Communicating European Citizenship

London, 22 March 2010

www.uaces.org

EU CITIZENSHIP DISCOURSE AS NEOLIBERAL GOVERNMENTALITY: THE EXAMPLE OF CITIZEN PARTICIPATION IN THE GOVERNANCE OF NEW TECHNOLOGIES

MARK L. FLEAR*

ABSTRACT

This paper shows EU citizenship discourse to be an instance of neoliberal governmentality. Discourses on law, official EU documents on citizen participation in governance and citizen/science relations, the 'public understanding of science and technology', and risk, construct citizens in a 'deficit model' as being in need of education through their participation in governance. The discourse stymies oppositional formations since citizens are deemed incapable of sharing power to govern new technologies. This construction suggests citizen participation is a legitimating technique. The paper also outlines some discourses that can be used to combat neoliberal governmentality and promote citizen participation.

Keywords: Citizenship; Science and Technology; Advanced Therapies; Governmentality.

1. INTRODUCTION

In this paper I use the example of citizen participation in the regulation of new technologies, specifically advanced therapy medicinal products, to trace how EU discourse on citizenship is an instance of neoliberal governmentality. The latter neologism alerts us to that which organises the conduct of conduct.[1] In other words, the way in which knowledge provides the basis for various modes and techniques of governance that in late modernity are fused with and ordered by neoliberal political rationality.[2] The latter uses technical reason, means-end or instrumental rationality to disseminate and enhance optimisation of life through markets. This engenders biopolitics,[3] an arena in which the public can 'demand and contest' the exercise of power over life.[4] However, neoliberal governmentality employs a variety of legitimating techniques or 'technologies of hubris', including predictive methods such as risk assessment and management, but especially for present purposes, citizen participation, which are designed to support the regime and 'keep the wheels of science and industry turning'.[5] This use of citizen participation is noted by others, who point out how citizens are

* Lecturer in Law, School of Law, Queen's University Belfast (m.flear@qub.ac.uk). This paper is a work in progress and is not to be cited without the permission of the author. The paper is based on: Flear, 'The EU's Biopolitical Governance of Advanced Therapy Medicinal Products', 16(1) *M. J.* 113 (2009). The focus on neoliberal governmentality draws on: Flear, 'The Open Method of Coordination on Health Care After the Lisbon Strategy II: Towards a Neoliberal Framing?', 13(1) *European Integration online Papers* (2009). View online at: http://eiop.or.at/eiop/texte/2009-012a.htm. I gratefully acknowledge funding from the British Academy (award number SG-48186) for the project *EU Governance of AIDS, Cancer and Obesity: Governmentality, Citizenship and Polity*, which the paper contributes towards.

[1] M. Foucault, *The History of Sexuality: Volume One, The Will to Knowledge*, (Penguin, 1998), 202.

[2] Rose et al. describe this as "a way of doing things that…[is] oriented to specific objectives and that…[reflects] on itself in characteristic ways": N. Rose, Nikolas, P. O'Malley and M. Valverde, 'Governmentality', 2 *Annual Review of Law Society and Science* 83 (2006), 84.

[3] M. Foucault, *The History of Sexuality: Volume One, The Will to Knowledge*, 14 and 139; M. Foucault, *The Birth of Biopolitics: Lectures at the Collége de France, 1978–1979*, (Palgrave Macmillan, 2008), 186.

[4] S. Jasanoff, *Designs on Nature*, (Princeton University Press, 2005), 36.

[5] Jasanoff, 'Technologies of Humility: Citizen Participation in Governing Science', 41 *Minerva* 223 (2003), 238. Cf. Blue, 'Food, Publics, Science', 19(2) *Public Understanding of Science* 147 (2010).

often included in governance only when their actual participation is required, such as when their tissue is 'biobanked' or when they are the consumers of products based on new technologies.[6]

Advanced therapies provide a useful case study for two main reasons. First, hitherto there has been little activism around these sorts of technologies.[7] Second, citizen participation in governance is envisaged by the Regulation on Advanced Therapy Medicinal Products (the Regulation),[8] which came into force on 30 December 2008. The Regulation, which I sketch in Section 2, provides a *lex specialis* and amends EU regulation of medical products for human use.[9] The Regulation applies EU level quality and safety standards to, and thereby harmonises, products and treatments from innovative new health technologies such as gene-therapy, cell-therapy and tissue engineering. Although there is currently a 'dearth of product'[10] it is noted that 'patients of diseases such as cancer, Alzheimer's and muscular dystrophy, and those victims of burns requiring skin grafts are likely to benefit from imminent yet potentially controversial treatments'.[11] Other potential beneficiaries of the Regulation include HIV/AIDS sufferers.

Reflecting demands by biosocial associations and communities for greater involvement in biomedical research and the development of therapies,[12] the Regulation gives patients organizations membership of the Committee for Advanced Therapies (CAT). This European Medicines Agency (EMEA)[13] committee provides oversight of advanced therapies and reports to the Committee for Medicinal Products for Human Use (CMPHU). The process of seeking appointees to represent patients' *associations* (and clinicians) on the CAT was initiated by the EU Commission on 9 January 2008[14] and resulted in the selection of the European Genetic Alliances Network and the European Organisation for Rare Diseases to serve as patients organizations.

The immediate context for my concerns, therefore, is the ongoing concern about a 'democratic deficit'[15] in EU governance as it engages with life and new technologies. I accept and welcome the potential for citizen participation in the EU's governance of technology. Indeed, the highly uncertain risks associated with new technologies means decision making cannot be left exclusively to those traditionally deemed 'experts' – it should therefore include citizens, particularly those who are or could be most affected. Nevertheless, the discourses producing, organizing and orchestrating citizen participation provide limited means for citizens to demand and contest the exercise of that power. The discourses outlined in Section 2, are not found only in law, such as the Regulation, but also EU documents on citizen participation and citizen/science relations. These are inflected with the discourse on the 'public understanding of science and technology' (often referred to as PUS, that is,

---

[6] Andreasen and Hoeyer, 'DNA Patents and the Invisible Citizen: The Role of the General Public in Life Science Governance', 6(3) *SCRIPTed* 538 (2009).
[7] See further, Flear, 'The EU's Biopolitical Governance of Advanced Therapy Medicinal Products'.
[8] Regulation (EC) No 1394/2007, OJ L 2007 324/121 (Advanced therapy medicinal products).
[9] Amending Directive 2001/83/EC, OJ L 2001 311/67 (Community code relating to medicinal products for human use) and Regulation (EC) No 726/2004, OJ L 2004 136/1 (Laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency). Advanced therapies are subject to Directive 2001/20/EC, OJ L 2001 121/34 (Clinical trials).
[10] Roche, 'Advanced Therapies and the Outer Limits of DNA Regulation: New Horizons for Patents or a Scaffold Too Far?', 3 *Journal of Intellectual Property Law & Practice* 210 (2008), 210.
[11] Ibid., 212.
[12] Rose, *The Politics of Life Itself*, (Princeton University Press, 2007), 186.
[13] This began operating in February 1995, and was established by Regulation 2309/93/EC OJ L 1993 214/1. See further T. K. Hervey and J. V. McHale, *Health Law and the European Union*, (CUP, 2004), 290-291.
[14] Roche, 'Advanced Therapies and the Outer Limits of DNA Regulation: New Horizons for Patents or a Scaffold Too Far?', 212. An implementation plan for the Regulation has been agreed with the EMEA.
[15] The literature on the 'democratic deficit' is vast. For an overview of the debate surrounding agencies see: Scott, 'Accountability in the Regulatory State', 27 *J. L. S.* 38 (2000); F. Scharpf, *Governing in Europe. Effective and Democratic?*, (OUP, 1999); A. Arnull and D. Wincott, *Accountability and Legitimacy in the European Union*, (OUP, 2002).

without reference to technology, and so amended to PUST) and risk. Undergirding all these discourses is the liberal view of delegating regulation to trusted experts,[16] in which public trust is construed as passive and granted without the need for two-way negotiation and ongoing renewal. These discourses aid and abet each other in the production of a 'deficit model' of citizens in need of education. Such neoliberal citizens are supposed to tend to their own interests, and they are deemed incapable of sharing power with fellow citizens in order to change and organise their options. I argue that this is an insufficient basis for legitimacy in late modernity. Rather, it is vital governance fosters *active* trust through more genuinely participatory means and fora.[17] Without such engagement the distance between governors and the governed can be expected to grow.[18]

This problem of closure is augmented where citizens deploy these discourses in their self-governance. Individually and collectively the discourses constructing citizen participation de-politicize with the consequence that the phenomena and subjects produced by the discourses appear natural. This effect serves to remove or mask those phenomena from comprehension of their '*historical* emergence and from a recognition of the *powers* that produce and contour [them]'.[19] De-politicization further undermines oppositional formations. As a linked problem, citizens might unwittingly assist their subjectification unless the undemocratic aspects of the discourses they deploy are outmanoeuvred. In Section 3 I outline some elements for combating the 'deficit model' of citizens, enhancing participation in the governance of new technologies by fostering biosociality and solidarity, reducing the distance with governance, and, if taken seriously at the EU level, assisting in the generation of active trust.[20]

2. CONSTRUCTING THE 'DEFICIT MODEL' OF CITIZENS

2.1 LAW

The Regulation is concerned with single marketing authorisations for advanced therapies.[21] These include gene-therapy, cell-therapy and tissue engineering. The cells or tissues used in advanced treatments may, under the Regulation, come from the patient him/herself (they are autologous) or from another human being (they are allogeneic). In addition, the Regulation provides for therapies based on human or animal cells or tissues. These are understood as those which can potentially regenerate, repair, or replace human cells or tissues after being subjected to manipulation such that their usual functions are altered in order to render them usable in the recipient.[22] As an exception, advanced therapy medicinal products that are developed, prescribed and provided on a one-off basis in the same Member State for a hospitalised patient are excluded from the Regulation.[23] This is presumably because the regulation of such one-off cases would represent no additional benefit to the establishment and functioning of the Internal Market in terms of ensuring quality and safety of cross-border movement and trade in advanced therapies, and therefore could be disproportionate.

The Regulation modifies the EMEA, creating the CAT which makes recommendations that are passed up to the CMPHU for further consideration, and then up to the Commission for the final, formal decision.[24] In the event it disregards the CAT's opinion, the CMPHU must provide scientific

[16] Majone, 'The Credibility Crisis of Community Regulation', 38 *J. C. M. S.* 273 (2000).
[17] This paper does not go beyond suggesting discourses that are more participatory.
[18] See Jasanoff, *Designs on Nature*, 6.
[19] W. Brown, *Regulating Aversion*, (Princeton University Press, 2006), 15. Original emphasis.
[20] Of course, patients' organizations and activism have been of growing importance since the 1980s, and so are long present at a national level (where they are becoming more important). See: Rose, *The Politics of Life Itself*, 148.
[21] Cf. Farrell, 'The Politics of Risk and EU Governance of Human Material', 16(1) *M. J.* 41 (2009).
[22] Article 1.
[23] Article 28(2), amending Directive 2001/83/EC.
[24] In accordance with the principle of non-delegation established in *Meroni v High Authority* [1957-58] ECR 133.

justification.[25] The CAT's rationale is to provide 'very specific *expertise*, which goes beyond the traditional pharmaceutical field and covers areas bordering on other sectors such as *biotechnology and medical devices*'.[26] From a regulatory perspective the Regulation will facilitate the provision of scientific advice, which will also be available from the EMEA at low cost. Since the EMEA runs a centralised procedure, it provides a single interface with applicants for marketing authorisation for advanced therapies. This should improve the adequacy and consistency of risk management strategies and surveillance after marketing.[27]

In providing optimal regulatory efficiency of advanced therapy medicinal products the EU derives legitimacy from its regulatory outputs. The Regulation's promotion of governance through information is profoundly neoliberal since it ensures law serves the economy through a focus on the rationality of optimisation found in the emphasis on quality, safety and efficacy rather than 'comparative therapeutic efficacy' and genuine need.[28]

The CAT, being placed within the EMEA is largely shielded from explicitly political processes by that institution's status as an agency, in particular, the founding statute, 'permanent staff, organizational independence, varying degrees of budgetary autonomy and direct networking with national administrators'.[29] The Regulation, and the CAT, and EMEA, are focused on gathering of information in order to make the recommendations that underpin market entry/exit regulation. As Smismans notes, the EMEA's information task, and by implication the CAT's ultimate task as feeding into the EMEA, has '*a considerable normative authority* since the Commission has to take into account the agency's expertise before taking a decision'.[30]

The 'holder of a marketing authorisation' is to 'establish and maintain a system for ensuring' traceability of 'the individual product...through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private practice where the product is used'.[31] This move is reinforced since the hospital, institution or private practice where the product is 'used shall establish and maintain a system for *patient and product traceability*. That system shall contain sufficient detail to allow *linking of each product to the patient who received it and vice versa*'.[32] The Regulation's subjects are neoliberal citizens, made traceable as their bodies are commodified and subsumed within economic processes.

The normative authority of the CAT and the EMEA and governance through information and knowledge obtains in large part from the valorisation of science as value-free and objective and the power-effects of its establishment as a norm. This point links very clearly with the discourses framing citizen participation which are sketched in the next section. This valorisation and its effects are exemplified by the scientific justification the EMEA must provide if it does not follow the CAT's opinion (noted above), and can be further demonstrated by focusing on the CAT and considering its membership and tasks. Chapter 7, Articles 21-23, are pertinent here. In terms of membership, the CAT is dominated by scientific expertise 'relevant to advanced therapies, including medical devices, tissue engineering, gene therapy, cell therapy, biotechnology, surgery, pharmacovigilance, risk

[25] Article 8(4).
[26] Recital 10.
[27] Roche, 'Advanced Therapies and the Outer Limits of DNA Regulation: New Horizons for Patents or a Scaffold Too Far?', 211.
[28] Hervey and McHale, *Health Law and the European Union*, 317-218.
[29] Everson, 'The Constitutionalisation of European Administrative Law: Legal Oversight of a Stateless Internal Market', in C. Joerges and E. Vos (eds.), *EU Committees: Social Regulation, Law and Politics*, (Hart, 1999), 285-286.
[30] S. Smismans, *Law, Legitimacy, and European Governance: Functional Participation in Social Regulation*, (OUP, 2004), 252. Emphasis added.
[31] Article 15(1).
[32] Article 15(2). Emphasis added. Under Article 15(3) these are to be 'complementary to, and compatible with, the requirements laid down in Articles 8 and 14 of Directive 2004/23/EC as regards human cells and tissues other than blood cells, and Articles 14 and 24 of Directive 2002/98/EC as regards human blood cells'.

management and ethics'.[33] Under Article 21(2)(1) the requirement of scientific expertise is a *precondition* for membership, except for patients associations and clinicians, who seem to require only (that is, without the qualification 'scientific') '*experience* in respect of advanced therapy medicinal products'.[34] This reliance on the norm of expertise helps to legitimate membership and the CAT's outputs.

Article 21 deals with the composition of the CAT.[35] Article 21(1) outlines four categories of members. Within the first category, Article 21(1)(a) provides for five members or co-opted members of the CMPHU from five Member States. Alternates are either proposed by their respective MS or, in the case of co-opted members of the CMPHU, identified by the latter on the advice of the corresponding co-opted member. The five members with their alternates are to be appointed by the CMPHU. The second category, under Article 21(1)(b), provides for one member and one alternate appointed by each MS whose national competent authority is not represented among the members and alternates appointed by the CMPHU. Article 21(1)(c) outlines the third category, two members and two alternates appointed by the Commission in order to *represent clinicians*.

The fourth category is most important for this paper since it deals with patient associations, noted in the introduction. Within Recital 11 these appear almost as an afterthought. Article 21(1)(d) provides that two members and two alternates (who shall represent and vote for the members in their absence) are to be appointed by the Commission in order to *represent patients' associations*. This is to be done on the basis of a public call for expressions of interest and after consulting the European Parliament. Yet, as I explain further in Section 2, 'functional participation' and representation of citizens through patients' organizations is noted as being problematic for citizen participation, basically because it is used to legitimate governance, and such collectivities do not necessarily represent the views of their members or ensure their participation within its structures. Article 21(3) states '[t]he members of the [CAT] shall be appointed for a renewable period of three years. At meetings of the [CAT], they may be *accompanied by experts*'.[36] Moreover, in providing a legal guarantee that patients' organizations might be assisted by scientific and medical expertise, the Regulation provides some scope for developing a strategy for citizens' engagement.

In terms of the CAT's tasks, Recital 10 explains the purpose of the CAT, which is created within EMEA, and is responsible for 'preparing a draft opinion on the *quality, safety and efficacy* of each advanced therapy medicinal product'.[37] As noted above, final approval is provided by the EMEA's CMPHU. The recital also states that 'the [CAT] should be consulted for the evaluation of any other medicinal product which requires specific expertise falling within its area of competence'.

Article 23 of the Regulation fleshes out these tasks, which range from, for instance, formulating a draft opinion on the quality, safety and efficacy of an advanced therapy medicinal product for final approval by the CMPHU,[38] providing advice on whether a product falls within the *definition* of an advanced therapy medicinal product,[39] advising and providing expertise to the CMPHU on the quality, safety or efficacy of any such product,[40] to providing expertise and advice on any question or initiative related to those products.[41] Given this huge range of tasks the CAT is a potentially hugely important site of engagement for citizens.

---

[33] Emphasis added. Article 22(2)(2) states: 'At least two members and two alternates of the Committee for Advanced Therapies shall have scientific expertise in medical devices'. Cf. Recital 11.
[34] Recital 11. Emphasis added.
[35] See: http://www.ema.europa.eu/htms/general/contacts/CAT/CAT_members.html#PO
[36] Emphasis added.
[37] Emphasis added.
[38] Article 23(a). Emphasis added.
[39] Article 23(b).
[40] Article 23(c).
[41] Article 23(d)-(g).

I move now to consider the other discourses constructing citizen participation, which are found in official EU documents on citizen participation in governance and citizen/science relations, and which are inflected with PUST and risk.

2.2 *'EUROPEAN GOVERNANCE'*

To begin with the EU documents on citizen participation, most instances of the EU's discourse on citizen participation in governance are produced by the Commission, although it is also propagated and constituted by formal institutional actors such as the Economic and Social Committee, politicians and scholars. The most important document is *'European Governance'*,[42] affirmed and developed in others,[43] including the White Paper *'Together for Health: A Strategic Approach for the EU 2008-2013'*[44] (*'Together for Health'*). These frame the inclusion of collective or civil society actors who are deemed to represent citizens, through construction of *inter alia* the establishment and publication of minimum standards for consultation on EU law and policy making, rationales for citizen and civil society inclusion, standards for their selection, as well as the conduct of included actors, and the provision of up-to-date, online information on EU law and policy making.[45]

'European Governance' arose in large part from the BSE crisis of the 1990s in which there was a 'collapse in consumer confidence caused by shortcomings in the institutionalisation of scientific knowledge'[46] in Member State and EU structures. In an effort to engender (or restore) public trust and legitimacy, especially in areas of risk and scientific uncertainty, the document calls for openness, transparency and enhanced participation by citizens in science-based decision making.[47] To this end the document's proposed reforms, many of which were introduced by the successive documents noted above, that would increase citizen and particularly civil society participation in EU policy formulation and implementation. Walters and Haahr note how techniques for enhancing consultation and strengthened participation of citizens and 'civil society' highlight their agency and define a public rationality. However, the stress on participation and consultation initiated in *'European Governance'* seems more like an education initiative.[48] Within *'European Governance'* the point of improved participation is that it is likely to engender greater confidence in the governance outputs produced by science and instrumental rationality[49] and, therefore, in governance and the institutions that dominate it. In other words, the point of increased participation is '*not* that improved participation will provide a more convincing and therefore a more rational basis for policy'.[50]

So, although the active citizen is emphasized in *'European Governance'*, participation and consultation are not designed to guarantee a genuine, truly open and rigorous discussion with those

[42] European Commission, *European Governance: A White Paper*, COM(2001) 428 final.
[43] For an overview of initiatives see: Commission Staff Working Document, *Report on European Governance (2003-2004)*, SEC(2004) 1153.
[44] European Commission, White Paper, *Together for Health: A Strategic Approach for the EU 2008-2013*, COM(2007) 630 final; Commission Staff Working Document Accompanying White Paper, *Together for Health: A Strategic Approach for the EU 2008-2013*, SEC(2007) 1376.
[45] De Jésus Butler, 'Non-Governmental Organisation Participation in the EU Law-Making Process: The Example of Social Non-Governmental Organisations at the Commission, Parliament and Council', 14 *E. L. J.* 558 (2008).
[46] Everson and Vos, 'The Scientification of Politics and the Politicisation of Science', in M. Everson and E. Vos (eds.), *Uncertain Risks Regulated*, (Routledge-Cavendish, 2009), 1.
[47] *European Governance: A White Paper*, 8, 19.
[48] W. Walters and J. H. Haahr, *Governing Europe: Discourse, Governmentality and European Integration*, (Routledge, 2005), 83. Emphasis added.
[49] Bellamy et al. (eds.), *Making European Citizens*, (Palgrave Macmillan, 2006).
[50] Walters and Haahr, *Governing Europe*, 83. Emphasis added.

members of civil society who are involved and consulted.[51] It appears, as Smismans points out, participation of these actors is about 'contributing to EU *legitimacy* but *not* defined as a contribution to more active citizenship'.[52] As Walters and Haahr explain, the rationality 'at least partially emerges in a *paternalistic version*'. This is because:

> 'involvement is not first and foremost a vehicle for the achievement of rational agreement on the basis of the free and equal exchange of arguments oriented towards understanding. It is more a *vehicle for persuasion*, for *rhetorical action* in which *the point is to convince the objects of rhetoric of certain given beliefs, preferences and identities*'.[53]

This public rationality finds its mirror image in the rationality of expertise. A distinction is made between experts and lay people or the public, a well-known strategy for the distribution of power.[54] The consequence of the valorisation of science even in conditions of uncertainty is an undermining of the importance of participation.

2.3 CITIZEN/SCIENCE RELATIONS

Another series of documents frame the EU's engagement with new technology and citizen/science relations, notably *'Promoting the Competitive Environment for the Industrial Activities Based on Biotechnology within the Community'* (*'Competitive Environment for Biotechnology'*)[55] and *'Science and Society Action Plan'* (*'Science and Society'*)[56] respectively. These extend and reinforce the rationalities in *'European Governance'*. *'Competitive Environment for Biotechnology'* can be summarised briefly in that it highlights the promotion of innovation and the competitive environment for the EU's biotechnology industry. The focus seems very much on ensuring the public acceptability of EU regulation, and for that purpose the importance of expert advice is seemingly emphasized as a way of legitimating decisions.[57]

'Science and Society' is, as the named suggests, more directly concerned with citizen/science relations in the EU context. The document is replete with references to the promotion of scientific education and culture, public awareness, science education and (interestingly) careers (which of course overlaps with the focus on innovation in the previous document), a science policy closer to citizens, involving citizen society, and the use of expertise. The basic view seems to follow the pattern noted in *'European Governance'*. The document makes the curious statement that the 'acquisition of a basic grounding in science and technology by the European public and a regular flow of information to the public from experts are not in themselves enough to enable people to form an opinion'.[58] Apparently direct engagement with expertise and a variety of fora is required (the following are noted: consensus conferences, citizens' juries, national and regional consultations and online forums[59]). Indeed, it is

---

[51] In a different vein see: Fraser, 'Transnationalizing the Public Sphere: On the Legitimacy and Efficacy of Public Opinion in a PostWestphalian World', in S. Benhabib et al. (eds.), *Identities, Affiliations and Allegiances*, (CUP, 2007).

[52] Smismans, 'New Governance – The Solution for Active European Citizenship, or the End of Citizenship?', 13 *Columbia Journal of European Law* 1 (2007), 9. Emphasis added.

[53] Walters and Haahr, *Governing Europe*, 83. Emphasis added.

[54] Hervey and McHale, *Health Law and the European Union*, 317. See further: Jasanoff, *Designs on Nature*.

[55] Communication from the Commission, *Promoting the Competitive Environment for the Industrial Activities Based on Biotechnology within the Community*, SEC(91) 629 final. Also see: Communication from the Commission, *Working Together for Growth and Jobs. A New Start for the Lisbon Strategy*, COM(2005) 24 final.

[56] Communication from the Commission, *Science and Society Action Plan*, COM(2001) 714. Also see: Commission Staff Working Paper, *Science, Society and the Citizen in Europe*, SEC(2000) 1973; Communication from the Commission, *Science and Technology, the Key to Europe's Future: Guidelines for Future European Union Policy to Support Research*, COM(2004) 353 final.

[57] Cf. Farrell, 'The Politics of Risk and EU Governance of Human Material'.

[58] *Science and Society*, 12.

[59] Ibid.

'not enough to keep them [citizens] informed…they must be given the opportunity to *express* their views in the appropriate bodies'.[60] Of course, the mere expression of views does not guarantee they are taken into account in governance.

In addition, the main route for citizen participation is, following *'European Governance'*, through civil society, including organizations.[61] This might seem reasonable enough, but perhaps even more clearly than in *'European Governance'* which it elaborates on, in *'Science and Society'* citizens are figured within a 'deficit model'. As such citizen contestation of EU law and policy is deemed to arise from ignorance and to be resolvable by education which will promote understanding. Education is to be achieved through various means and involving various other actors, such as media, researchers, research institutions and universities, and even industry.[62]

2.4 PUBLIC UNDERSTANDING OF SCIENCE AND TECHNOLOGY

An additional layer of discourse is provided by the inflection of PUST throughout *'Science and Society'* in particular. This more clearly *extends* the expert and public rationalities found in *'European Governance'*. Jasanoff notes how professional science associations use and exploit this notion, and she points out, appropriately, that it has been 'defined, measured, and deployed as an *instrument of governance*' in the EU.[63] PUST has tended to use a range of techniques and resources – the *Eurobarometer* on attitudes to new technologies such as biotechnology,[64] reports, questionnaires, statistics, all usually with the aid of social scientific methods – which construct the 'Euro-public' and citizens, but so they are one-dimensional non-knowers. One effect of this deployment is obvious. Perceived legitimacy crises of scientific decision making are explained away as a consequence of a 'deficit' in public knowledge which is to be rectified through education.[65] PUST as inflected in EU documents has tended to abet and undergird the other discourses constructing citizen participation in EU governance with the consequence that citizens are seen as being in need of education, but are nevertheless included to help legitimate EU governance.

2.5 RISK

This operation is reinforced by the widespread inflection of risk as an instrument of neoliberal governmentality[66] in the Regulation (as part of its rationale and that of the CAT) and throughout the discourses figuring citizen participation.[67] For instance, in *'Science and Society'* risk governance[68] is framed by the idea of placing 'responsible science at the heart of policy making'.[69] Reference is made to the use of expertise in the context of scientific uncertainty[70] and a sense of 'frustration and despair when experts fail to provide simple answers to apparently simple questions. The conclusion: 'Even the experts don't know what they're talking about!''. The document builds on these in recognising 'a need to open up the process [of science-based decision making] by providing

[60] Ibid., 14-15. Emphasis added.
[61] Ibid.
[62] Ibid., 6.
[63] Jasanoff, *Designs on Nature*, 251. Emphasis added.
[64] See generally: http://ec.europa.eu/public_opinion/index_en.htm and http://ec.europa.eu/public_opinion/index_en.htm. On biotechnology see: G. Gaskell et al., *Europeans and Biotechnology in 2005: Patterns and Trends, Eurobarometer 64.3*, (London, 2006).
[65] Leach and Scoones, 'Science and Citizenship in a Global Context', in M. Leach et al. (eds.), *Science and Citizens: Globalization and the Challenge of Engagement*, (Zed Books, 2005), 16.
[66] M. Power, *Organized Uncertainty*, (OUP, 2007).
[67] Reinforced by Committee for Medicinal Products for Human Use, *[Draft] Guideline on Safety and Efficacy Follow-Up – Risk Management of Advanced Therapy Medicinal Products*, London, 20 November 2008.
[68] *Science and Society*, 17-24.
[69] Ibid., 17.
[70] Ibid., 22.

opportunities for the *voicing of alternative views* ('a competition of ideas'), for *scrutiny* and for *constructive* debate'.[71]

Such pronouncements should be read with caution. One reason is that here risk is underpinned by *scientific definitions* of risk and the importance of *technical* expertise. As a corollary there is a tendency for regulatory priorities to be established with reference to technical criteria.[72] Since such an understanding of risk is ultimately undergirded by the liberal notion of delegating regulatory tasks to trusted experts, there is a consequential diminution in the importance and scope of citizen participation. While the latter is noted as important, in the Regulation at least, participation is limited to the trappings of oversight through the CAT and the EMEA more widely.

There is a linked reason for caution. Power points out how accountability has become linked with organisation in a single logic. This complicates and thwarts moves towards democratisation of science and technology, since societal risks engender institutional risks that must themselves be tackled and regulated.[73] As Power elaborates, democratic ideals 'are *increasingly positioned* within ideals for good governance of the risk analysis process...'.[74] Consequently, techniques for accountability such as participation become part of a broader process of rendering organisations auditable and inspectable. Techniques for participation 'are *increasingly framed* as an organizational *strategy to manage public expectations*'.[75] This brings out another point: public perceptions are a source of risk, and so risk management is partly an exercise in governing '*unruly perceptions*' and maintaining the '*production* of legitimacy in the face of these perceptions'.[76] It is no surprise then that, as Black states, the rhetoric of risk is a 'useful *legitimating* device'.[77] In light of these insights the EU's proclamations on inclusion of alternative voices seem rather disingenuous. Hence, any approach aimed at strengthening participation must be mindful of its *use* as a legitimating technique.

2.6 SUMMARY

The various discourses traced above work together to produce a 'deficit model' of citizens in need of education. Such neoliberal citizens are supposed to tend to their own interests, and they are deemed incapable of sharing power with fellow citizens in order to change and organise their options. This construction stymies oppositional formations and therefore undermines the fostering of a public sphere aimed at democratic political culture and community.[78] Overall it appears citizen participation is used to service the EU's legitimacy needs.

Of course, it might be that a focus on science and instrumental rationality are sufficient to engender public trust in, and the legitimacy of, the EU's governance of advanced therapies. Yet, this is questionable. The notion of trust implicit in the discourses figuring citizen participation is a notion of *passive* trust. As I explore further below, in conditions of late modernity *active* trust is more important, especially in areas of scientific uncertainty such as advanced therapies. In addition, the 'deficit model' ignores the many examples of individual and collective citizen engagement in science and technology which have given rise to terms like 'biological citizenship' and 'ethical pioneers',[79]

---

[71] Ibid. Emphasis added.
[72] Murphy and Whitty, 'Risk and Human Rights in UK Prison Governance', 47 *British Journal of Criminology* 798 (2007), 802. Emphasis added.
[73] Rothstein, Huber and Gaskell, 'A Theory of Risk Colonization: The Spiralling Regulatory Logics of Societal and Institutional Risk', 35(1) *Economy and Society* 91 (2006).
[74] M. Power, *Organized Uncertainty*, 20. Emphasis added.
[75] Ibid., 20-21. Emphasis added.
[76] Ibid., 21. Emphasis added.
[77] Black, 'The Emergence of Risk-Based Regulation and the New Public Risk Management in the United Kingdom', 519, cited in Murphy and Whitty, 'Risk and Human Rights in UK Prison Governance', 810. Emphasis added.
[78] Brown, *Regulating Aversion*, 89.
[79] Rose, *The Politics of Life Itself*.

such as in activism around HIV/AIDS, cancer and reproductive technologies.[80] Overall then, it seems likely that the distance between EU governance and the citizens who are its subjects will grow. Moreover, where citizens uncritically engage with these discourses they might reinforce their subject position. That is unless they are able to develop a discursive strategy that might provide for a different figuration, not just of citizen participation in EU governance, but more widely and as they govern themselves.

3. FOSTERING CITIZEN PARTICIPATION

In this section I develop such a strategy by suggesting a few discursive elements that can help to operationalise democratic impulses, and foster humility in the face of uncertainty, by providing a rhetorical and operational opening for participation. The elements are: the rhetoric of human rights, citizenship-as-participation, newer work on PUST that reconceptualises citizen/science relations, and the social construction of risk. To begin with human rights, although it is used as a legitimating technique, as demonstrated by references to it in *'Together for Health'*,[81] it can be used by citizens to enhance their participation.[82] As Brown notes, it is 'in their figuration of an egalitarian political community – that…[rights are] most valuable in the democratic transformation of these particulars'.[83] Rights rhetoric is (perhaps the main) part of what Stychin terms the 'unruly edge'[84] of EU citizenship, the potential the latter has 'to mean something *more*' than the economic end of free movement, an 'excess which might be exploitable in the cause of active, democratic citizenship'.[85] Rights discourse can therefore be deployed to, for instance, reveal problems around vulnerability and distribution of new technologies. Rights discourse can also orient citizens towards participation, foster biosociality and solidarity,[86] and it can be used to tackle the ways in which participation in EU governance is thwarted in the absence of formal, binding rights, to generate a rhetorical and operational 'way in'.

Another discursive element for enhancing citizen participation is to be found in the streaks of civic republicanism through the discourses analysed above. The potential of this strain of citizenship is enhanced by its use as a description and prescription for the EU and citizen/science relations in academic discourse.[87] Civic republicanism tends to be concerned with promoting citizenship-as-participation, and therefore values practices that require active participation through deliberative forms of democracy, fostering the transformation of subjects by and through their participation.

Conveniently, civic republicanism's emphasis on participation undergirds newer work on PUST by Irwin, Wynne and others.[88] Such work draws attention to 'citizen science' and scientific citizenship. Public understandings of science and technology are shown to be more complex than the 'deficit model' of citizenry in need of education. Indeed, the research finds a public endowed with greater

---

[80] See further, Flear, 'The EU's Biopolitical Governance of Advanced Therapy Medicinal Products'.
[81] http://ec.europa.eu/health/ph_overview/Documents/strategy_wp_en.pdf, 4.
[82] As well as human rights the other two major ethical positions creating a 'bioethical triangle' underpinning positions and views on new technologies are utilitarianism and 'dignitarianism'. Human dignity in particular is noted as an empowering discourse of growing importance. See: D. Beyleveld and R. Brownsword, *Human Dignity in Bioethics and Biolaw*, (OUP, 2001); R. Brownsword, *Rights, Regulation, and the Technological Revolution*, (OUP, 2008), especially 'The Challenge of Regulatory Legitimacy I'.
[83] W. Brown, *States of Injury*, (Princeton University Press, 1995), 134.
[84] Stychin, 'Sexual Citizenship in the EU', 5 *Citizenship Studies* 285 (2001), 290. Original Emphasis.
[85] Ibid., 292. Original Emphasis.
[86] For examples of this phenomenon, see: S. Gibbon and C. Novas (eds.), *Biosocialities, Genetics and the Social Sciences*, (Routledge, 2007).
[87] Bellamy et al. (eds.), *Making European Citizens*; Leach et al. (eds.), *Science and Citizens: Globalization and the Challenge of Engagement*.
[88] A. Irwin, *Citizen Science*, (Routledge, 1995); A. Irwin and M. Michael, *Science, Social Theory and Public Knowledge*, (Open University, 2003); Irwin, 'The Politics of Talk: Coming to Terms with the "New" Scientific Governance', 36(2) *Social Studies of Science* 299 (2006); MacNaughten et al., 'Nanotechnology, Governance, and Public Deliberation: What Role for the Social Sciences?', 27(2) *Science Communication* 268 (2005) (co-authored by B. Wynne).

levels of agency, and who have different but no less valid frames for their problematization of science and technology issues.[89] The example of HIV/AIDS activism is again useful. As Leach and Scoones explain 'claims and interests related to knowledge and experience emerge and are refracted through political dialogue. Factional groups, united by common experiences of science, technology and its risks, may press claims based on their experiential knowledge, as in the actions of HIV/AIDS activists...'.[90] An emphasis on experience might bolster citizens as they seek membership of the CAT through patients' associations, as well as with the network of actors in the wider assemblage and governance of advanced therapies.

Civic republicanism also undergirds much thinking on the social construction of risk. As Murphy and Whitty point out,[91] quoting Baldwin et al., an understanding of risks as *socially constructed* leads to the view that 'regulatory priorities and policies cannot be left to the 'objective' evaluations of experts but have to emerge from democratically legitimate processes of debate and consultation'.[92] Moreover, where risk governance operates in contexts of scientific uncertainty, like advanced therapies, the use of science and instrumental rationality as the main sources of legitimacy is undermined.[93] This context opens up the possibility of pluralising biological and biomedical knowledge production and expertise, highlighting *lacunae* in knowledge, introducing doubt and controversy into often settled assumptions, knowledges and practices, and relocating science in what Rose calls 'fields of experience, politics, and capitalism'.[94] Thus, the social construction of risk in a context of scientific uncertainty gives citizens leverage to enhance their participation in risk governance and resist hubris.[95]

As a note of caution, linking back to Power, risk discourse of whatever kind also has an impact on the strategic use of the elements outlined in this section. To take human rights as an example, since the logic of risk permeates governance, it transforms human rights into an institutional risk. As Murphy and Whitty put it, '*managing risk means managing the risk of rights*...[which is] not limited to legal risk, that is, (potential) claims and litigation for violation of human rights obligations...'. Moreover, the risk also 'encompasses the potential for human rights *consciousness* (as manifested, for example, in a public campaign) to disrupt the interests and overall standing of governments and organisations'.[96] Combating the logic of organisation and accountability could be achieved by a 'risk within human rights' approach, which is developed elsewhere by Murphy.[97] By stressing risk as part and parcel of human rights, rather than as merely an organisational risk, this approach strengthens human rights *in* organisational and regulatory contexts, thereby *enhancing* participation. Similarly, newer work on PUST could be used to highlight a 'public understanding of risk' approach to strengthen participation.

By contrast with the discourses constructing citizen participation from above, which are undergirded by liberalism's emphasis on passive trust, each of the discursive elements for enhancing citizen

---

[89] Cf. 'civic epistemology': Jasanoff, *Designs on Nature*, 270.
[90] Leach and Scoones, 'Science and Citizenship in a Global Context', 24.
[91] Murphy and Whitty, 'Risk and Human Rights in UK Prison Governance', 5-6.
[92] R. Baldwin and M. Cave, *Understanding Regulation: Theory, Strategy and Practice*, (OUP, 1999), 142, cited in Murphy and Whitty, 'Risk and Human Rights in UK Prison Governance', 803.
[93] Cf. Everson and Vos, 'The Scientification of Politics and the Politicisation of Science', 2.
[94] Rose, *The Politics of Life Itself*, 142. Cf. S. Jasanoff (ed.), *States of Knowledge*, (Routledge, 2004).
[95] As Farrell points out ('The Politics of Risk and EU Governance of Human Material'), the precautionary principle is seldom used in the context of EU regulation of human materials. Still, it is useful for participation given how, as Boisson de Chazournes puts it, 'the determination of a tolerable risk level generally requires the involvement of the public in one way or another' (Boisson de Chazournes, 'New Technologies, the Precautionary Principle, and Public Participation', in T. Murphy (ed.), *New Technologies and Human Rights*, (OUP, 2009), 179).
[96] Murphy and Whitty, 'Is Human Rights Prepared? Risk, Rights and Public Health Emergencies', 17 *Med. L. Rev.* 219 (2009), 233. Emphasis added.
[97] Murphy, 'Technology, Tools and Toxic Expectations: Post-Publication Notes on *New Technologies and Human Rights*', 2 *Law, Innovation and Technology* (2009) 181.

participation are undergirded by civic republicanism's emphasis on *active* trust. As Giddens points out, in late modernity where citizens are more (self-) reflexive, passive trust is no longer a sufficient basis for governance. Giddens explains that 'trust…has to be won from the other and others', and that this necessitates 'a two-way negotiation rather than dependence; and…that trust has to be consistently renewed in a deliberate way'.[98] That EU governance here is predicated upon liberalism's destabilised foundations suggests that its legitimacy and engagement with citizens could be undermined. Citizens might use the elements sketched above to foster biosociality and solidarity in order to demand and contest the exercise of EU power over life more effectively. If deployed in a genuine way at the EU level the elements might also help renew the EU's legitimacy as it governs advanced therapies and other new technologies.[99]

4. CONCLUSION

In this paper I used the example of citizen participation in the regulation of new technologies, specifically advanced therapy medicinal products, to trace how EU discourse on citizenship is an instance of neoliberal governmentality. In Section 2 I traced how various discourses aid and abet the production of a 'deficit model' of citizens in need of education through their inclusion in governance. In this mould citizens are supposed to tend to their own interests – and they are deemed incapable of sharing power with fellow citizens in order to change and organise their options. This stymies oppositional formations. It appears, therefore, that citizen participation is used to legitimate governance. In Section 3 I explored a number of discursive elements that could help citizens to break out of the 'deficit model'. Elements such as the rhetorical aspect of human rights, citizenship-as-participation, newer work on PUST that reconceptualises citizen/science relations, and the social construction of risk, could be combined to provide a rhetorical and operational opening for citizen participation in governance. This reorientation would help to ground the production of legitimacy in active trust, and ensure that participation is not merely a support for hubris, but rather part and parcel of regulatory humility in the face of uncertainty.

[98] A. Giddens, *Europe in the Global Age*, (Polity, 2007), 116.
[99] Leach and Scoones, 'Science and Citizenship in a Global Context', 16-17.