complete lack of value-oriented arguments in both countries promotes pragmatic solutions that fix a compromise between opposing positions. Only if strong principle-based opposition is missing in the final stages of legislation can such compromises be achieved. While such opposition was expressed in Britain during the revision of the HFE Act, it declined during the reform process. In contrast, Japan has never had a debate on biomedical issues in which opinions could change and majorities shift. Accordingly, the compromises are mostly worked out by expert committees, rather than being the result of a political debate. Accordingly, despite existing parallels of both countries regarding the contents of biomedical regulation, the regulations are the result of successful dissent management in Britain but not in Japan.

II. Procedural Strategies

Procedural strategies are classified in parliamentary involvement in dissent management and the involvement of expert committees in the process. The latter category further differentiates between committees in the legislative and the executive process. Finally, public participation strategies in the biomedical legislation process are also evaluated.

1. Role of Parliament

The Japanese parliament hardly plays a role at all in biomedical regulation. With the exception of the Organ Transplant Act, all biomedical legislation has been passed by parliament following only brief debates. In addition, parliament shows a hands-off approach in ethically controversial matters and almost entirely leaves regulation to ministerial expert committees. The British parliament, on the contrary, plays a major role in biomedical legislation. It influences the early drafting process of a bill by pre-legislative scrutiny measures of its committees, namely the House of Commons Select Committee on Science and Technology. In the final stages of voting on the bill there are long and controversial debates on the major issues. As the government is obliged to answer to the reports of the select committees within weeks, the dialogue between legislative and executive organs is provided for already in the early stages of a bill.

Thus, the Japanese strategy of dissent management includes an avoidance of parliamentary debates on ethical issues while Britain follows a strategy of early on dialogue between the organs of legislation. In Japan, this leads to a downgrading of biomedical debate to the level of ministerial committees while in Britain Parliament is heavily involved through various committees.

2. Expert committees in the legislative process

Strategies of external consultation in the legislative process depict the establishment of expert-committees designated to deliberate on fundamental biomedical issues. Further differentiation is made between ad-hoc committees that are established in order to prepare a specific legislative act and permanent committees observing and reporting on biomedical issues on a long-term-basis.

In the first phase of biomedical legislation, ad hoc-committees have played a major role in both countries. In Britain, the Warnock Committee had great influence in the drafting of the HFE Act, and the Donaldson Committee reported on research purposes for therapeutic cloning, thus influencing regulations that came into force in 2001. In Japan, three ad-hoc subcommittees to the Expert Panel on Bioethics reported on cloning, embryo research and genomic research respectively and recommendations were also transferred to the legislation following the reports. The reports mentioned have had immense influence on biomedical legislation lasting to the present.

The experts elected to the ad-hoc committees were mainly scientists with medical or biological background working in the area of biomedicine as well as lawyers and, but only in Britain and in a small number, philosophers and theologians. This professional composition of committee members may well have influenced their recommendations that have in all cases been rather pragmatic and practical while ethical reflections have mostly been of lesser significance. In both countries, independent specialists were appointed to deal with ethically problematic issues in an all-encompassing manner in order to prepare legislative measures. Obviously the experts, rather than a parliamentarian committee, were expected to find a regulative solution. This method enabled them to make recommendations that were acceptable to all political parties. The reports, while making clear recommendations as to the contents of possible regulation, were not irrevocable but served as a basis for the parliamentarian deliberations. As such they definitely made a great contribution to dissent management and augmented the quality of the resulting legislation. As for democratic legitimacy, this method is not problematic as long as the recommendations of the reports are not automatically included in the legislation. This works for the British approach but has negative impact on Japanese biolaw as many of the reports were not debated in parliament but implemented in the respective ministerial guidelines.

Following the first ad-hoc committees and their successful work, both countries have introduced permanent committees to deal with biomedical issues. In Japan, a standard procedure of appointing expert committees for various subjects within the ministries has been established. They are to review existing and design new guidelines in the same way as the already mentioned ad-hoc committees have. This procedure works in an efficient and well-coordinated way, but the Japanese people remains widely uninformed as public relations are only a subordinate duty of the committees. In essence, the procedure has led to "legislation by experts", as the involvement of the minister in the process tends to be a mere formality. Dissent management thus takes place by expert consensus without any influence by parliament or the Japanese people. The superordinate "Expert Panel on Bioethics", composed of both experts and politicians, that is expected to coordinate bioethics policy in Japan does not have any recognizable effect on dissent management. Despite its regular open meetings it does not function as a coordinator between politics, the public and science and its relevance for Japanese biolaw remains unclear.

In Britain, the Human Genetics Commission is in charge of public relations in its field of operation while the function of an advisory commission to the ministry of health is a minor part of its duties. It is an entirely deliberative committee that has only indirect influence on legislation. Due to its interdisciplinary, pluralistic composition and transparency it serves well as an agent of communication between the legislator and the public and has a positive impact on dissent management.

The Nuffield Council on Bioethics also is a mere deliberative council but deals with all sorts of bioethical issues. Its main characteristic is its complete independence of the state which is a historical peculiarity. However, this does not affect its role and influence as "ethics committee of Great Britain" and its great impact on dissent management as it increases the citizens' awareness of bioethical issues.

3. Regulation in the executive process

A potent strategy of dissent management is the delegation of regulative power and decision-making to regulatory authorities such as the British Human Fertilization and Embryology Authority (HFEA) and the Human Tissue Authority (HTA). This strategy allows for quick reaction to technological changes. It maintains legal certainty without abandoning the legislative supremacy of parliament. It can also enhance transparency and lead to higher public attention to the respective field of regulation if a high level of transparency of these bodies and a duty to keep the public informed and involved in their daily business is warranted. Another important requirement is the accountability to Parliament which nonetheless should not infringe upon the agencies' general independence. As for the range of delegated powers, it has to be ensured that Parliament keeps deciding on fundamental issues and the authorities only deal with day-to-day business such as licensing procedures. This was problematic in the applications to allow research on hybrid-embryos that were submitted to the HFEA in 2006, before Parliament had decided on the general acceptability of this research practice. This shows that Parliament has to keep up with new developments of biomedical technologies in order to guard its supremacy over the authorities. The pluralistic and transparent composition of the authorities that includes non-scientific members from other fields of expertise warrants that licensing decisions are not uncritically made in favor of technological advancement. So far, the HFEA and HTA have achieved the respect and acceptance of the British public and have contributed greatly to dissent management in the field of biomedicine.

4. Participation

Measures of public participations have gained importance in biomedical legislation in both countries. In Japan, the public comments procedure has been introduced to all administrative procedures in 2005 and in Britain numerous consultations on biomedical issues have been carried out recently. In Britain, deliberative procedures such as citizens' juries and focus groups are also occasionally conducted. These procedures can contribute to dissent management as they create a forum for citizens to publicly express their opinion. However consultative procedures in most cases only lead to a disclosure of existing dissent as communication usually works just one-way. It depends mainly on the body conducting the procedure whether feedback on the comments is given and whether this eventually leads to coping with a diagnosed dissent. In Britain, despite the existing Code of Practice on Consultation, comments received from the public are often left without reaction. In Japan, government agencies are obliged to answer all comments received. However, the number of public comments received by Japanese authorities remains too small to really count as significant interaction with the public. Accordingly, the capacity of existing participation procedures for dissent management appears limited.

One specific means of participation that is applied in the British Human Genetics Commission is a promising device. The so called consultative panel, composed of persons affected by the technology in question, achieves a continuing involvement of affected people in the deliberative process and thus provides for a possible influence on legislation by relevant input as well as for constant exchange between members of the public and the government.

C. Other suggestions and draft of a strategy of dissent management

I. Other suggestions of the practice and literature

Another method to cope with dissent that neither Britain nor Japan applies is a national ethics committee. National ethics committees as they exist for example in Germany are state-run, independent advisory bodies with members from pluralistic professional fields that issue reports on general biomedical issues regarding their ethical implications. Further tasks include the identification of legislative need for action and the stimulation of public debate on bioethical questions. Acting as forums of discourse they connect political decision-making to collective delib-

eration on ethical questions and thus integrate politics with the public. They achieve objectification and rationalization of the deliberation on ethical issues and thus account for dissent management within society and parliament. Their reports do not replace parliamentary decision-making but rather increase its objectivity which makes them a democratically legitimate means of dissent management.

In Switzerland, citizens have already directly influenced legislative acts on biomedical issues several times by means of direct democracy, precisely by facultative referendum. As an example, the law on stem cell research of 2003 has been approved by referendum in 2004. The eventuality of a referendum on any law passed by parliament forces the legislator to include minority opinions in the process of legislation at an early stage, as acts passed by narrow majority tend to be challenged in a referendum later on. In addition, putting a referendum boosts public deliberation on the matter in question which contributes to opinion-formation among the citizens. That is why elements of direct democracy are a potent and democratically legitimate means of dissent management. However, their establishment appears too complex and demanding a task to be transferred to other countries that do not yet have a functioning structure of direct democratic elements.

Enacting a comprehensive law on biomedicine appears to be an effective means of dissent management in those countries that do not yet have detailed regulations on all relevant biomedical issues. For instance, in France a legislative process of 10 years has lead to the enactment of three interrelated laws on bioethics ("lois de bioéthique") in 1994. These laws regulate all major fields of biomedicine and state fundamental principles of bioethics. Since a revision in 2004 they also contain the modalities of the French national bioethics committee. This makes biolaw in France well-structured and easy to comprehend. The enactment of one comprehensive biolaw adds to the stringency and consistency of the legislative outcome as all important issues have to be discussed connectedly and common principles need to be determined. Unintentional regulatory gaps are avoided and the law-making process should automatically provoke a nation-wide debate on biomedical issues. All these factors contribute to effective dissent management.

There are three proposals on dissent management to be found in the literature. These include the report by Francis Fukuyama and Franco Furger "Beyond Bioethics: A Proposal for Modernizing the Regulation of Human Biotechnologies" (2006), the essay "Legislation on Ethical Issues: Towards an Interactive Paradigm" by Wibren van der Burg and Frans Brom (2000) and the ideas of Roger Brownsword on "Rights,

Regulation and the Technological Revolution" (2008). While all these works depict innovative approaches towards regulation on biomedical issues, none provides for input on the topic of this thesis that could alter its results leading to the strategy of dissent management outlined in the following section.

II. Draft of a strategy of dissent management

The thesis closes with a draft model of ideal dissent management and suggestions for improvement in the two countries studied before. The ideal model of legislation in the field of biomedicine that copes with existing dissent from the start includes the following elements: (1) A national ethics committee as well as a parliamentarian committee on science and ethics are established in order to consider and balance all relevant input and ethical arguments in the law-making process. (2) Comprehensive laws with a revision clause are enacted that provide guidelines for the formation of (3) pluralistic, transparent regulatory agencies which further develop the legal framework in their daily business of licensing etc. (4) The national ethics committee and the regulatory agencies employ various measures of public participation in order to stay connected with public opinion.

The concrete suggestions for the countries examined are the following: Great Britain should establish a Parliamentarian ethics committee in order to provide for better balance of ethical and science-based arguments in biomedical decision-making. In addition, all major acts on biomedical issues should have a revision clause that provides for regular updates within periods of five years. This would warrant that the acts did not loose effectiveness by being outdated by new developments in biomedical technology. Finally, the Code of Practice on Consultation that already exists should be made legally binding in order to strengthen the positive effects of public participation measures on dissent management and legitimacy.

In the case of Japan, the establishment of a national ethics committee is considered an absolute necessity in order to set the preconditions for the public debate on bioethics that has not taken place until now. This debate would be an important requirement for the enactment of a comprehensive law on bioethics, being another suggestion of this thesis. In the drafting procedure of this law a permanent parliamentary ethics committee could serve to intensify the bioethical debate in Parliament as well as in society. The revision clause already contained in some biomedical regulations would then probably cease to be of merely sym-

bolic meaning by mobilizing the Japanese Parliament towards regular revision procedures. The existing Expert Panel on Bioethics should be abolished as it does not have any noticeable relevance for either dissent management or legitimacy. The expert committees established by the ministries should be given a legal foundation that also stipulates their pluralistic composition. Finally, the new regulation of reproductive medicine should lead to the establishment of regulatory agencies.