REGULATING THE LIFE SCIENCES, PLURALISM AND THE LIMITS OF DELIBERATIVE DEMOCRACY

This article considers to what extent processes of public engagement and deliberative democracy are appropriate in pluralistic communities, where there are many different views about the "acceptability" of emerging life science technologies. It argues that, where the pluralism arises from (a) a variety of self-interested prudential judgments or (b) competing interpretations of shared baseline ethical values (so-called "closed ethical pluralism"), then deliberative democracy is an appropriate regulatory approach. However, where regulators face conditions of "open ethical pluralism", where baseline values are contested, it is less clear that deliberative democracy can work. In the most challenging cases of open ethical pluralism, it is not sufficient for regulators to appeal to the integrity of the decision-making process; here, the final regulatory appeal is to the shared aspiration to build a moral community.

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I. Introduction

1 In modern societies, confronted by a raft of innovative technologies, we place a considerable burden on our regulators.[1] For those who bear this burden, one of the first tasks is to ensure that the life sciences are conducted and applied in ways that are not harmful to humans. However, the avoidance of harm is not enough; even where the life sciences can be practised safely, reliably, and beneficially, regulators are expected to enforce ethical standards. On this view, life science is sound only when it is compatible with standards of both safety and ethics; and, by the same token, the regulatory framework is sound only when it controls for acceptable risk as well as for ethical acceptability. Even if the assessment of risk (and calculations of safety) can be left to expert committees, bioethics cannot be judged in the same way – or, at any rate, in morally pluralistic communities, there is no easy way to

1 In general, see Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: Oxford University Press, 2008).

align the law with ethical requirements. In the context of ethical pluralism, what is the way ahead?

2 Responding to this challenge, Professor Amy Gutmann, recently appointed to chair the (US) Presidential Commission for the Study of Bioethical Issues (and first tasked to report on the implications of synthetic biology), has declared her intention to champion informed debate in the spirit of deliberative democracy.[2] According to Professor Gutmann, deliberative democracy, in contrast to "sound-bite democracy", is about engaging the public:[3]

> Deliberative democracy is about … listening to competing points of view, considering opposing arguments and coming to a decision that ideally finds common ground – or at least respects competing points of view.

3 On the face of it, this is a promising strategy; for, deliberative democracy, as elaborated by Professor Gutmann,[4] decrees that all freely expressed views are to be heard and that, so long as they are not wholly unreasonable, they are to be accorded equal consideration. At the end of the process, differences should have been minimised and regulators should be in a position to act on reasons that are at least acceptable to all persons who are committed to fair terms for political and social co-operation. To be sure, this does not quite guarantee that the eventual outcome will attract everyone's vote; but, because the decision in question will be supported by acceptable reasons, reasonable people should respect it. Moreover, it is characteristic of Professor Gutmann's version of deliberative democracy that debates can be re-opened; decisions are, thus, reviewable, which means that the time might still come for today's dissenting views. In this way, the life sciences can proceed and pluralistic societies can settle their differences in a civilised way.

4 Yet, is it so simple? In this article, in paras 6–35, the author starts by drawing a distinction between two types of pluralism, "prudential pluralism" and "ethical pluralism". Where the problem is one of prudential pluralism, deliberative democracy seems to be an entirely appropriate response. In paras 36–41, with the focus on ethical pluralism, a further distinction is drawn, this time between "closed" and "open" types of ethical pluralism. In the case of the former, fundamental

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2 See Meredith Wadman, "Bioethics Gets an Airing" Nature (7 July 2010) at <http://www.nature.com/news/2010/070710/full/news.2010.340.html> (accessed 1 October 2010).

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4 See Amy Gutmann & Dennis Thompson, *Why Deliberative Democracy?* (Princeton: Princeton University Press, 2004).

ethical principles are agreed and it is in the interpretation and application of those principles that we encounter different views. In the latter, the differences reach back to the baseline principles. Whilst the author accepts that deliberative democracy is an appropriate response to closed ethical pluralism, it is much less clear that it can handle open ethical pluralism in a satisfactory way. In paras 42–61, within the setting of what the author calls a "community of rights", the way in which closed ethical pluralism can be handled by deliberative democratic processes is discussed. Finally, in paras 62–79, with the focus on open ethical pluralism, one final distinction is drawn, this time between "convergent" and "non-convergent" open ethical pluralism. Where deliberative democracy generates an agreed regulatory position (even though the underlying reasons for agreement are varied), we have convergence; and this is the basis for a workable accommodation of the competing ethical views. However, where there is no such convergence, it is unclear how regulators are to enjoin respect for the position that is taken.

5 In this most difficult of cases, it is suggested that the final appeal that regulators can make is that they are, at least, trying to do the right thing and that a community so regulated merits more respect than one regulated without any moral aspirations. In other words, we reach the limits of deliberative democracy where, in a context of open ethical pluralism, there is neither a convergent regulatory position nor a common baseline conception of reasonableness. At this point, all is not quite lost. However, if regulators are to enjoin respect for the position that has been taken, they need to do more than simply appeal to the fact that all sides have had a fair hearing – rather, they must appeal to the generic moral aspirations of their morally divided regulatees.

II. Prudential and ethical pluralism

6 Pluralism signifies that that there are a number of different views about a particular matter. However, there are many reasons why people can have different views and some reasons are far more fundamental than others. Sometimes, nothing of any moment rides on our differences – for example, it is easy for me to live with your preference for Thai curries and, conversely, for you to live with my preference for Indian curries. In some cases, our differences might even be complementary but, on occasion, they can be conflictual. Suppose, for example, that you are a vegetarian and I am not, but that we both believe that it is important to respect the welfare of animals; here, we agree on a matter of first principle (concerning respect for animals) but we disagree about the application of the principle. Faced with such a difference, we might reasonably agree to disagree. However, if we also dispute the first principle – suppose that I deny that we have any

responsibility for animal welfare – then our differences go much deeper and it is more difficult for us to let the matter rest. And, in the same way, where differences do matter and where they go deep, it is more difficult for regulators to shrug off their responsibilities.

7 As a first step towards bringing pluralism more clearly into focus, we need to distinguish between two types of pluralism, namely, "prudential pluralism" (a pluralism of self-regarding interests) and "ethical pluralism" (a pluralism of "legitimate" interests, both of oneself and others). Broadly speaking, we can say that it is only when we get to ethical pluralism that the difficulties with deliberative democracy begin to reveal themselves.

A. Prudential pluralism

8 Paradigmatically, a "prudential" judgment is one that is directed at identifying what is in one's own interest; such a judgment is intended to be entirely self-serving. Thus, for example, agent A might prudentially judge that it is, or is not, in his or her self-interest to undergo surgery or to be tested or screened for some condition. It is a matter of weighing the costs and the benefits and judging where the balance of self-interest lies. In making such a judgment, A takes no account whatsoever of the interest of others.

9 Where agents are each invited to make their own prudential judgment about a matter, there are likely to be a number of different judgments made. Suppose, for example, that the question is whether it is prudent to contribute to a charity that conducts research into cancer. While agent A might be persuaded that it is in his interest to contribute because the anticipated benefits seem to outweigh the costs, agent B might value the benefits and calculate the costs differently, leading to the judgment that prudence does not dictate contribution. Of course, the way in which these prudential judgments come out has a practical impact on the charity but the prudential pluralism that exists between A and B does not, as yet, invite regulatory attention.

10 Suppose, though, that the question concerns a matter about which there is little reliable information, then we might expect regulators to take steps to ensure that the public is properly informed. In other words, even if regulators need not be concerned about some forms of prudential plurality, they should take reasonable steps to ensure that, where there is a plurality, it is at least based on a correct understanding of the respective risks and benefits. In some cases – for example, where health care professionals want to steer agents towards a particular test, screen or procedure – there might be a tension between the professional paternalistic judgment as to what is in an agent's best interest and the agent's own prudential judgment; but regulators must do their best to

ensure that the information is framed and presented in the way that facilitates prudential decision-making.[5]

11 Often regulators cannot allow agents to make their own (informed) prudential judgments and then leave it at that. For example, regulators will be pressed to set a framework for the safe research and development of synthetic biology or the safe application of nanomedicine. This is not usually understood as a demand for zero risk but that regulators should set standards that manage the risk at an acceptable level.[6] However, what constitutes an acceptable risk will depend upon how the costs and benefits are calculated. Just as agents A and B might arrive at different prudential judgments when it comes to supporting a cancer research charity, they might reach different prudential judgments about what is an acceptable risk in relation to new developments in the life sciences and, concomitantly, about the position that regulators should take up. While agent A, who is highly risk averse, may judge, prudentially, that synthetic biology should be prohibited or, at least, subjected to a moratorium, agent B, who is a biotechnological entrepreneur, might take a radically different view. The views of A and B, it must be emphasised, are not the least bit noble; it is purely and simply a matter of A and B making judgments that each calculates to be self-serving; A, in making his prudential judgment, takes no account of B's preferences or interests; and B, in making his prudential judgment, takes no account of A's preferences or interests.

12 Where a regulatory position needs to be taken, how should regulators respond to a prudential plurality? In a democracy, there is a reasonable expectation that there will be a process of public engagement before a position is taken. Before settling upon a legal framework, there needs to be a process that, in the spirit of deliberative democracy, seeks out a reasonable position – in this case, a position that reflects a reasonable view about an acceptable level of risk.

13 However, engaging the public on questions concerning emerging technologies is far from straightforward.[7] For example, how

5 See, for discussion, Roger Brownsword & Jonothan Earnshaw, "The Ethics of Screening for Abdominal Aortic Aneurysm" Journal of Medical Ethics 2010 (forthcoming).

6 Compare, *eg*, the European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Nanomedicine* (Opinion No 21, 2007) at para 4.2.3: "[R]isk management actions should be aimed at identifying the 'acceptable risk' threshold with regard to the values at stake – and respect for the human body is undoubtedly one of the values deserving the highest legal protection."

7 Compare, *eg*, International Risk Governance Council, *Risk Governance of Synthetic Biology* (Geneva, 2009); and *Reconfiguring Responsibility: Lessons for Public Policy (Part 1 of the report on Deepening Debate on Nanotechnology)* (Sarah Davies, Phil Macnaghten & Matthew Kearnes eds) (Durham: Durham University, 2009).

are researchers to cope with what can be extremely variable levels of public understanding of the technology; how are they to distil attitudes towards a particular technology from a medley of predispositions (to science, technology, commerce, and so on); and how are they to overcome the public's suspicion of stakeholders in the technology?[8] Reflecting on the public debate on GM foods in the UK, Sheila Jasanoff identifies a number of difficulties and dilemmas:[9]

> It was conducted, to start with, under severe resource and time constraints by the government's dubiously legitimate and competent public relations unit, the Central Office of Information. As a result, many regional meetings drew those already knowledgeable about the issues, who were least likely to contribute fresh perspectives to the exchanges. Coordination with the other two strands of the process [the first strand was a cost/benefit study undertaken by the Strategy Unit, and the second was a Science Review led by the government's chief scientific adviser] proved difficult. Even the website, organized around bland questions and oversimplified answers, seemed ill suited to arousing the interest of persons not already involved in the debate. In sum, the effort underscored a dilemma confronting state efforts to democratise the politics of new and emerging technologies: on the one hand, interacting only with identifiable stakeholders may simply strengthen the traditionally cozy relations between business and government; on the other hand, the public that needs to be engaged in broader debates about the pros and cons of technology is elusive and, in the absence of reliable precedents, hard to engage in deliberations whose very authenticity and purpose are widely questioned.

14 How might these obstacles be overcome? In the influential report by the Royal Society and the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*,[10] it is recommended that: dialogue and engagement should occur early, and before critical decisions about the technology become irreversible or "locked in"; dialogue should be designed around clear and specific objectives; the sponsors should publicly commit to taking account of the outcome of the engagement process; dialogue should be properly integrated with other related processes of technology assessment; and resourcing for the dialogue should be adequate.[11] Even with attention to these matters, however, there might be doubts about how fully the

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8 See Ruth Sheldon, Nicola Cleghorn, Clarissa Penfold, Ashley Brown & Thomas Newmark, *Exploring Attitudes to GM Food* (London: Social Science Research Unit, Food Standards Agency, 24 November 2009) at p 21 where it is reported that some of the participants who were undecided about GM foods "argued that it is not predetermined whether the technology will be used for good or bad purposes and judgement should be withheld until it is possible to see what happens in practice".

9 Sheila Jasanoff, *Designs on Nature* (Princeton: Princeton University Press, 2005) at p 129.

10 Royal Society Policy Document 19/04 (London, July 2004).

11 Royal Society Policy Document 19/04 (London, July 2004) at para 38.

public is engaged; and, of course, it is difficult to immunise a citizens' jury against the influence of the media.

15 Assuming, though, that the public can be adequately engaged, their prudential calculations are likely to be varied and, concomitantly, their preferred regulatory responses will be at different points of the spectrum from outright prohibition to simple permission or even promotion. Still, in a democracy, this is the stuff of politics; decisions that are made today can be revised tomorrow; and, while this might not be the ideal way of accommodating the variety of self-interested views, it is a civilised way of living with pluralism. Accordingly, even if the realisation of deliberative democracy is challenging, it appeals as the right way to deal with prudential pluralism.

B. Ethical pluralism

16 There is a great deal to say about ethical pluralism but let us start by specifying the nature of an ethical judgment. As against a prudential judgment (where A judges only what is in A's own interest), an ethical judgment involves judging what is in the legitimate interests of all affected "parties", both oneself and others. Ethical pluralism can arise in various ways but particularly because agents have competing views about what counts as a "legitimate" interest (of oneself and of others) as well as who counts as a relevant "party" – for example, do the unborn, future generations, or animals, count as relevant others when we make an ethical judgment? In this part of the article, the dominant ethical plurality will be sketched by focusing on the criterion of legitimate interest.

17 The modern development of biolaw (and of bioethics) has hinged on two "civilising" reactions. Firstly, the utilitarian and paternalistic ethics that underpinned professional biopractice was rejected in favour of an ethic that took the rights of individuals seriously, that put its emphasis on free and informed choice, whether by patients or by research participants, whether by individuals or by a larger group. Secondly, there has been a reaction against the individualism, autonomy, and consumerism that has come in the wake of the first reaction. In part, this second civilising reaction, the taming of autonomy, has encouraged a return to utilitarian patterns of thinking but the outstanding feature of this reaction has been the resort to human dignity – to the axiomatic idea that human dignity should not be compromised – in order to set limits to autonomy. Ironically, though, it was the thought that utilitarianism fails sufficiently to respect the intrinsic dignity of humans that galvanised the first of these reactions.

18 At all events, it is in the much-debated United Nations Educational, Scientific and Cultural Organization ("UNESCO") Universal Declaration on Bioethics and Human Rights[12] – this Declaration being addressed to "ethical issues related to medicine, life sciences and associated technologies"[13] – that we find an heroic attempt being made to set a global framework for bioethics. So, immediately after Art 4 which emphasises (in a utilitarian way) the maximisation of benefit and the minimisation of harm, we find a run of Articles that highlight the importance of individual autonomy (Art 5) and consent (Art 6), and that require respect for privacy and confidentiality (Art 9). Moreover, reflecting the impact of the second of the civilising reactions referred to earlier, the Declaration is peppered with demands that human dignity should be respected – a prominent example being Art 3(1) which enjoins that "[h]uman dignity, human rights and fundamental freedoms are to be fully respected".

19 Quite clearly, this is a pluralistic cocktail of ethical approaches; but how should we characterise it? To start with the elusive concept of human dignity, we find that this notion acts as an umbrella for two quite different conceptions of human dignity[14] – one a rights-based conception of human dignity as empowerment, the other a duty-based conception of human dignity as constraint. In modern bioethics, these two conceptions map as two of the three points of a "bioethical triangle",[15] the third point being utilitarian. Here, an attempt will be made to sketch rather more carefully this pluralistic ethical landscape so as to draw out some of the corollaries of this view.

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12 Adopted by acclamation on 19 October 2005 by the 33rd Session of the General Conference. For discussion and analysis, see, *eg*, *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, Principles and Application* (Henk A M J ten Have & Michèle S Jean eds) (Paris: UNESCO, 2009); Abdulqawi A Yusuf, "UNESCO Standard-Setting Activities on Bioethics: Speak Softly and Carry a Big Stick" in *Biotechnologies and International Human Rights* (Francesco Francioni ed) (Oxford: Hart, 2007) at p 85; and Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: Oxford University Press, 2008) ch 2.

13 See, United Nations Educational, Scientific and Cultural Organization ("UNESCO") Universal Declaration on Bioethics and Human Rights Art 1.

14 See Deryck Beyleveld & Roger Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford: Oxford University Press, 2001).

15 See, *eg*, Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: Oxford University Press, 2008) ch 2. Gathering around the conception of human dignity as constraint, we have an alliance of dignitarian views: see, Roger Brownsword, "Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the 'Dignitarian Alliance'" (2003) 17 University of Notre Dame Journal of Law, Ethics and Public Policy 15.

(1) The matrix and the triangle

20 First, we will take it that there is a basic matrix that sets the mould for ethical debates, a matrix that involves three essential *forms*: namely, goal-orientated (consequentialism), rights-based and duty-based forms. It follows that the form of an ethical argument will either prioritise some end state goals, or it will start with a declaration of rights or a declaration of duties.

21 Each form within the matrix is a mould or a shell, open to substantive articulation in many different ways: different goals, different rights, and different duties may be specified. Nevertheless, in principle, the basic pattern of ethical debate, whatever the particular technological focus – whether it be biotechnology (and bioethics), ICT (and cyberethics), nanotechnology (and nanoethics), or neurotechnology (and neuroethics) – is governed by this matrix.[16]

22 Although, in principle, the matrix sets the pattern, in practice, it does not follow that the matrix is always fully expressed in debates about the ethics of new technologies. Often, we find only a two-sided debate with utilitarian cost/benefit calculations being set against human rights considerations. In general, unless there are major safety concerns, while utilitarians will assert the "green light" ethics of proceeding, a case of promotion (of the technology) modulated by a degree of precaution,[17] human rights theorists will take an "amber light" approach insisting that the technological traffic pauses (to ensure rights clearance) before proceeding.

23 By contrast, in relation to debates concerning the ethics of modern biotechnology, we have a three-way articulation of the matrix, the key substantive positions being utilitarian, human rights and dignitarian. Here, in this distinctive bioethical triangle, we find the dignitarian alliance taking issue with both utilitarians and human rights advocates. While the latter can sometimes find a common position, it is much more difficult to reach an accommodation with the dignitarians. For, according to the dignitarian ethic, some technological applications are, quite simply, categorically and non-negotiably unacceptable. In this sense, of the three ethical perspectives, it is only the dignitarian view that is genuinely "red light".

16 In relation to nanoethics, see Roger Brownsword, "Regulating Nanomedicine – the Smallest of Our Concerns?" (2008) 2 Nanoethics 73, and "Nanoethics: Old Wine, New Bottles?" (2009) 32 European Journal of Consumer Policy 355.

17 Compare, Department of Biotechnology, Ministry of Science and Technology, Government of India, *National Biotechnology Development Strategy* (2006) at p 23: "A precautionary, yet promotional approach should be adopted in employing transgenic R & D activities based on technological feasibility, socio-economic considerations and promotion of trade."

24 Somewhat confusingly, as has already been remarked, the idea of human dignity underlies both the human rights and the dignitarian view. However, once this double-take is identified, it is easier to see which version of human dignity is being contended for or presupposed. Moreover, with the bioethical triangle as our reference map, we can track and locate the positions taken on particular issues such as the use of human embryos as research tools or the recognition of proprietary rights over removed body parts and tissues. But, of course, none of this makes it any easier for regulators who are trying, against the backcloth of this contested plurality, to strike regulatory positions that meet the demands of all three constituencies. Nor, it seems, do regulators always find it easy to articulate the details of regulatory positions in a way that is entirely consistent with those sections of the plurality that they are privileging.[18]

25 Before moving on to the next part of the discussion, it should be emphasised that the particular *substantive* articulations that are represented in the bioethical triangle are by no means exhaustive of all substantive ethical possibilities. In other words, the bioethical triangle should be viewed as a particular conjunction of ethical form and substance that reflects the way in which certain positions have come to dominate modern bioethical discourse and debate. There is no doubt that, in another time, and possibly in relation to other technologies, other voices will be heard.

(2) Corollaries

26 One of the most significant corollaries of the author's analysis of the basic pattern of ethical reasoning is that notions such as "harm to others", "informed consent", "precaution" and "proportionality", which commonly figure in ethical arguments, are not neutral. Rather, we have to read each of these ideas through the lens of the particular substantive articulation of the matrix. If the regulators of the life sciences are looking for a steer from bioethics, they will find that they are being steered in many different directions.

27 To take just one example, consider the case of consent, an idea that is absolutely central to the first of the modern revolutions in biolaw.[19]

18 See, further, Roger Brownsword, "Ethical Pluralism and the Regulation of Modern Biotechnology" in *The Impact of Biotechnologies on Human Rights* (Francesco Francioni ed) (Oxford: Hart, 2007) at p 45.

19 Generally, see Deryck Beyleveld & Roger Brownsword, *Consent in the Law* (Oxford: Hart Publishing, 2007).

28 Utilitarians count utility and disutility; and, for utilitarians, utility and disutility is all that counts. As such, there is nothing special about consent or the lack of it. In general, it is easy to see the negatives in relation to consent collection. Obtaining consent might not always be practicable; where it is, it nevertheless incurs transaction costs; and, on some occasions, it might be downright distressful. Waiting for consents to be cleared might involve opportunity costs. Moreover, policies might be frustrated if, instead of saying "yes", those who are asked to consent say "no". On the other hand, dealing on the basis of consent might ease matters *ex ante*, it might allay concern and weaken opposition, and it might be a convenient justificatory response *ex post*. Thus, for utilitarians, there is no golden rule requiring that the consent of those upon whom an action or decision impacts should be obtained. For example, requiring researchers or doctors to deal on an informed consent basis with research participants or others is not necessarily an improvement on compulsion, ignorance or paternalism. The calculation always depends on context, convenience, contingency and circumstance. Having said this, in a culture where preferences strongly favour the currency of consent, even if there is no golden rule requiring consent, utilitarians might well accept the sense of a general rule to this effect.[20]

29 Against the utilitarians, human rights theorists hold that what counts is respect for individual autonomy, entailing recognition of the right of individuals to make their own choices, to exercise control over their own person, property and privacy, and to say "yes" or to say "no". Taking individuals seriously, taking rights seriously, means taking consents and refusals seriously.

30 At the third point of the bioethical triangle, we have the duty-driven perspective of the dignitarians. For the dignitarians, it is human dignity, not consent, that fundamentally matters; and it is the interests of all members of the community that count, not merely those of the consenting community. The fact that all parties consent to participation in dwarf-throwing, or to playful killing at the Laserdrome, is irrelevant insofar as these activities compromise human dignity – as, indeed, it is irrelevant that all adult stakeholders consent to co-operating with, or carrying out, research that uses human embryos. The duty to respect

20 Although consent has been proclaimed as the cornerstone principle of the UK human tissue legislation, the underlying rationale is essentially utilitarian. Thus, according to a House of Commons Research Paper (No 04/04 on the *Human Tissue Bill*), the Government believes that the effect of the consent provisions will be to "prevent a recurrence of the distress caused by retention of tissue and organs without proper consent", to "help improve public confidence so that people will be more willing to agree to valuable uses of tissue and organs" (such as for research and transplantation purposes), and to "improve professional confidence so that properly authorised supplies of tissue for research, education and transplantation can be maintained and improved" (p 4).

human dignity is not switched off by the consent of others any more than it is switched on again by a withdrawal or a refusal of consent. Consent, for the dignitarian, is largely a sideshow.[21]

31 The general irrelevance to dignitarians of both "benefit" and consent is nicely illustrated by the opposition of the indigenous Tongan people to the agreement made between Autogen, an Australian firm, and the Tongan Ministry of Health for the collection of tissue samples with a view to researching the causes of diabetes.[22] Given the high incidence of diabetes in Tonga, there was some prospective health benefit for the local community. However, there were difficulties in modifying the Western model of individual consent so that it accommodated local custom and practice. Before it was clear whether these consent difficulties could be surmounted, Autogen decided against proceeding with the project. However, the key point is that, even if the consent issues could have been resolved, indigenous Tongans have a sense of human dignity that militates against any actions that compromise the sanctity of the person, their life force and their genetic legacy.[23] In other words, even if all the other objections were surmounted, the Tongans might still have judged it unethical to give up tissue samples.

32 Having said this, it should not be thought that all duty-driven perspectives regard consent as unimportant – we should recall that the dignitarianism of the bioethical triangle is simply a particular substantive articulation of the duty-based form that is available within the basic ethical matrix. Indeed, in their important (obligation-driven) analysis of informed consent, Neil Manson and Onora O'Neill take consent just as seriously as rights-led thinkers.[24] Moreover, at least two of the key themes in Manson and O'Neill's account correspond with the view that would be taken from a rights perspective. First, getting information across from agent, A, to another agent, B, is not just like copying data across from one disk to another (and, to this extent, the metaphors of "conduits" and "containers" for the transmission of information are unhelpful). When A informs B, this is a communicative transaction in the context of agency. It involves a degree of inter-subjective understanding, and a successful transaction presupposes respect for "a wide range of epistemic and ethical norms, including

21 Compare Shayana Kadidal, "Obscenity in the Age of Mechanical Reproduction" (1996) 44 American Journal of Comparative Law 353.

22 Drawing on Donna Dickenson, *Property in the Body* (Cambridge: Cambridge University Press, 2007) ch 8.

23 Donna Dickenson, *Property in the Body* (Cambridge: Cambridge University Press, 2007) especially at pp 167–168.

24 Neil C Manson & Onora O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge: Cambridge University Press, 2007).

norms of accuracy and honesty".[25] Secondly, consent is to be understood as a waiver relative to a backcloth of rights, obligations and expectations – "[t]hese obligations and expectations [being] *presupposed* by informed consent practices" [emphasis in original].[26] Hence:[27]

> In consenting, we *waive* certain requirements on others not to treat us in certain ways (sometimes this will include waiving rights), or we *set aside* certain expectations, or *license* action that would *otherwise* be ethically or legally unacceptable … Where an act would *otherwise* wrong an individual or disrupt their legitimate expectations, that individual's consent can waive their right, or modify their expectations in particular cases, and so justify an act that would *otherwise* be unacceptable. [emphasis in original]

33 So, we should not make the mistake of thinking that a duty-driven ethic in itself entails that consent is downgraded. However, as Manson and O'Neill recognise, where autonomy-limiting dignitarianism is in play, actions that are judged to degrade others will be treated as unacceptable, the consent of those degraded others notwithstanding.[28]

34 In the light of this short analysis, we can see that it is the human rights constituency that is most strongly committed to the significance of consent. Even here, it would be a mistake to say that consent is to be treated as a fundamental value because consent is always parasitic upon rights.[29] Nevertheless, it is the human rights constituency that is consistently concerned that consent should be taken seriously. By contrast, the dignitarians, as we have just said, do not attach significance to consent (at any rate, not where human dignity is compromised); and, as ever, the utilitarians modulate their view as context and contingency require.

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25 Neil C Manson & Onora O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge: Cambridge University Press, 2007) at p 185.

26 Neil C Manson & Onora O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge: Cambridge University Press, 2007) at p 187.

27 Neil C Manson & Onora O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge: Cambridge University Press, 2007) at pp 72–73.

28 Neil C Manson & Onora O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge: Cambridge University Press, 2007) especially at pp 20–21. Compare Dennis J Baker, "The Moral Limits of Consent as a Defense in the Criminal Law" (2009) 12 New Criminal Law Review 93.

29 See Deryck Beyleveld & Roger Brownsword, *Consent in the Law* (Oxford: Hart, 2007); and Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: Oxford University Press, 2008).

C. Taking stock

35 Prudential judgments operate only on self-interested considerations; ethical judgments operate only on legitimate interests, the interests of both oneself and relevant others. Prudential pluralism does not always demand regulatory attention; but, where it does, deliberative democracy is a commendable approach. The question of how regulators should address ethical pluralism is more complex and it is to this that we now turn.

III. Two types of ethical pluralism

36 As indicated in the introductory remarks, two types of ethical pluralism are to be distinguished, a closed and an open version.[30] In the closed type, there is agreement as to the baseline principles or values; in the open type, there is no such agreement. So, for example, if it is agreed that the maximisation of utility is the ultimate criterion of right action, but there is disagreement about the application of utilitarian tests, we have a closed version of ethical pluralism; and the same would apply if, instead of the maximisation of utility, it was agreed that respect for human rights or human dignity were the fundamental criteria. Characteristically, we do not have such agreement. What we have is disagreement that involves two or three of the points of the bioethical triangle; and this is open ethical pluralism.

37 The following is a short example of how this difference might work in relation to a particularly difficult life science issue, the patentability of human gene sequences. In the landmark case of *Diamond v Chakrabarty*,[31] the US Supreme Court paved the way for treating the processes and products of modern biotechnology as patentable. However, very recently, Judge Robert Sweet, sitting in the Southern District Court of New York, caused a stir by deciding that Myriad Genetics' patents on the BRCA1 and BRCA2 markers were invalid.[32] According to Judge Sweet, isolated DNA is not materially different from naturally occurring DNA and, thus, fails to qualify as an invention. Although, this might seem to be a technical decision, there is, as we shall see, an underlying moral issue. In Europe, where the moral debate has been much more explicit, the patentability of modern biotechnology has been bitterly contested at both the European Patent

30 See, too, Roger Brownsword, "Framers and Problematisers: Getting to Grips with Global Governance" (2010) 1 Transnational Legal Theory 287.

31 US SCR 65 L Ed 2d 144 (1980).

32 See, Phillippa Brice, "Latest Twist in Gene Patent Saga as BRCA Patent Revoked" <www.phgfoundation.org/news/5324> (accessed 1 October 2010).

Office (starting with the *Harvard Oncomouse* application[33] and running through to the *Wisconsin Alumni Research Foundation* ("*WARF*") case decided by the Enlarged Board of Appeals in November 2008)[34] and in the European Community (with Directive 98/44/EC on the Legal Protection of Biotechnological Inventions at the eye of the storm). Somewhat evocatively, the question has been debated as one of whether there should be "patents on life". Relating the troubled legislative history of the Directive, Gerard Porter captures the mood of the time:[35]

> [T]he slogan '*no patents on life*' began to gain a degree of political currency within the Parliament during the 1990s. This umbrella term crystallized a wide range of concerns about the proliferation of intellectual property rights in the life sciences. The concerns voiced included the fear that biotech patents would stifle scientific research by inhibiting access to key technology; unease about the degree of social power granted to private organizations through monopoly rights over key life science technologies; objections to the instrumentalization and commodification of living things (particularly the human body and the human genome) on the grounds that living matter is part of the 'Heritage of Humanity and Nature in general' and should not be 'classified as private property'; animal rights and welfare; environmental safety; the interests of European farmers; and, finally, anxieties over the impact of 'bio-piracy' and 'bio-colonialism' on the developing world.

38 Where, in such a range of views, can we find a distinction between open and closed ethical pluralism?

39 First, we should set to one side those self-interested (prudential) views that were pressed on the regulators. Often commercially-driven views will be presented as representing the public interest or as protecting jobs, and the like; but, at root, the arguments are prudential and political.[36]

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33 Decision *Onco-mouse/Harvard*, 14 July 1989 (OJ EPO 11/1989, 451; [1990] 1 EPOR 4. Initially, the examiners did not see the application as raising an issue under Art 53(a) of the European Patent Convention ("EPC"). Rather, they rejected the application on the grounds: (i) that there had not been sufficient disclosure of the working of the invention (as required by Art 83 of the EPC); and (ii) that Art 53(b) excluded the patenting of "animal varieties". It was only when the case was referred to the Board of Appeal that the centrality of Art 53(a) was recognised: see EPO Decision T 19/90 (OJ EPO 12/1990, 476; [1990] 7 EPOR 501).

34 Case G 0002/06, 25 November 2008.

35 Gerard Porter, "The Drafting History of the European Biotechnology Directive" in *Embryonic Stem Cell Patents* (Aurora Plomer & Paul Torremans eds) (Oxford: Oxford University Press, 2009) p 3 at p 13.

36 See Deryck Beyleveld & Roger Brownsword, *Mice, Morality and Patents* (London: Common Law Institute of Intellectual Property, 1993).

40 With these prudential views filtered out, we are left with the genuinely ethical judgments. Now, we can start at any point in the bioethical triangle and, from there, construct a view about the patentability of human gene sequences. If we start with utilitarian criteria, we will have no categorical objection against treating human gene sequences as patentable. The only issue will be whether this serves to promote utility. Similarly, if we start with human rights as our criterion, we will see no problem about patentability provided that those who have participated in the research (for example, those who have provided tissue to the researchers) have given their informed consent.[37] However, if we start with dignitarian criteria, we are likely to regard the patenting of human genetic material as a commodification (or commercialisation) of the human body and thus categorically wrong. Indeed, what caused so much difficulty in the passage of the Directive was that a group of dignitarians in the European Parliament frustrated the largely utilitarian proposals that were made by the Commission. With the parties deeply opposed in this way, we have a case of open ethical pluralism.

41 However, in the patentability debates, we can also encounter cases of closed ethical pluralism. For example, although utilitarians might generally support the idea that modern biotechnology should be treated as patentable, they have concerns that the patent system should not become counter-productive and put unjustifiable obstacles in the way of downstream researchers – they are all too aware that patent thickets and broad patents can lead to a tragedy of the anti-commons.[38] And, indeed in the Myriad case, it seems that Judge Sweet was moved to revoke the patents for just this kind of reason. Similarly, while those who argue from human rights will in general be disposed to permit the patenting of biotechnologies that enhance the autonomy of agents, they might worry that, in practice, consent protocols are not properly observed and this might encourage a more restrictive view. Where there are internal differences of this kind, arising within a particular ethical approach, we have a case of closed ethical pluralism. First principles are agreed but not their application in a particular case.

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37 For discussion of the controversial decision of both the Opposition Division in *Howard Florey/Relaxin* [1995] EPOR 541 and the informed consent challenge to Directive 98/44/EC (in *Kingdom of the Netherlands v European Parliament and Council of the European Union* Case C-377/98, see Beyleveld & Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford: Oxford University Press, 2001) ch 9.

38 See, *eg*, Michael A Heller & Rebecca S Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" Science 1998; 280(5364): 698–701; and Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (London, 2002).

IV. Closed ethical pluralism and the community of rights

42 In this part of the article, the way closed ethical pluralism can be handled within the setting of what the author calls a "community of rights" will be discussed. Firstly, the salient features of a community of rights will be outlined; then the range of differences (the closed ethical pluralism) that can arise within such a community will be indicated; and, finally, it will be suggested how deliberative democracy is compatible with such a setting.

A. The salient features of a community of rights

43 The first mark of a community of rights is that it is a *moral* community. By this, it is meant that this is a community that holds its commitments sincerely and in good faith, that treats its standards as categorically binding and universalisable, with the standards themselves having an overall integrity and coherence. It is also, of course, a community that distinguishes itself from other instantiations of moral community by taking a rights-led approach.[39]

44 Secondly, as with any community of rational agents, in a community of rights there will be a deep commitment to protect the conditions that comprise the agency commons. We can argue about the details of this commons; but, for humans, it will include elements pertaining to our well-being (clean air and water, food, environmental integrity, and the like) and our freedom (security, an absence of fear and intimidation, and so on). Quite simply, without the commons, there can be no community.[40]

45 Thirdly, the community of rights is committed to a master principle that governs interactions and transactions between agents – that is, that governs life on the commons. This master regulative principle requires that each agent respects the rights of one another to enjoy freedom and a basic level of well-being. Without respect for these (generic) rights, agents cannot freely choose and pursue their purposes; without such respect, agency cannot flourish. Ideal-typically, the community's deepest values and its guiding standards will be regarded as rationally justifiable (members viewing the guidance as a dialectically necessary entailment of agency). Having said this, for most practical

39 See, further, Roger Brownsword, "Making People Better and Making Better People: Bioethics and the Regulation of Stem Cell Research" (2005) 1 Journal of Academic Legal Studies 3; and "Cloning, Zoning and the Harm Principle" in *First Do No Harm* (S A M McLean ed) (Ashgate, 2006) at p 527.

40 See, further, Roger Brownsword, "Friends, Romans, and Countrymen: Is There a Universal Right to Identity?" (2009) 1 Law Innovation and Technology 223.

purposes, it matters little how a community that is committed to respect for the generic rights of agents arrives at this position.[41]

46 Fourthly, following on from the previous point, the author conceives a community of rights as a society that views itself as a process rather than a finished product. By this, it is meant that it is a community that constantly keeps under review the question of whether the current interpretation of its commitments is the best interpretation – similarly, whether the way that it responds to cases of competing or conflicting rights claims is the best response. There is also an awareness by members of their limited knowledge and understanding; members do not regard themselves as morally omniscient; what seems like the best interpretation or response today might look less convincing tomorrow.

47 Fifthly, if we imagine a community of rights within the setting of a modern nation State, then the community will need to be politically organised so that it is geared for collective decision-making (concerning, for example, economic and trade policy, social policy and foreign policy). Whatever the policy focus, however, decision-making will be constrained by the overriding requirement that the physical and psychological well-being of agents is to be protected and that each agent should be given the space and opportunity to lead their own life in their own way.

48 Sixthly, in a community of rights, the discourses of ethics and of regulation are regarded as both contiguous and continuous. Debates about the ethics of rights flow straight into the regulatory consciousness; and regulatory reflection on rights flows back into ethical debate.[42] It is not enough that regulation is effective and fit for purpose; the first priority is that regulators should have the right purposes (rights-respecting purposes) and that the regulatory standards that are

41 Compare, *eg*, the position staked out by James Griffin, *On Human Rights* (Oxford University Press, 2008). At p 149, Griffin summarises his position thus:

> Human rights are protections of our normative agency … Normative agency has [three] stages. The first stage consists in our assessing options and thereby forming a conception of a worthwhile life … characteristically [amounting to] piecemeal and incomplete ideas about what makes life better or worse. That is … 'autonomy'. [Secondly] to form and then to pursue that conception, we need various kinds of support: life itself of course, a certain level of health, certain physical and mental capacities, a certain amount of education, and so on … [Thirdly, autonomy together with such minimum provision] are not enough for agency if others then stop us; we must also be free to pursue that conception … All human rights will then come under one or other of these three overarching headings: autonomy, welfare, and liberty. And those three can be seen as constituting a trio of highest-level human rights.

42 Compare Roger Brownsword, "Bioethics: Bridging From Morality to Law?" in *Law and Bioethics* (Current Legal Issues vol 11) (Michael Freeman ed) (Oxford University Press, 2008) at p 12.

set are legitimate relative to the community's rights values. In a community of rights, regulation, like ethics, is an enterprise that is dedicated to doing the right thing; and the thing that is right is the protection, preservation and promotion of the community's commitment to rights.

49 Finally, it should be said that, even with these shared characteristics, there is considerable margin for each community of rights to express and articulate its commitments in its own way – for example, from one community to another, there might be different views about the status of non-paradigmatic rights-holders, and especially so in relation to the details of the array of recognised rights.[43] This takes us to the next part of our elaboration of pluralism in such a community.

B. Ethical pluralism in a community of rights

50 Although agents within a community of rights start with the same ethical principles, there are many ways in which they can reasonably disagree with one another – there are many opportunities, in other words, for debates that express closed ethical pluralism to arise. Without attempting to be exhaustive, some of the more pressing and recurring questions to be addressed, debated and (at least, provisionally) resolved within a community of rights are the following.

51 Firstly, there is a large cluster of questions concerning which rights (negative and positive) are to be recognised and what the scope of particular rights is.[44]

52 Secondly, there are questions arising from conflicts between rights as well as from competition between rights-holders.[45] Sometimes the conflict might be between one kind of right and another – for example, between the right to privacy and the right to freedom of expression. At other times, there are competing rights – that is, cases where two rights-holders present with the same general right. If relative need is the criterion, this might facilitate an easy resolution where, say,

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43 Compare Deryck Beyleveld & Roger Brownsword, "Principle, Proceduralism and Precaution in a Community of Rights" (2006) 19 Ratio Juris 141.

44 Compare, *eg*, James Griffin, *On Human Rights* (Oxford University Press, 2008) ch 5 (on positive rights) and chs 12 and 13 (on the scope of the particular rights to life and death and to privacy).

45 Again, compare, *eg*, James Griffin, *On Human Rights* (Oxford University Press, 2008) ch 3 (which opens, at p 57, with the insightful remark that there "is no better test of an account of human rights than the plausibility of what it has to say about rights in conflict", and that there "is no better way to force thought about human rights to a deeper level than to try to say something about how to resolve conflicts involving them").

a seriously ill person claims a right to the one available hospital bed in competition with a less ill person. Inevitably, however, there will also be hard cases where good faith (but nevertheless hard) choices have to be made.

53 Thirdly, because consent is an extremely important dynamic in a community of rights, the community needs to debate the terms on which a supposed "consent" will be recognised as valid and effective. In particular, how does the community interpret the requirement that consent should reflect an unforced and informed choice, and how is consent to be signalled (will an opt-out scheme suffice, for instance), and so on?[46]

54 Fourthly, a community of rights must debate whether there are limits to the transformative effect of the reception of rights.[47] In particular, this invites reflection on the relationship between one community of rights and another.[48]

55 Finally, there is the vexed question of who has rights.[49] Do young children, foetuses, or embryos have rights? What about the mentally incompetent or the senile? And, then, what about non-human higher animals, smart robots, and, in some future world, hybrids and chimeras of various kinds? Each community of rights must debate such matters, responding to the inclusionary question (who has rights?) as well as determining its approach to those life-forms that are to be excluded.

C. Deliberative democracy in a community of rights

56 Suppose that, in a particular community of rights, there are different views about the regulatory position that should be taken up with regard to the use of human embryos for research. Some believe that, so long as we cannot be confident about the agency status of a human embryo, or so long as there are grounds for thinking that induced pluripotent stem cells might be an adequate alternative to human embryonic stem cells, we should take an extremely precautionary approach; others believe that, so long as the community

46 See, further, Roger Brownsword, "The Cult of Consent: Fixation and Fallacy" (2004) 15 King's College Law Journal 223; and Deryck Beyleveld & Roger Brownsword, *Consent in the Law* (Oxford: Hart, 2007).

47 Compare Deryck Beyleveld & Shaun Pattinson, "Horizontal Applicability and Direct Effect" (2002) 118 Law Quarterly Review 623.

48 Compare, *eg*, Thomas Pogge, "Aligned: Global Justice and Ecology" in *Reconciling Human Existence with Ecological Integrity* (Laura Westra, Klaus Bosselmann & Richard Westra eds) (London: Earthscan, 2008) at p 147.

49 Again, compare, *eg*, James Griffin, *On Human Rights* (Oxford University Press, 2008) ch 4.

accepts that couples have the right to create human embryos for assisted reproductive purposes, it must be permissible to use surplus embryos for research purposes; and others believe that it is permissible to create and then use human embryos for research purposes provided that this takes place before the appearance of the primitive streak or 14 days (after the first cell division), whichever is earlier. In each case, it must be emphasised, those who hold these different views – views that indicate a range of legitimate regulatory positions from prohibitory to permissive – believe that their judgments are, at the very least, compatible with their baseline rights commitments.

57 Would it make sense for such a community to attempt to settle its differences by a process of deliberative democracy? As has been said above, it is characteristic of a community of rights that it is an interpretive community, constantly re-examining its best understanding of its commitments, eschewing claims to moral omniscience, and placing great practical weight on process. Clearly, in such a community, debate and deliberation is necessarily part of its daily life; and, so far as possible, because the views of each agent count, these debates need to be inclusive. In short, the model of deliberative democracy fits very neatly the constitutive ideals of a community of rights.

58 In this article, the question of the detailed design of deliberative democracy cannot be entered into and, in a sense, there is no need to do so; for, each community of rights will strive, in its own way, to adopt a model of deliberative democracy that best serves its interpretive and decision-making requirements. One thing that it will need to do, however, is to establish how the deliberations and recommendations of expert groups (whether those groups are experts in the life sciences, in the social sciences, in ethics, and so on) can be integrated into larger consultative and deliberative processes. No doubt, this challenge will be very much in the mind of Professor Gutmann's expert group as they begin their deliberations on the social and ethical implications of synthetic biology.

59 In this light, if we consider the hypothetical scenario sketched above, we might think that some of the issues invite the attention of expert groups – for example, expert groups might be asked to advise on the possibility of a human embryo being a locked-in agent, or on the potential utility of induced pluripotent stem cells, or on the significance of the appearance of the primitive streak (relative to the community's rights commitments), or on the cogency of the belief that permitting the creation of human embryos for reproductive purposes entails the permissibility, too, of using such embryos that are now surplus to reproductive requirements for research purposes. However, there is no straightforward line that divides questions for experts from questions for the community at large. Where experts are themselves divided on an

issue or simply uncertain, the community needs to debate the appropriate response – especially concerning they way that a precautionary principle should be applied to deal with uncertainty.[50]

60 Whatever the particular design that is adopted, there must be a process for re-examination and review of decisions that have been taken; in this sense, regulatory determinations must be treated as provisional. So, to take another example, in the UK there has been an anxious debate about the measures adopted to prevent early onset neonatal group B streptococcal ("GBS") disease. The disease is potentially fatal and so the stakes are high. Critics of the UK's risk-factor approach argue that pregnant women should be routinely screened for GBS carriage (as they are in the US and in a number of other countries). However, quite apart from any other considerations, the evidence concerning the effectiveness of screening relative to non-screening alternatives is open to competing interpretations. Hence, a population-based study in the US concluded that antenatal bacterial screening for GBS carriage significantly decreases the risk of early-onset GBS as compared to risk-based screening. Yet, the incidence of neonatal sepsis attributed to GBS in the UK (without screening) is similar to the rate in the US (with screening) and, in both cases, vaginal carriage rates are comparable.[51] After careful consideration of the matter at a workshop that was held in 2003, the UK National Screening Committee decided against recommending screening for GBS. That decision was re-examined at another more recent workshop and duly reaffirmed. In the spirit of deliberative democracy, the Committee needs to treat its decision as provisional and reviewable in the light of fresh evidence or fresh argument; and opponents, while reserving the right to challenge the determination, should respect it for the time being.[52]

61 There is one other point: even in conditions of closed ethical pluralism, regulatees can reasonably expect their regulators to be sensitive to the range of views articulated in deliberative processes. In particular, regulators should be sensitive to the way in which permitted actions can be finessed. For example, to return to the case of using

50 For discussion, see Deryck Beyleveld & Roger Brownsword, "Complex Technology, Complex Calculations: Uses and Abuses of Precautionary Reasoning in Law" in *Evaluating New Technologies: Methodological Problems for the Ethical Assessment of Technological Developments* (Marcus Duwell & Paul Sollie eds) (Springer, 2009) at p 175.

51 See, Stephanie J Schrag *et al*, "A Population-Based Comparison of Strategies to Prevent Early-Onset Group B Streptococcal Disease in Neonates" New England Journal of Medicine 2002; 347(4): 233–239. And, for comparable rates, see Royal College of Obstetricians and Gynaecologists ("RCOG") Guidelines, guideline 36 (prevention of early onset neonatal group B streptococcal disease) 2003.

52 For a position paper on this issue, see Roger Brownsword & Da Lin, "Initiating New Screening Procedures: Principles, Policy, and Pressure" (TELOS, London, July 2008) (on file with author).

human embryos for research purposes, the headline question for regulators is whether such research should be prohibited, permitted or even required. Where, as is the case in many regulatory regimes, the decision is some form of permission, we know that the permission can be broad or quite limited (concerning the type of embryos that are available to researchers as well as the purposes for which research may be pursued). However, where an activity is permitted, regulators also need to decide whether they will then set the permission with a positive, neutral or negative tilt. There is a difference between signalling to researchers that the use of human embryos is permitted and signalling not only that this is permitted but also that it is encouraged (notably through the patent system) or incentivised (for example, through the tax regime).[53] Where there is significant opposition to the use of human embryos for research, one way in which regulators might think it appropriate to show that they respect the views of such opponents is by doing no more than permitting this research activity.

V. Open ethical pluralism, convergence and non-convergence and the final regulatory appeal

62 In this part of the article, one further distinction is drawn, this being between "convergent" and "non-convergent" viewpoints in a context of open ethical pluralism. Where deliberative democracy generates an agreed regulatory position (even though the underlying reasons for agreement are varied), we have convergence; and this is the basis for a workable accommodation of the competing ethical views. However, where there is no such convergence, it is unclear how regulators are to enjoin respect for the position that is taken. Here, it is suggested that the final appeal that regulators can make is that they are, at least, trying to do the right thing and that a community so regulated merits more respect than one regulated without any moral aspirations. In other words, we reach the limits of deliberative democracy where, in a context of open ethical pluralism, there is no convergent regulatory position.

53 Compare Roger Brownsword, "Tax Exemption, Moral Reservation, and Regulatory Incentivisation" (2010) 3 European Journal of Risk Regulation 219 discussing, *inter alia*, Case C-262/08 (the *CopyGene* case) and Case C-86/09 (the *Future Health Technologies* case). In these cases, the question was whether private cord-blood banking activities were tax exempt. The European Court of Justice denied that the activities in question failed to come within the terms of the exemptions that were pleaded but this was not ostensibly because of the moral controversy that surrounds cord-blood banking.

A. Convergent and non-convergent outcomes

63 In conditions of open ethical pluralism, processes of deliberative democracy can lead to both convergent and non-convergent outcomes. Sometimes, even though the protagonists apply very different principles, they will agree that some action or practice should be treated as permissible (or prohibited, as the case may be). In such a case of convergence, the application of rival ethical principles leads to a common position. Although the protagonists remain disagreed as to baseline principles, in the particular case they agree as to the outcome; and, in practice, this gives regulators a clear steer. However, in ethics, as in life more generally, where one starts typically exerts a strong influence over where one finishes; and, different starting points in ethics can lead to different finishing points. In other words, the application of different baseline principles can lead to non-convergent results. Where this is the case, regulators have no easy practical steer.[54]

64 A textbook illustration of the distinction between convergent and non-convergent outcomes can be seen in the attempts made by the United Nations ("UN") to agree a position on human reproductive cloning and non-reproductive therapeutic cloning. After some four years of deliberation, and notwithstanding open ethical pluralism, all 191 members of the UN supported a prohibition on human reproductive cloning. However, there was no such consensus in relation to therapeutic cloning. On 18 February 2005, the Legal Committee voted 71 in favour, 35 against, with 43 abstentions, to recommend to the General Assembly that Members should be called on "to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life".[55] Even with the recommendation drafted in this ambiguous form – the phrase "inasmuch as they are incompatible with human dignity and the protection of human life" is pregnant with ambiguities[56] – the Members were unable to achieve a consensus. On 8 March 2005, the General Assembly accepted this recommendation, 84 members voting in favour of the (non-binding) UN Declaration on Human Cloning, with 34 against and 37 abstentions.[57]

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54 Compare Roger Brownsword, "Stem Cells and Cloning: Where the Regulatory Consensus Fails" (2005) 39 New England Law Review 535.

55 See United Nations ("UN") press release GA/L/3271 at <http://www.un.org/News/Press/docs/2005/gal3271.doc.htm> (accessed 1 October 2010).

56 See, further, Roger Brownsword, "Ethical Pluralism and the Regulation of Modern Biotechnology" in Biotechnologies and International Human Rights (Francesco Francioni ed) (Hart, Oxford, 2007) at p 45.

57 See UN press release GA/10333 at <http://www.un.org/News/Press/docs/2005/ga10333.doc.htm> (accessed 1 October 2010).

65 To some extent, the drafting of the UN Declaration on Human Cloning represents a regulatory "fudge" and we can see this kind of response even more strikingly in the eventual form of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions. While Art 5 of the Directive responds to utilitarian arguments by clearing the way for the patenting of inventive work on the human genome, Arts 6(1) and 6(2), in conjunction with a number of the Recitals, respond to dignitarian concerns by placing moral limits on patentability. As a result, disputes about the patentability of biotechnology draw out an underlying tension between these different parts of the Directive. Thus, we find the European Patent Office ("EPO") agonising about the patentability of the processes and products associated with human embryonic stem cell research.[58] If the EPO applies its general approach, it will ask whether there is an overwhelming consensus in Europe that the use of human embryos for stem cell research is immoral. To which, the answer, of course, is that there is no such consensus – Europe could scarcely be more divided.[59] Given such a plurality, the EPO's general approach indicates that it should decline to rule against the patentability of innovative human embryonic stem cell work. On the other hand, the EPO also has to contend with the prohibitions listed in Art 6(2) of the Directive (now incorporated in the European Patent Convention ("EPC") Rules that govern the EPO's work). So far as is material, this Article provides:

> On the basis of paragraph 1 [*ie*, Art 6(1)], the following, in particular, shall be considered unpatentable:
>
> (a) processes for cloning human beings;
>
> (b) …;
>
> (c) uses of human embryos for industrial or commercial purposes;
>
> (d) ….

58 See, *eg*, Graeme Laurie, "Patenting Stem Cells of Human Origin" [2004] European Intellectual Property Review 59; and, for a general overview, see Aurora Plomer & Paul Torremans eds, *Embryonic Stem Cell Patents* (Oxford: Oxford University Press, 2009).

59 See, *eg*, see Samantha Halliday, "A Comparative Approach to the Regulation of Human Embryonic Stem Cell Research in Europe" (2004) 12 Medical Law Review 40; Rosario M Isasi & Bartha M Knoppers, "Towards Commonality? Policy Approaches to Human Embryonic Stem Cell Research in Europe" in *Embryonic Stem Cell Patents* (Aurora Plomer & Paul Torremans eds) (Oxford: Oxford University Press, 2009) at p 29; and Josef Kuře, "Human Embryonic Stem Cell Research in Central and Eastern Europe: A Comparative Analysis of Regulatory and Policy Approaches" in *Embryonic Stem Cell Patents* (Aurora Plomer & Paul Torremans eds) (Oxford: Oxford University Press, 2009) at p 57.

66 Arguably, prohibitions (a) and (c) might cover stem cell work;[60] and, even if they do not fit, there is still the background question of whether the relevant processes and products should be declared unpatentable on the ground that they compromise human dignity.

67 In the *Wisconsin Alumni Research Foundation* ("WARF") case,[61] the Enlarged Board of Appeal ("EBA") was asked by the Technical Board of Appeal[62] to rule on four questions of law – one of which was whether Art 6(2)(c), as incorporated in the EPC Rules, forbids the patenting of a human embryonic stem cell culture which, at the time of filing, could be prepared only by a method that necessarily involved the destruction of human embryos (even though the method in question is not part of the claim). Treating this as an exercise in interpretation of a particular rule, rather than a more general essay in European morality, the EBA said:[63]

> On its face, the provision … is straightforward and prohibits the patenting if a human embryo is used for industrial or commercial purposes. Such a reading is also in line with the concern of the legislator to prevent a misuse in the sense of a commodification of human embryos … and with one of the essential objectives of the whole Directive to protect human dignity …

68 Then, responding to the argument that this prohibition applies only where the use of human embryos is within the terms of the claim, the EBA said:[64]

> [T]his Rule … does not mention claims, but refers to 'invention' in the context of its exploitation. What needs to be looked at is not just the explicit wording of the clause but the technical teaching of the application as a whole as to how the invention is to be performed. Before human embryonic stem cell cultures can be used they have to be made. Since in the case referred … the only teaching of how to perform the invention to make human embryonic stem cell cultures is the use (involving the destruction) of human embryos, this invention falls under the prohibition of [the Rule] … To restrict the application of [the Rule] to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim.

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60 For the national implementation of this provision, see Åsa Hellstadius, "A Comparative Analysis of the National Implementation of the Directive's Morality Clause" in *Embryonic Stem Cell Patents* (Aurora Plomer & Paul Torremans eds) (Oxford: Oxford University Press, 2009) at p 117.

61 Case G 0002/06 (25 November 2008).

62 T 1374/04 (OJ EPO 2007, 313).

63 Case G 0002/06 (25 November 2008) at para 18.

64 Case G 0002/06 (25 November 2008) at para 22.

69 Finally, rejecting the argument that human embryos were not actually being used for commercial or industrial purposes, the EBA held that, where the method of producing the claimed product necessarily involved the destruction of human embryos, then such destruction was "an integral and essential part of the industrial or commercial exploitation of the claimed invention";[65] and, thus, the prohibition applied and precluded the patent. If we want to know where we stand, the present state of the EPO's jurisprudence reminds us that a regulatory fudge is unlikely to be helpful.

B. The limits of deliberative democracy

70 Where there is no convergent outcome, how are regulators to justify their position? As we have seen, some form of deliberative democracy argument might be offered as the answer. In addition to Gutmann and Thompson's advocacy of deliberative democracy,[66] a procedural approach of this kind has been sponsored by such influential theorists as John Rawls[67] and Jürgen Habermas,[68] these thinkers trumpeting the virtues of deliberative democracy, public reason and the quest for an overlapping consensus at the commanding heights of the regime. The basic idea is very simple: if a society is to get away from trench warfare between the rival constituencies, the protagonists have to relax their positions and come to the table to talk their way to a reasonable accommodation.

71 Although this high theory of proceduralism comes with an impeccable pedigree, under conditions of open ethical pluralism, it might seem a pretty unlikely story. Granted, the diagnosis is sound: for, in a context of pluralism, the problems of stability and authority are most acute when the law takes sides on opposed moral positions; and it is in just these circumstances that a legitimacy crisis is prompted. However, the proceduralist response (as the earlier Rawls might have expressed it) puts too great a strain on the parties. Quite simply, if the protagonists and pluralists are to bargain their way to a solution, where the only force is the Habermassian force of the better argument, then something very fundamental has to give. What the proceduralists ask of the disputants is not that they should give an inch or two but nothing less than that they should abandon their deepest (but incompatible) moral convictions – that is, those very beliefs that are the source of the instability, and which, if insisted upon, would fatally obstruct a

65 Case G 0002/06 (25 November 2008) at para 25.

66 Amy Gutmann & Dennis Thompson, *Why Deliberative Democracy?* (Princeton: Princeton University Press, 2004).

67 John Rawls, *Political Liberalism* (New York: Columbia University Press, 1993).

68 Jürgen Habermas, *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy* (trans by William Rehg) (Cambridge Mass: MIT Press, 1996).

consensual accommodation of all reasonable viewpoints, or of principles that could not be reasonably rejected.[69] This is quite a price and the question is: why would it be rational for morally divided agents to accept such a procedural demand? For, it is surely an unstated premise of proceduralism that, given the right bargaining situation, it can be rational for persons to consent to being governed by a framework that might produce rules and decisions that go contrary to what those persons believe to be morally acceptable. On the face of it, the only setting in which it might be rational to give ground in this way is where, from the viewpoint of each constituency, the consequences of accommodation better serve one's moral ideals than the consequences of standing firm.

72 Where these conditions do not obtain, then, while procedural integrity is important, it can only reach so far in a context of entrenched pluralism. If the outcome of the process is a regulatory decision that offends deeply held ethical convictions, procedural propriety (particularly the claim that all viewpoints were "fully taken into consideration") cannot bear the burden of justification. For, as Frank Michelman[70] has convincingly pointed out, those of the relevant ethical conviction will not accept the process as legitimate unless certain outcomes are either vouchsafed or excluded by the terms of reference – and, where we are dealing with hard cases, this is simply too hard to do.[71]

73 In short, in a context of open ethical plurality, it seems that a procedural strategy will not overcome the legitimacy crisis unless (a) for each set of protagonists, (b) relative to its own distinctive ethical lights, (c) it is judged that the constituency's ethical commitments are better served by an adjustment of position and by reaching an

69 Compare Scanlon's contractualist approach. In T M Scanlon, "The Aims and Authority of Moral Theory" (1992) 12 Oxford Journal of Legal Studies 1 at 5, Scanlon conceives of a moral wrong in the following terms: "[A]n act is morally wrong just in case it would be disallowed by any principles that no one could reasonably reject if they were seeking principles which could be the basis of informed, unforced general agreement." Then at 11:

> According to my version of contractualism, for example, we have reason not to be cruel to people or to break our promises to them because such actions would not be allowed by principles that they could not reasonably reject.
>
> Despite the multiple negatives in these formulations, the governing principles seem to be those that we could not reasonably reject if we hoped to achieve a consensus as to our governing principles. This is saying something more than that we are bound by reasonable principles; but, so long as the test hinges on disputants having a reasonable attitude (in the context of a desire to achieve consensus), it is not altogether clear precisely what or how much is being asked of parties, except that it is a great deal.

70 Frank I Michelman, "Constitutional Legitimation for Political Acts" (2003) 66 MLR 1.

71 See Roger Brownsword, "Regulating Human Genetics: New Dilemmas for a New Millennium" (2004) 12 Medical Law Review 14.

accommodation with one another rather than by unreflectively standing one's ground. Where these conditions are not met, the persuasive force of proceduralism will be seriously diminished; and any attempt to defend a regulatory position by reference to the integrity of the process is liable to be rejected as defective.

C. The final regulatory appeal

74 Where, in conditions of open ethical pluralism, there is no convergent outcome and where the reason for non-convergence goes back to the baseline principles (rather than some empirical question), how are regulators to present their position as legitimate? To exhort reasonableness is to deny the deep plurality. To claim that a particular accommodation serves the parties' rival ethical views better than any alternative is again to deny the depth of the plurality. Rather, in such circumstances, it is suggested that the final appeal that regulators can make runs along the following lines: we are all committed to a moral community; we are all trying to do the right thing; but we have different baselines principles and, in this instance, the application of those principles lead us to different (and incompatible) views; we cannot regulate in a way that is compatible with all views but a regulatory position needs to be taken; there will be an opportunity to revisit the issue; but, in the interim, we ask regulatees to respect the position that has been taken.

75 Essentially, regulators, in this final appeal, are attempting to keep the moral community together (even though it is a pluralistic community) in the hope that regulatees will judge that this will better serve their moral aspirations than the alternative – namely, a divided and fragmented moral community that can be overtaken by regulators who take moral considerations much less seriously. This is by no means a hopeless appeal for it is all too easy to see how a regulatory discourse that excludes or collateralises moral considerations can take hold.[72] "Divide and rule" is an ancient maxim that still has a modern resonance.

76 There is one other consideration that lends support to the regulators' appeal. Developments in the life sciences, and in emerging technologies more generally, offer regulators new instruments of social control. Unlike traditional normative instruments of control (characteristic of legal rules and ethical principles), these new instruments place much greater emphasis on prudential calculation than on moral considerations and, in *extremis*, they simply eliminate all but the options that regulators wish to permit.

72 See Roger Brownsword, "Human Dignity and Nanotechnologies: Two Frames, Many Ethics" (Bielefeld Handbuch, 2010) (forthcoming).

77 To spell this out a little more,[73] the key changes occur in two stages. First, in the criminal justice or other security-focused systems (such as airports), with the use of CCTV, DNA profiling, RFID tracking and monitoring devices, and the like, the message to regulatees is that the chances of detection (and correction) are significantly increased. The primary signal of the classical criminal code is still moral (these acts are prohibited because they are wrong) but, with the introduction of these technologies, the secondary prudential signal is amplified. At the second stage, however, technologies are employed in ways that render deviation either impracticable or, in a future of perfect control, impossible. In this future, constitutive technologies, like the coding of software or the design of buildings, become the model for social control. At this stage, the regulatory environment is corrosive not just of moral agency but of agency and autonomy *simpliciter*.[74]

78 Now, even in conditions of open ethical pluralism, there is the common ground of moral aspiration; and that aspiration is that agents should do the right thing and that they should do it for the right reason. Securing an apparently moral act by a technical fix devalues the act. Agents who have no choice other than to do *x*, merit neither praise nor blame for the doing of *x*. If a community, despite its ethical pluralism, is to persist with its moral aspirations, then members need to come together to protect the conditions that are essential for that aspiration to be realised. So long as regulators are sensitive to the importance of the contextual conditions for moral community, the final appeal has an added force.

79 A coda can be added that connects this part of the article to the vexed concept of human dignity, a concept that has proved so troublesome in modern bioethics. Some might wonder whether it really matters whether agents act on the right reasons.[75] After all, if the application of these regulating new technologies produces a pattern of behaviour that is in line with moral requirements, if the pattern is of people doing the right thing, does it really matter why they do it? To be sure, if humans were morally omniscient, and to the extent that moral requirements were beyond question, we might well reason that it would not matter. Indeed, even absent moral omniscience, we might reason that, where moral requirements are agreed, it does not matter – for example, why should it matter whether train drivers respect the life and

73 See Roger Brownsword & Han Somsen, "Law, Innovation and Technology: Before We Fast Forward – A Forum for Debate" (2009) 1 Law Innovation and Technology 1.

74 Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: Oxford University Press, 2008) especially chs 9–10. And, compare, Mireille Hildebrandt & Bert-Jaap Koops, "The Challenges of Ambient Law and Legal Protection in the Profiling Era" (2010) 73 Modern Law Review 428.

75 See Roger Brownsword, "Brain Science in the Regulatory Spotlight" Science in Parliament 2010; 67(2): 18.

well-being of their passengers by freely choosing to stop when the signals are on red, or whether they stop because the train is designed in such a way that it cannot pass signals that are on red?[76] However, for communities with moral aspirations, the moral development of humans does matter; and the much-maligned idea of human dignity can be understood as being precisely about humans trying to do the right thing in the face of opportunities to do the wrong thing. This is not to say that we should turn our backs on emerging technologies. Far from it; we want to enjoy the benefits of the technologies; but we also need room for moral debate and development. In the coming decades, a major question for deliberative democracy will be: How do we create regulatory environments that employ smart technologies to safeguard and promote vital human interests while still cultivating the virtue of human dignity, of doing the right thing for the right reason?

VI. Conclusion

80 Developments in the life sciences are accelerating and they provoke a wide range of views. There is a problem with plurality, particularly with ethical plurality. How far is deliberative democracy the answer to this problem? In part, the answer depends upon what kind of plurality we are presupposing. Is it prudential or ethical? If ethical, is it closed or open? In part, the answer depends upon why it is that people disagree. Is it because they have competing baseline ethical principles? Is it simply a matter of preferences? Or, is it because of some empirical question? In part, too, the answer depends upon whether public engagement and debate leads to convergent or non-convergent outcomes. Some cases are going to be more difficult than others. It has been suggested that the most difficult case is that of open ethical pluralism where there are non-convergent outcomes.

81 In a community of rights, where there is closed ethical pluralism, there can be some difficult cases. Sometimes, members will judge that regulators have gone wrong. Nevertheless, assuming that there is no suggestion of regulatory corruption, bad faith or neglect, regulatees should exercise restraint. In this community, it is understood that the application of the shared baseline principles is not always straightforward and that decision-making processes (and their outcomes) need to be respected.[77]

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76 There is a great deal that can be said about such a technological fix, especially where it is targeted at unintentionally harmful conduct. See, further, Roger Brownsword, "So What Does the World Need Now? Reflections on Regulating Technologies" in *Regulating Technologies* (Roger Brownsword & Karen Yeung eds) (Oxford, Hart, 2008) at p 23.

77 For the underlying theory of regulator accountability and regulatee restraint, see Deryck Beyleveld & Roger Brownsword, *Law as a Moral Judgment* (London: Sweet

(*cont'd on the next page*)

82 What can be done to respond, though, to the most difficult case? This is, indeed, a tough nut to crack. It might well be that, in the larger picture, the non-convergent outcome that puts the regulatory position in the spotlight is relatively exceptional and that, while it is a matter for continuing debate, it is not a cause of destabilisation. In other cases, though, where the pluralism is chronic, acute cases of conflict might agitate unrest or even segregation or separation. To avoid such destabilising consequences, the author has suggested that the final appeal that regulators can make is to the shared (generic) moral aspirations of the community. There is no guarantee that regulatees will respond positively to this appeal; but, if clearly articulated, it should at least give regulatees pause. Deliberative democracy might not be *the* answer to all cases of ethical pluralism; but, if we are to develop fitting regulatory frameworks for the practice of the life sciences, we could do much worse than follow the lead given by Professor Gutmann.

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and Maxwell, 1986) (reprinted by Sheffield Academic Press in 1994), and "Principle, Proceduralism and Precaution in a Community of Rights" (2006) 19 Ratio Juris 141.