

# Chapter 2

## ‘Big Picture’ Manifesto: Democratic Policymaking in Contested Domains

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### Introduction

Consider the following policy questions that have recently been debated in a number of democratically-governed countries around the world:

- Should human embryos be used for research purposes?
- Should access be restricted (or denied) to the ‘morning after’ pill or abortifacients?
- Should genetic modified organisms (GMOs) be grown as food crops?
- How should we decide when nanotechnology products are safe enough to be sold to consumers?

In different countries, and among jurisdictions within these countries, different answers have been generated to the same questions: some of these answers are codified in actual law and others emerge as more informal practices, often in the absence of specific regulations or direct state involvement. In addition, the policy mechanisms for addressing the questions, and more generally for the governance of controversial ethical issues, vary considerably, as do the processes for involving the public in policymaking.

With regard to embryo research, for example, the United Kingdom has a comprehensive and well-established regulatory framework which allows embryonic stem cell research, subject to the granting of a licence from the Human Fertilisation and

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Embryology Authority. Sweden and Spain also have detailed and comprehensive legislation with regard to embryo research. Canada has law restricting use of human embryos in public and private research organisations (the *Assisted Human Reproduction Act* 2004), as well as regularly updated guidelines applying to all research involving human embryos that is funded by the three national research funding bodies or is conducted in institutions receiving funding from those research funding bodies (see <http://www.cihr-irsc.gc.ca/e/42071.html>; Baylis and Herder, this volume, Chap. 6). In some EU countries, such as Austria, Italy, and Germany, research on embryos (including the derivation of embryonic stem cell lines) is banned, although some allow research with imported stem cell lines under specific circumstances; a few others, notably Ireland, have no specific regulations concerning embryonic stem cell research (see <http://www.eurostemcell.org/stem-cell-regulations> for more details). The United States has a complex federal situation, which originally hinged on restriction of federal research funds rather than an outright regulatory ban: prior to an executive order by President Barack Obama in 2009 which overturned previous legislation, federal funding was limited to non-embryonic stem cell research and embryonic stem cell research based upon embryonic stem cell lines which had been in existence prior to August 9, 2001. Some US states have laws that specifically ban (e.g. South Dakota, Ohio) or permit (e.g. New Jersey, California) embryonic stem cell research, while others do not have any specific legislation (National Conference of State Legislatures 2008). Australia has relatively detailed legislation governing embryonic stem cell research which has been modified over time and which emerged out of an extended policymaking process (see Skene et al. 2008; Dodds and Ankeny, this volume, Chap. 7), as does Canada (see Baylis and Herder, this volume, Chap. 6).

Ireland has prohibited access to all forms of abortion including abortifacients, which has resulted in women seeking these drugs outside of the county. Most other EU jurisdictions permit abortion including use of abortifacients although there is a wide variation in the restrictions under which use is permitted. After initial regulatory moves in Australia to ban the import of a particular abortifacient under import/export laws, emergency contraception is now available over the counter there, as well as to non-minors in the United States (Quedding et al 2011; Thompson et al 2013).

On GMOs, the United States has a very liberal approach compared to the EU, where GMOs are largely prohibited and the regulatory system is based on the process underlying the products rather than on the end products alone, as is the case in the United States and in the World Trade Organization regulations. The EU relies on a case-by-case analysis of risk, together with use of the precautionary principle. Australia has a mixed approach, with some individual states such as South Australia and Tasmania retaining moratoria on growth of GMO crops on the local level at the same time as various crops are being considered for licensure at the Commonwealth level, although its federal laws and regulations depend largely on a product-based approach through Food Standards Australia and New Zealand. Canada is one of the largest producers of GMO crops (corn, soy, canola, and sugar beets) with Health Canada holding responsibility for evaluating the safety of 'novel foods' including GM foods (Health Canada 2012). Despite these differences in approach to GMOs, the different jurisdictions share an underlying set of assumptions that the only valid

considerations for risk assessment should be scientific and related to potential harms to the environment or to human health, and not any wider economic or sociocultural criteria. Hence, despite differences in policy outcomes in this domain, this shared set of assumptions left little room for public participation in debates over GM policy, except until a new EU directive in 2001 included a requirement for public consultation (see Torgersen et al. 2002; Gottweis 2008).

Nanomaterials have been present in sunscreens for the last 8–10 years, with some questions about whether more rigorous testing is needed. In Europe, there has been an emphasis on the need for specialized testing, whereas in the United States, the products are not viewed as requiring any oversight beyond the usual consumer protection measures. In Australia, there has been debate about whether there should be special restrictions on the use of nanoparticles in sunscreens, depending in part on whether these products are viewed as therapeutic or cosmetic goods, with some attempts at public engagement about these issues (Petersen and Bowman 2012). The Australian government commissioned a review of the regulatory impact of nanotechnologies which indicated that the current regulatory systems were presumptively adequate to address known issues (health and environmental risks) associated with nanotechnologies and also identified a number of triggers for addressing regulatory gaps that could emerge in the further development of the technology (Ludlow et al 2007).

In the face of such diversity, what tools can bioethics bring to the evaluation and critique of these types of policy responses? Traditionally, the field of bioethics has approached policy questions and policy evaluation from within a particular ethical framework or theory derived from philosophical and political theory. For example, policy proposals can be assessed using an application of utilitarianism (or some other form of consequentialism), which will require determining the consequences of the policy for all those who are (or may be) affected by it. Alternatively an approach that centres on respect for personhood could be taken by considering the ways in which the policy options demonstrate respect for persons, promote personal autonomy, or protect individuals' rights (or undermine these values). A virtue ethic approach would seek to establish the meaning and significance of policy alternatives for the cultivation and expression of a range of relevant virtues. A communitarian approach to bioethics would assess the impact of alternative policy options in terms of their impact on a societal community or specific communities within a society. A principalist approach would deploy the principles of autonomy, justice, beneficence, and non-maleficence in determining whether a policy attended adequately to competing ethical demands.

For some types of questions and in circumstances where there is no fundamental ethical disagreement or conflict in values, where there are shared underlying concepts and epistemologies, where there is agreement about who is an 'expert' regarding a particular question, or where the main task is values clarification, mechanisms that draw on these standard approaches to bioethics might work well enough. But in the face of commitments to moral pluralism, transparency, and accountability, and where the empirical grounding of the policies may be rapidly changing as is the case with many emerging biotechnologies, then mere application of an abstract theoretical approach to a policy problem is not likely to be fruitful.

There is promising, recent work in empirical bioethics (a subfield which uses social science methodologies to contest or inform our understandings of ethical concepts and principles) has developed a range of critical methodologies for eliciting public valuations about ethically contentious matters, novel technologies and potential policy alternatives (e.g., see Hoffmaster 1992; Hope 1999; Haimes 2002; Hasman 2003; Hedgcock 2004). Among the approaches that inform what we are term ‘empirical bioethics’ are medical anthropology, systems bioethics, historical institutionalism, and the sociology of medicine and health. Empirical bioethics is developing a range of critical tools for finding out what the ethical issues are in an area of policy and in determining public and expert views. The benefit of an empirical approach to aspects of bioethics is that it does not start from the assumption that ethicists can, for any given ethical debate, correctly articulate the ethical issues associated with a particular development in medicine or healthcare from the metaphorical armchair. Rather, applying ethical analysis to real life policy development ought to be informed by a level of empirical input—including input about what people are prepared to accept or endorse in a policy—and that empirical input itself should be subject to critical scrutiny. In our view, this empirical turn in bioethics can make some contribution to a more legitimate approach to bioethics, but as these approaches largely describe and analyse, but do not evaluate attitudes, practices, and institutions, these empirical approaches do not, in themselves yield defensible policy recommendations (as their practitioners are well aware).

Hence although the different ethical approaches traditionally deployed in bioethics as well as those approaches that are emerging under the banner of empirical bioethics can provide an ethical evaluation of alternatives in the narrowest sense, they are not adequate for the evaluation of the policymaking process itself, as an activity of states (or authorities created by state institutions). Such processes seek not simply a determinate outcome, but one that will be defensible to all those who are affected by the policy, whether or not they hold a particular ethical outlook. Taking one specific, traditional ethical approach hence fails to justify decision making at a policy level. Policies in liberal democracies are open to public questioning of justification and legitimacy, and in order to in fact be legitimate, there is a requirement that a range of processes be in place to negotiate a final decision, which often reflects compromise as well as consensus.

The task of formulating public policy is made more difficult by the need to (somehow) take account of the range of values held by members of pluralistic societies. Of course various philosophical approaches have devised solutions to developing policy under such conditions. Among the more widely accepted of these is a Rawlsian approach which assumes that citizens share a sufficient set of shared or overlapping values that can drawn on to achieve consensus about matters in the political realm, through a process of reflective equilibrium. In contrast, a Habermasian approach assumes the possibility of communication and justification in principle, but leaves the question about the scope of the political or public realm open; furthermore Habermasian approaches do not assume or require consensus.

Given that bioethics policy often occurs in contentious domains where the assumption of the ability to achieve an overlapping consensus seems empirically

unwarranted, a Habermasian-style solution appears to offer a more plausible starting point for evaluation of public policy on contentious bioethical issues. The question then remains as to whether such an approach can be adapted to with areas where there are multiple publics who take a stake in the policy issues under discussion. In addition, it is unclear how a policy could be agreed upon when those engaged in deliberation do not agree that they are willing to be moved by the reasons of others and where various parties are not committed to rational deliberation, conditions which often apply in bioethics policy debates. This then leads us to wonder how can the legitimacy of such policies be justified, when a country/jurisdiction is seeking policy in controversial bioethical domains?

These considerations, then, serve to shape the starting points of our project, which we call 'Big Picture Bioethics.' The project seeks to examine bioethics in its broader social and political contexts. In particular, it is interested in the rather large subset of issues in bioethics that have implications for the formation and critique of public policy. We wish to be able to evaluate the processes that have been used to develop these different public policies in response to ethically contentious issues. We focus on these types of issues not because we wish to presuppose that themes relating to what others have termed the '(new) politics of life' (see, e.g., Rose 2006; Gottweis 2008) have resulted in unique governance mechanisms or policy questions, but because we wish to investigate how bioethics (where these issues are core business) might better engage with such policy questions and processes. We do not presume that our evaluation of those processes and policies can be conducted in a vacuum, but rather that there needs to be adequate consideration of the range of structural, institutional, political, and cultural factors that shape both how a particular ethical challenge will be understood in a particular jurisdiction and the policy frameworks available for addressing the perceived need for policy. Our overarching question is *what approaches to bioethics can be used to assess how, and to what degree, the legitimacy of policies can be established when a jurisdiction is seeking to establish policy in a controversial bioethical domain?* This chapter outlines the framework within which we address that question.

We argue to the extent that the dominant approach to bioethical evaluation is framed within particular ethical frameworks (or by adopting principlist pluralist approaches that do not demand justification)—what we call (perhaps unfairly) “bioethics as usual”—bioethics has been limited in its capacity to provide answers to this question, even though bioethicists are often consulted about such matters. We believe that we need a new method for the evaluation of policymaking processes on ethically-contentious issues that meet the demands of democratic justification.

## Legitimacy of Bioethics Policy

Our project starts with the view that public policy on contentious ethical issues requires a determinate (if not definitive) outcome, that the outcome is publicly justifiable, and that such justification needs to attend to the fact of ethical

disagreement. We use a framework based in deliberative democratic theory as a test of the relative legitimacy of a policy outcome: a policy is to be thought more legitimate if a greater proportion of those affected by the policy are able to view the process that led to that outcome as one that allowed their concerns to be articulated and answered, if those who are affected by the policy are able to articulate the reasoning that could justify how the policy process addressed competing views, and if those who were charged with developing policy are able to offer a justification for deciding the policy as they have.

The scope of policy deliberations we have in mind are precisely those where there is no widely accepted consensus on a matter of policy nor issues where it is widely accepted that the matter is largely or wholly a personal decision. How issues come to be understood as controversial material for policy debates is a matter of socio-historical contingency. The issues that we have in mind as central to this book are those which are considered to be ones with significant ethical content, where the matter is viewed by at least substantial portion of the citizenry (or their representatives) as requiring some form of public policy response, and where there are clear differences of view about how the ethical content should be reflected in policy. Where policy matters address issues of access to health care, regulation of medical research, or new developments in health technology, we describe them to be matters of "bioethics policy."

Policy relating to a health or medical issue typically falls into the category of bioethics policy where policymakers feel a need to establish the explicit legitimacy of the policy process and to involve members of the public, or an array of expert stakeholders in the policy development process. Frequently this arises when politicians or regulators feel obliged to make policy in areas where there is clear ethical disagreement and where they claim that the policy should reflect public values.

Bioethics policy is thus characterised by increased interest in procedural transparency, public accountability, and consultation, and deliberation or other input from a wider range of stakeholders than is the norm for other areas of health policy. The kinds of current bioethics policy issues raised earlier provide an indication of how the push for greater transparency, accountability, and stakeholder involvement may occur. First, these areas of public policy arise in contexts where technological or medical change is occurring rapidly and the policymakers lack definite advice about the values that may be affected by the policy. Secondly, because of the novelty of the area, policymakers may not know who is affected by the policy and how they will be affected, so may not be able to draw on existing representatives to provide advice and, third, they need to defend the policy which will not reflect the (unmediated) preferences of all affected.

The approach we are proposing seeks to develop a new framework for evaluating policy that assumes heterogeneous publics holding diverse views, and who may be able to communicate and deliberate but are unlikely to achieve overlapping consensus on particularly contentious ethical issues. We believe that this framework can be useful in the evaluation of a range of current policy debates. It is not intended to be an idealistic approach, as it seeks to attend to the local social, cultural, institutional,

and political factors that enhance or impede the development of democratically-legitimate policy. Rather, it offers a means of evaluation that can assess how close or how far particular processes of policy development are from "better" or "more legitimate" processes, and by attempting to identify the structural and institutional or social, cultural, and political factors that have served to limit the degree of legitimacy that can be conferred on that policy process.

Although this approach is primarily concerned with understanding the extent to which procedures can be developed for legitimate policymaking without invoking absolute or exclusive ethical commitments, our approach is not itself ethically neutral. Rather it assumes a set of norms of democracy, justification, and justice that should shape political institutions, policymaking, and policy implementation. The test for legitimacy developed here is a relative one, and we are open to the possibility that there may be some debates on ethically-contentious issues where the development of policy that meets a threshold level of legitimacy is impossible (at least for a particular population, at a particular historical point). Challenges to legitimacy may arise for a number of reasons including: an apparently monolithic hegemonic authority that makes it effectively impossible for particular alternatives or positions to be heard; the absence of a culture of public deliberation that may render formal processes for public reasoning ineffective; an array of "pathologies of deliberation" that may distort deliberative process (Sunstein 2003); the presence of overwhelming economic or geopolitical threats that divert the policy process; or, finally, substantive ethical disagreement about the ethical issues under consideration and the value given to these by key groups, relative to the values of democratic legitimacy and respect. However, it is not yet clear how intransigent any of these challenges to legitimacy will be, given alternative policy processes, alternative policy issues, and alternative socio-cultural or political situations. Therefore one of the tasks of our approach is to attempt to use this approach to identify that threshold and current debates for which such legitimacy may be unrealisable, in a given set of circumstances, through examination of "real life" policy processes.

## Big Picture Bioethics

Our criticisms sketched above about the prospects for "bioethics as usual" or the familiar bioethical approach to the evaluation of public policy, have at their heart the sense that "bioethics as usual" is "little picture bioethics": it often relies on simplified case studies that intentionally obscure the complexity of real life policy implications; it tends to narrowly frame the range of ethical approaches relevant to policy decisions; it pre-frames salient empirical information in terms of competing expert or ethical positions; and it fails to attend to broader political and social contexts shaping public discourse. We present here our desiderata for a more legitimate approach to bioethics policy evaluation and (potentially) enhanced legitimacy in the development of bioethics policies. We believe that the following elements are

required: (1) a theoretical framework grounded in the normative demands of legitimacy and justice; (2) a method (or range of appropriate methods) for empirically identifying and assessing what is at stake in a particular policy debate; and (3) one or more processes for interpretation of the findings gained from experts, technicians, and the empirical findings on stakeholder views which are then used to generate coherent and determinate policy proposal justifications that are testable and contestable, and that foster informed debate and engagement. We call this a ‘big picture’ bioethics approach because it aims at encompassing the full range of concerns and understandings about an issue of bioethics policy at a given time within a jurisdiction; because it aims at approaches that respond to the arguments and concerns expressed within that public debate; because it recognises that the legitimacy of bioethics policy decisions is open to revision in light of changed information or social concerns; and because it appeals to the transparency of publicly articulated reasons and arguments for accountability. The following sections present in more detail the issues and requirements for each of these key elements to this approach.

### ***Theoretical Framework: Justification and Deliberation***

For any particular argument concerning the value of liberal democratic institutions, there is a challenge to establish the role of the state in, on the one hand, protecting and promoting certain basic rights of individuals or collective values (e.g., justice towards disadvantaged social groups) while on the other affording due regard to the value of democratic self-determination or popular sovereignty in the determination of political matters. While much of the writing of John Rawls (1971 onward), for example, is concerned to establish *just institutions* for the resolution of the complex coordination problem of overlapping individual interests, this approach is not readily applicable to concrete or specific policy development in the contested ethical terrain discussed here. What norms of policymaking are required to meet the demands of liberalism for justification and those of democracy for equal respect and public reasoning as tests of legitimacy? The two strands articulated below together point to the role of justification, deliberation, and public reasoning in establishing the legitimacy of policy affecting citizens.

Contemporary liberal theory emphasises the significance of justification in the moral defence of liberal conceptions of the role of the state. Jeremy Waldron has argued that the legitimacy of public policies depends, in principle, on the ability of the policy-maker to justify those policies to any reasonable member of the society (Waldron 1993, 44). For Stephen Macedo “[t]he moral lodestar of liberalism is...the project of public justification” (Macedo 1991, 78). The central issue for the state in developing policy can be framed within Charles Larmore’s characterisation of political respect for persons:

To respect another person as an end is to insist that coercive or political principles be just as justifiable to that person as they are to us. Equal respect involves treating all persons, to which such principles are to apply in this way. (Larmore 1990, 349)



The demand for justification, grounded in respect, concerns the nature of the limited authority of the state to use its coercive force to compel adherence to law. If the liberal individual is to submit to state authority, that authority must be able to provide a justification that can, in principle, be accepted by those individuals so compelled. The concern for justification generates a demand for public accountability and transparency of policymaking processes.

Within democratic theory, there has been considerable recent work on the significance of public deliberation for the realization of democratic values. In this work, deliberative legitimacy involves the participation of citizens in reasoning about what policies or institutions ought to be adopted (Fishkin 1995; Gutmann and Thompson 2003). The deliberative approach to democratic legitimacy emphasizes the use of argument to establish the justification for policy and processes of deliberation to establish political legitimacy. This approach is closely associated with the work of Jürgen Habermas (1975), but has been elaborated and refined by a wide range of democratic theorists. Habermas describes this model as a return to the "original meaning of democracy as in terms of the institutionalisation of a public use of reason jointly exercised by autonomous citizens: (Habermas 1996, 23). According to Jon Elster, the deliberative approach to democracy emphasizes the legitimation of policy that comes from the *transformation* of interests through processes of "collective decision making by all those who will be affected by the decision... and decision making by means of arguments offered by and to participants who are committed to the values of rationality and impartiality" (Elster 1998, 8).

Critical theorists and feminists who work on questions of justice and inclusion have drawn on the deliberative and justificatory ideals of the Habermasian approach, while articulating the range of institutional, procedural and structural impediments to inclusion, communication, and free and uncoerced participation. Iris Marion Young (1990, 2000), Seyla Benhabib (1996), and John Dryzek (2000) (among others) incorporate critical assessment of established power structures that may shape and limit deliberation and assess the significance of the historical absence or exclusion of oppressed groups from public reasoning fora.

In our view, a normative political theoretical framework based on critically informed justificatory and deliberative approaches to political legitimacy promises a sound basis for evaluating policy processes based on democratic norms that can be justified independently of particular ethical commitments. Is our approach to deliberative policy development unique? No, authors like Amy Gutmann and Dennis Thomson (2003) have argued for a form of deliberative democracy in health policy development and evaluation and others have argued for using "citizen juries" in development of contentious health policy (see also Dryzek 2000; Dolan and Cookson 1999). We are, however, extending the critical engagement with these approaches drawn from political philosophy by asking whether deliberative legitimacy is possible in areas of significant ethical contention, and, if they are, what institutions and mechanisms are required to enhance the process. Further, because we accept that there may be some ethical disagreements that challenge the capacity for this kind of political theory to generate legitimate policy, our project provides an important test for the limits of democratic legitimacy.

## *Empirical Evidence for Values Underlying Policy Debates*

The process of ‘participatory governance’ has been defined as “the practice of consulting and involving members of the public in the agenda-setting, decision-making and policy-forming activities of organizations or institutions responsible for policy development” (Rowe and Frewer 2004, 512). We focus here on more formal mechanisms for public engagement in policymaking, although of course there are a range of more informal, yet commonly utilized, forms of public participation such as lobbying, public protests, media engagement, and communications via a variety of internet technologies (see Gottweis 2008). Where a deliberative, justificatory approach to policy development is adopted by a governmental-based entity, those involved in developing and deliberating about policy alternatives will need to develop mechanisms for identifying what is at stake for the public— the range of values, alternative perspectives, and contested interests—in a particular policy debate. There are a number of methodologies for eliciting more formal ‘public valuations’ about ethically contentious matters, novel technologies, and potential policy alternatives, and extensive discussions about the advantages (and limitations) of each option (for reviews, see Laroux et al. 1998; Mullen 1999; Ryan et al. 2001; Bellucci and Joss 2002; Rowe and Frewer 2004).

Opinion polls are common ways of determining what people believe about controversial bioethical issues, but they only allow assessment in terms of the particular questions asked at a specific point in time and also assume a basic level of public knowledge about the issue in question, hence often reinforcing a “deficit model” of the public’s understanding of the underlying science or of the issue more generally. More importantly for purposes of this project, they also focus on individuals’ opinions and not group beliefs, and do not allow interaction with the public to assess underlying values. More open-ended interviews of individuals or in groups do not presuppose particular answers (or types of answers), do not make as many assumptions about baselines of knowledge about an issue, and may allow respondents to pursue themes in much greater detail than more close-ended surveys. However, some commentators argue that even interviewees participating in relatively open-ended protocols may still tend toward conformist responses, such as those they think are socially desirable or acceptable (see e.g., Holm et al. 1996). Furthermore, surveys assume a certain “projectability” and generalisation of results which relies on the construction of a “docile social body” which can be reliably measured (Ashcroft 2003), an assumption that is not particularly warranted because the stability condition can only be assumed to hold for a limited time or within a limited population, particularly with regard to emerging or contentious issues.

In contrast, group-based approaches are claimed by some to be “optimal” allowing ‘study of moral reasoning in real-life groups, discussing real-life dilemmas’ (Holm et al. 1996). For instance, reasons for decisions or opinions can be elicited through conversation and deliberation within groups, such as citizen juries (for use of these with regard to bioethical issues, see e.g. Braunack-Mayer et al. 2010; for critiques, see e.g. Pickard 1998; Price 2000). Consensus conferences bring together

citizens with varied interests to gather their opinions on specific scientific and technical issues (see Laroux et al. 1998). Similarly, number of authors have drawn on the potential for public participatory approaches to contribute to technology assessment and public engagement with science (for example, O'Doherty and Einseidel 2013). The underlying concept is that any average citizen who is provided with the necessary time and resources to learn about a particular issue can understand complex considerations and make well-grounded decisions on the issue. Consensus conferences allow real-time assessment of the needs of participants in terms of further information required to be able to render a decision regarding a particular issue, and oftentimes it is the participants themselves who select the experts or presenters to be engaged (Joss and Durant 1995). These methods have the advantage of being open ended, and thus do not restrict respondents to a particular theoretical framework or set of background assumptions. The interviewer or facilitator's role also can be diminished (or eliminated in the case of consensus conferences), thus mitigating concerns about conformist responses. However, empirical research which focuses on capturing group decision making often suffers from other sorts of influences, notably that underlying values systems or reasons are not always made apparent and groups can tend toward compromise or even engage in strategic behaviours that may not reflect actual beliefs or preferences, and participants are largely self-selecting (Einseidel and Eastlick 2000).

Where the research question is related to group interests, group-based techniques may well be most appropriate, as they have been argued to encourage respondents to consider the common good and not merely individual interests (Bowie et al. 1995; Mossialos and King 1999). In some formats, such as in citizens' juries or consensus conferences, they may explicitly require participants to come to a jointly agreed decision. As it appears that within the type of justification sought for policy in bioethics legitimacy will need to be established through claims about the "common good" and the defence of these claims, attending to group deliberations and processes is more likely to provide useful empirical content. However, we would argue, as this empirical content will not be sufficient to determine the justifiability of policy, more theoretical ethical analysis of these empirical claims about the good (or goods) also will be required.

At the most basic level, all of the methodologies that can be encompassed under the rubric of public participation may perturb the status quo, in that research can become a social intervention. The public may come to expect to have a right to participate and expect to have a certain sort of role in decision-making in the future. As Ashcroft (2003, 9) argues, "attitudes" are often "made", not "found", and may be unstable, or sensitive to framing effects and a variety of contextual factors more associated with the methodology chosen than with any underlying social variables'.

In summary, considerations when assessing whether a participatory mechanism will yield the desired results include:

1. access (who participates, what or who are they "representing", and who determines who participates?)

2. autonomy and influence of the participants (are they free to make decisions, and do the decisions actually have any impact?)
3. the framing and scope of the issue under discussion (is it limited enough for useful discussion, but not so limited so as to close off certain views? [cf. Irwin 2001])
4. ability to foster high-quality dialogue and debate
5. limitations of context (what are the pre-existing social and political structures which may close off deliberation and debate?)

### ***Translation into Policy***

Having drawn on the range of empirical information and discursive positions held within the public discourse relevant to a given area of bioethics policy, the next step for the policymaking process is the interpretation of the information provided by expert and public stakeholders and the transformation of that information into policy. Policymakers may think they are implicitly asking experts (for instance social scientists or survey makers) for this type of answer, but often instead only unprocessed, descriptive information is provided. There is a need for bodies charged with making policy recommendations that respond to the arguments and evidence provided (Cohen 2005; Dodds and Thomson 2006). Depending on the complexity and political sensitivities involved, this could be a one-step process or a two- (or more) step process that respond to and refine information and arguments. These processes need to be sensitive to differences in the salient features of policy issues: ideally where policies will have significant impact on citizens' lives there will be the time and resources for iterative consultation and testing of both the empirical information about what is valued, the range of stakeholders whose perspectives are relevant and responses to policy alternatives. This would yield one or more clear policy recommendations that are framed as an argument for the policy recommendation grounded in the evidence considered.

Where the policy matter requires legislation, the interpretation of arguments and information to frame policy recommendations may be separated from the specific policy debate in the political forum of legislatures. In several parliamentary jurisdictions, contentious bioethical debates are recognised as transcending party politics and party discipline, so that political representatives can exercise independent judgement on a "free" or conscience vote. In other cases, political parties may draw on an articulated "party line" in response to the bioethics policy matter which will shape responses to the interpretation of arguments and concerns from the broader public debate.

According to the big picture bioethics approach, these processes for interpretation and policy formation will be more legitimate and defensible where they provide arguments for the policy direction taken that are responsive to the arguments presented in public debate, where the reasoning is transparent and accountable, and where aspects of the policy that rest on contentious or speculative factual claims are

open to regular review. Our approach points to a need to make the processes of clearly articulating the empirical data and the advice more transparent in legislative processes, and also need to recognize that these are time-sensitive and contextual to resist entrenching outdated values or decisions.

## Conclusions and Implications

Big picture bioethics aims at the evaluation of public policymaking processes on the basis of their informed, democratic legitimacy, where (as stated above) a policy is more legitimate if a greater proportion of those affected by the policy are able to view the process that led to that outcome as one allowing their concerns to be articulated and answered, if those who are affected by the policy are able to articulate the reasoning that could justify how the policy process addressed competing views, and if those who were charged with developing policy are able to offer a justification for deciding the policy as they have. Hence legitimacy is clearly a matter of degree, and arises as part of a process (rather than as a simple product); policies will need to be continuously contested and revised in order for a high degree of legitimacy to hold.

We recognise that this kind of democratic legitimacy of bioethics policy may not, in practice, be possible in a given jurisdiction, in relation to a particular area of policy. For example, there remains a question of whether legitimate (in our sense) public policy can be developed in areas where there is ethical “standoff”, and particularly where various groups or publics refuse to engage in good faith in deliberation. A similar problem may occur in cases where the public has become “disengaged” following a gap between what the state promised and what it was able to do, resulting in disillusionment (Jasanoff 1997).

However, this question is not only a theoretical one but one that must be considered in light of empirical evidence about a range of policymaking processes examined within their sociopolitical contexts. An advantage of the big picture bioethics approach is that it can allow for this possibility without resorting to the view that policy that does not reach a threshold of legitimacy (“legitimate-enough bioethics policy”) is wholly without defence. There may be circumstances where a *modus vivendi* among contested positions can be achieved: this could occur where intractable ethical differences are recognised as being inextricably tied up with specific policy issues (for example, the use of human embryos in research) and that the most defensible policy positions that respond to the greatest range of arguments and concerns raised by lay and expert stakeholders in the public debate cannot bridge these fundamental ethical differences. A *modus vivendi* response may be achieved, which clearly articulates that impasse while articulating a policy approach that has sufficient support to be justifiable (Iverson 2002). Those whose commitments are not adequately addressed within the policy outcome can retain pressure on legislators to respond to their unmet arguments and concerns, rather than being simply silenced by majoritarian democratic process.

This chapter has sketched an approach to evaluating bioethics policies and policy development processes which avoids assumptions about consensus, which are endemic to most of what is said about policymaking processes within liberal democracies that seek to attend to diversity. In addition, the approach favoured is non-substantive in the sense that it does not prescribe a particular moral framework, beyond a commitment to democratic legitimacy. It draws on both empirical information about opinions and values of a variety of publics, and the problematization of that empirical evidence informed by political theoretical debates.

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