

Context, Approach and Overview

I. INTRODUCTION

THIS BOOK IS about governing public health—and its core concern is with biopolitics and especially the role, scope and potential of citizen participation in legal and regulatory decision-making. The site of this study is the European Union’s (EU’s) public health governance and regulatory interventions. Citizen participation includes various techniques that seek to incorporate the perspectives of individuals and communities in regulating or governing.¹ From the outset of this project I was hopeful about the potential for citizen or public participation,² but I was also far more pessimistic about its actual incorporation and use in decision-making. This was despite the widespread view, which I share, that citizen participation is an important social good³ and tool of governance, particularly in areas where the regulation of science and technology are very much at the fore.⁴ This chapter explains the mix of pessimism and optimism that initially prompted the book, outlines its aims and arguments, and overviews what follows.

¹ The main reasons for the focus on ‘governing’ are mentioned below, but ‘regulating’ is used in places, for reasons that shall become apparent in the outline of the conceptual approach. Black’s definition of regulation is ‘the intentional use of authority to affect behaviour of a different party according to set standards, involving instruments of information-gathering and behaviour modification’ (J Black, ‘Critical Reflections on Regulation’ (2002) 27 *Australian Journal of Legal Philosophy* 1). This understanding of regulation includes technologies with ‘hard law’, ‘soft law’, social norms and the market. See further: R Baldwin, M Cave and M Lodge, ‘Regulation, the Field and the Developing Agenda’ in R Baldwin, M Cave and M Lodge (eds), *The Oxford Handbook on Regulation* (Oxford, Oxford University Press, 2011).

² Unlike many of the actors and institutions that make use of participatory techniques, I do not use these terms interchangeably, but tend to prefer ‘citizen participation’. My preference is informed by how I conceive of ‘citizens’, which is discussed later in the chapter in relation to biopolitics. For more detail on forms of participation and engagement, and its relation to scientific governance, see: A Irwin, ‘The Politics of Talk: Coming to Terms with the “New” Scientific Governance’ (2006) 36 *Social Studies of Science* 299. See further the discussion in ch 6.

³ See: J Wilsdon and R Willis, *See-Through Science: Why Public Engagement Needs to Move Upstream* (London, Demos, 2004).

⁴ See, eg Royal Society and the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (London, Royal Society, 2004) ch 7 ‘Stakeholder and Public Dialogue’. For example a critique of participation offered by J Schummer, ‘Identifying Ethical Issues in Nanotechnologies’ in H ten Have (ed), *Nanotechnologies, Ethics and Politics* (Paris, UNESCO, 2007), 81, cited in R Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford, Oxford University Press, 2008) 121, and with further discussion of definition and spheres of application, 120–22; J Tait, ‘Upstream Engagement and the Governance of Science’ (2009) 10 *EMBO Reports* S18–S22.

A. Starting Points

My initial prompt for this project came from the regular news reports on public health problems. Cancer and especially efforts to combat its causes, both at the national level and through global efforts to stem the consumption of tobacco products, is one example. Obesity is an increasingly important global concern related to patterns of consumption as well as the production and nature of what is consumed—and looking further back in time, food production methods were the cause for the vCJD crisis of the 1990s.⁵ The terrible toll of the HIV/AIDS pandemic with deaths in the millions and many more affected principally in the global South has been a recurrent news item too and, like other pandemics, perhaps more so than non-communicative diseases. Those other pandemics include avian or bird flu and the strain known as H1N1, which although rarer and, as yet, not having anything like the impact of HIV/AIDS, have emerged in poorer countries. Those diseases tend to become recognised as a significant concern by the global North only when they threaten to spread quickly between distant locations across the globe and into the North. Ebola is just emerging as another prominent example of a disease chiefly affecting parts of the (poor) global South (in Africa) and threatening the (rich) global North. Reporting of those pandemics is often accompanied by reminders of past experience, especially Spanish influenza after World War I (which killed perhaps 20 million people). This background helps to ratchet up the sense of threat posed by public health problems and their potential to produce widespread and perhaps large scale death and social disruption. There are, of course, many other examples of public health problems that could be flagged. However a public health ‘problem’ is defined, it is necessarily to the exclusion of the many others that go largely unreported and unnoticed to widespread public and arguably regulatory perception. That said the reports related that public health *mattered*—and then in certain ways.

Indeed, the reports also have some features in common. They usually have significant transnational dimensions. More specifically, their cross-borderness is typically related to the movement of people and things, that is, markets. There is a sense, then, that these problems are a threat, danger or risk not just to people (who can suffer and die), but also to the normal functioning of the economy or marketplace, and that they emerge, at least in part, from its operation. Decisions are taken by actors in overlapping national, regional and international sites, spaces and fora. In the European context the EU is increasingly prominent and arguably eclipses the World Health Organisation (Europe) (WHO) as ‘the’ transnational actor in the field of public health.

In addition, a sense of emergency often accompanies transnational public health problems, especially those where the threat, danger or risk presented is high

⁵ Variant Creutzfeldt-Jakob disease, which is said to develop from the transmission of bovine spongiform encephalopathy (BSE) from infected animal products to humans.

or even low but with potentially disastrous consequences; and that demands a response. Prominent if not always used responses in the EU and elsewhere include: increased monitoring and surveillance especially at national borders; adjustment of pandemic alert levels to the real or perceived threat level; border controls such as the refusal of entry and (even if not widely used, the potential for) quarantine; preparedness of public health infrastructures for pandemic influenza, with the latter including the stockpiling of vaccines; hospitalisation and other forms of social distancing; increased attention on anti-retrovirals or ARVs for HIV/AIDS; and, widespread and even ubiquitous hygiene advice. Unsurprisingly given the EU context of democratic societies, there is also a stress on justifying and legitimating interventions by reference to ethics and human rights, including those that involve voluntary take-up and compliance by the public, but especially those that might override individual consent and compel compliance.

A lot of effort goes into relating public health interventions to the EU's citizenry and other concerned parties (such as other regulatory authorities). Yet, legal and regulatory decision-making in relation to public health (at any level) seems dry and technical and, consequently, without at least a significant normative dimension. At the same time decision-making demonstrates the tightening links between formally accountable power and scientific and technical knowledge and expertise. These links are present not just in public health problems typified by high degrees of risk, but also rare pandemics, where there is usually scientific uncertainty or non-knowing about, *inter alia*, the type, scale and likelihood of risk.

B. Research Agenda and Aims

Whereas the scientific and technical nature of decision-making and a focus on security oriented and medical responses imply a narrowing of the potential for political-democratic contestation, the growing role of the EU (and wider transnationalisation) increases the distance between governance and the governed. In short, the democratic legitimacy and accountability of decision-making in public health clearly seems a lot more difficult, particularly in terms of citizen participation in governing. What makes this even more problematic is that it is happening at a time when scientific and technical knowledge and expertise in this context and others remain dominant even as uncertainty and non-knowing about the scale and nature of risk mean that they are increasingly undermined. Despite being key addressees of public health regulation, and being implicated in its implementation, the role of the EU's citizenry or indeed those who are not formally speaking citizens but are nevertheless affected by EU governance is rather opaque. It is unclear quite how citizens or publics are constructed, animated and mobilised by, in and through governance, and how they and their knowledge and expertise are implicated in decision-making (if at all) and in defining and shaping the boundaries of responsibility and accountability. All together, these are the main points underlying my pessimism about the current institutionalisation—role, use and

configuration—of citizen participation in decision-making. More than that, this series of anecdotes and related features provides a central hunch: that a focus on public health, and its transnational dimension by reference to the EU, provides a window into governing at this time, what is often called late modernity, and in particular that it highlights key implications for democracy. A key context for this book, therefore, is the ongoing concern about a ‘democratic deficit’⁶ in EU governance, particularly as regards the regulation of risk.

The foregoing prompted the following cluster of related questions, which form the research agenda for this book, its aims and the arguments I seek to advance. How are public health problems constituted and understood—as a danger or threat to the circulation of people and things that is to markets? How are they regulated? What are the roles of risk and security in that regulation? And what are the roles of ethics and human rights in this relation? How do these relationships shape responsibilities and accountabilities in relation to the governance of public health? What is the significance of public health for the production and legitimation of the EU’s identity, imagined socio-political order and project of rule? What are the attendant paradoxes, pitfalls and blind spots? In particular, how do the relationships determine or shape the (de)selection of certain responses and interventions? Further, how are citizens or publics configured in relation to legal and regulatory decision-making and how is that related to defining and shaping the boundaries of responsibility and accountability? Specifically, how do the relationships shape and constrain, but also open up, the possibilities for citizens (including those who are subject to governance) to demand and contest legal and regulatory decisions in the field of public health? How might citizens (again including those others) contribute towards legal and regulatory decision-making and why is their participation important?

The agenda for this book therefore picks up several ‘big issues’ of EU (legal) studies, and looks at them through the prism of public health as the particular case study. These ‘big issues’ include competence and its concretisation through policy, risk and security, human rights and bioethics, accountability and legitimacy, democracy and citizenship, and the nature, essence and ‘future trajectory’ of the European integration project. In bringing together these issues and considering

⁶ The literature on the ‘democratic deficit’ is vast and some of the most salient examples include: C Harlow, *Accountability in the European Union* (Oxford, Oxford University Press, 2002); C Joerges and E Vos (eds), *EU Committees: Social Regulation, Law and Politics* (Oxford, Hart Publishing, 1999); PL Lindseth, ‘Democratic Legitimacy and the Administrative Character of Supranationalism: The Example of the European Community’ (1999) 99 *Columbia Law Review* 628; G Majone, ‘Europe’s “Democratic Deficit”: The Question for Standards’ (1998) 4(1) *European Law Journal* 5; G Majone, ‘The Politics of Regulation and European Regulatory Institutions’ in J Hayward and A Menon (eds), *Governing Europe* (Oxford, Oxford University Press, 2003); R Dehousse and C Joerges (eds), *Good Governance in an Integrated Market* (Oxford, Oxford University Press, 2002); C Joerges, ‘Integration through De-legalisation’ (2008) 33 *European Law Review* 291; F Scharpf, *Governing in Europe. Effective and Democratic?* (Oxford, Oxford University Press, 1999); A Arnull and D Wincott, *Accountability and Legitimacy in the European Union* (Oxford, Oxford University Press, 2002).

them in relation to an increasingly important substantive area of EU governance the book aims to make a distinctive contribution to both EU studies and the burgeoning literature on ‘law and public health’⁷ in two related ways. The first contribution is to underline the role, responsibility and importance of the EU as a public health actor, the growing significance of its public health policy domain and beyond that the transnational dimension to public health (by reference to the EU). In that regard this book narrows its attention to reflect on citizen participation in *governing* at the EU level, a term that is selected in order to query the scope and role of citizen participation and advance the idea that it can and should amount to an active and substantive contribution to decision-making. The discussion in this book therefore advances a notion of citizen participation that is more akin to ‘citizenship-as-participation’ inspired by civic republican ideas of participants who genuinely share in power in order to shape and steer governance,⁸ rather than ‘citizenship-as-rights’ often favoured in liberal accounts of formal citizenship, including in the EU context.⁹

In furthering that central aim the second contribution of this book is to adopt an analytic perspective that combines insights from critical theory, and in particular that inspired by Foucault and his notion of governmentality, with law and regulation studies, and key cognate disciplines, especially science and technology studies (STS), sociology, anthropology and bioethics.¹⁰ Together the insights in this conceptual approach are used to highlight the framing and shape of public health governance, its significance to the EU’s integration project in light of late modern configurations of power, and finally, to tease out the normative dimensions and implications for democratic rule. These issues have not been discussed together in law and regulation studies, especially not in EU studies. As such a related aim of this book is to encourage the growing discourse between law and regulation studies and those cognate disciplines seen in other areas.¹¹ In that regard this book also seeks to enrich those other disciplines with an indication of the resources that law and regulation can provide towards citizen participation as a way of revealing the normative in the scientific and technical.

⁷ The most important field, but there are others too, such as ‘law and health’, ‘law and science’ and ‘law and technology’, to name the main ones.

⁸ For discussion in the EU context see: A Wiener, *‘European’ Citizenship Practice: Building Institutions of a Non-State* (Oxford, Oxford University Press, 1998). More generally see: SR Arnstein, ‘A Ladder of Citizen Participation’ (1969) 35(4) *Journal of the American Institute of Planners* 216.

⁹ R Bellamy, D Castiglione and J Shaw (eds), *Making European Citizens* (Basingstoke, Palgrave Macmillan, 2006); see further: D Kostakopoulou, *The Future Governance of Citizenship* (Cambridge, Cambridge University Press, 2008).

¹⁰ These last three disciplines are salient to the discussion in the second part of the book.

¹¹ See: J Abraham and H Lawton-Smith (eds), *Regulation of the Pharmaceutical Industry* (Basingstoke, Palgrave Macmillan, 2003); J Aronson, *Genetic Witness: Science, Law, and Controversy in the Making of DNA Profiling* (Piscataway, Rutgers University Press, 2007); E Cloatre and M Pickersgill (eds), *Knowledge, Technology and Law* (Abingdon, Routledge, 2014); A Daemmrich, *Pharmacopolitics: Drug Regulation in the United States and Germany* (Chapel Hill, University of North Carolina Press, 2006); R Hindmarsh and B Prainsack (eds), *Genetic Subjects: Global Governance of Forensic DNA Profiling and Databasing* (Cambridge, Cambridge University Press, 2010); S Jasanoff (ed), *Reframing Rights: Bioconstitutionalism in the Genetic Age* (Cambridge MA, MIT Press, 2011).

The focus in this book is not only on the EU level of the multi-level system of governance,¹² but more particularly on the concrete techniques, processes and practices—the assemblages or technologies—deployed by the EU level in the area of public health, and teasing out how they are reflective of, embedded within and oriented towards the production and legitimation of the EU's identity, socio-political order and project of rule aimed at European integration. The study undertaken in this book is empirical in that it draws on extensive analysis of documentary sources assisted by interviews with key civil society actors that engage with the EU's public health governance.¹³ The book is also normative in that it provides a critical account of the current institutionalisation of citizen participation in decision-making, a diagnosis of its limited scope and marginal status as a key concern based on an analysis of the techniques, processes and practices of the EU level of governance, and on the basis of the subsequent reflection a prescription for the enhancement of participation and through it wider governance and its regulatory interventions.¹⁴

C. Key Arguments and Next Steps

More than that citizen participation can and should amount to an active and substantive contribution to decision-making. The core or overall argument of this book is that engagement with citizen participation is vital not just as a value in itself, but also in order to enhance the quality of governance and its regulatory interventions. The diagnosis of the current institutionalisation of citizen participation in decision-making as a key concern offered by this book (and outlined below) helps to underscore why, while the prescription for the enhancement of participation and through it wider governance and its regulatory interventions, seeks to move the discussion forward and prompt further reflection. In relation to the diagnosis I make three related arguments, the first two of which are set out in the first part

¹² Put differently, this book is focused on the EU's regulatory order, which is one level of the multi-level system of governance. Within that system the EU level interacts with a range of other regulatory orders including those at the national level. See further: L Hooghe and G Marks, *Multilevel Governance and European Integration* (Oxford, Rowman & Littlefield Publishers, 2001).

¹³ The project was funded by a British Academy Small Grant (SG-48186) with the ideas being developed further through support from an ESRC Seminar Series (RES-451-26-0764), for which I was PI, and which led to ML Flear and others (eds), *European Law and New Health Technologies* (Oxford, Oxford University Press, 2013). It was the former grant that provided the funding for visits to Brussels and Amsterdam, where I met with civil society actors involved in EU governance, and to London where I met with officials at the European Medicines Agency. The discussions with these actors informed the perspective taken in this book. Both sources of funding are gratefully acknowledged, as is the time of those who shared their insights.

¹⁴ For reasons introduced in theory, concepts and methods below and that are deployed and elaborated in the second part of this book I do not reduce citizen participation to *civil society* or *stakeholder* involvement in governance. Further, my concern is with reflection on the techniques, processes and practices as found in and constituted by discourse and their implications for citizen participation.

of the book. The first argument is that markets, risk and security, and ethics and human rights, provide the key contours for the EU's technology (that is, assemblage of components) governing public health and the policy domain and are related in particular ways. Risk and more broadly security are geared towards regulating the dangers and threats attendant to the circulation of people and things within the internal market. In this relation ethics and human rights have limited roles and are principally deployed as legitimating devices. As a key consequence of this risk-based and market-oriented technology there is a distortion of public health attention, priorities and resources towards a focus on consequences and treatment using technological and magic bullet medical responses that optimise the circulation of people and things. At the same time prevention and related interventions in population that attend to the social, economic and political causes of public health problems might (and in some cases that are noted in the first part of the book actually seem to) receive less attention and resources.

The second argument is that this analysis points to the importance of neoliberalism through the underlying use, infiltration, perpetuation and extension of market-oriented ideas, values and rationalities into wider and formally non-market domains like public health. Importantly, the features of governance and their configuration by and through market reasoning are part of attempts to establish the boundaries of EU responsibility, that is, what the EU sees and projects as its responsibility, shaping its ability to take the credit for success, as well as the limits of its accountability and blame in the event of failure. In attempting to define the limits of its responsibility the EU is, in part, seeking to define failure—the trigger for determining the circumstances in which it can be held accountable. As well as the latter attempt at delimiting the boundaries of responsibility and accountability, the extension of market reasoning ensures knowledge is increasingly made to serve power, and the latter is itself extended materially (ie in terms of what it covers) and territorially, that is, in terms of the places where it applies and people enfolded into the regime and in relation to whom it has effects. These (re)configurations are central to neoliberalism and are also the structuring themes of the policy domain. The themes are embedded within, reflective of and central to efforts at producing and legitimating the EU, its identity, related imagined socio-political order of market actors and ultimately the project of European integration.

Reflecting on the latter in the opening chapter of the second part of the book (chapter six), I make a third argument, which is my diagnosis of the limited nature, shape and use of the current institutionalisation of citizen participation as a key concern. The centrality and valorisation of scientific and technical knowledge and expertise by and within the risk-based technology used to regulate public health implicitly devalues and limits the scope and potential for citizen participation in decision-making. In light of this I understand citizen participation itself as a technology or assemblage of components through which the EU's citizenry are rendered less as regulatory publics and are instead regulated into providing public

legitimation and mediating the boundaries of responsibility and accountability.¹⁵ The scientific and technical foundations of decision-making help to depoliticise and naturalise governance, which obscures its attendant paradoxes, pitfalls and blind spots, including the distortion of regulatory priorities and responses and the marginalisation of citizen participation. Revealing these normative dimensions of the technical and scientific is, given the stakes for the distribution of benefits and risks across society, and for health and life, perhaps ‘the’ core potential contribution of citizen participation, that is in that it can help to correct them.

In that regard, there remains the potential for citizens, including those that are subject to governance, to demand and contest decisions, in this context those that intervene in and relate directly to their lives, engendering what Foucault called biopolitics.¹⁶ It is recognition of this potential that moves the discussion from diagnosis and towards a prescription that might bolster citizen participation in governing. The paradoxes, pitfalls and blind spots attendant to governance, and the effective limits on citizen participation, have common foundations in the contours and the underpinning structuring themes of governance and regulatory design. Reflecting on this there follows a fourth argument, which is that the foundations of governance and its paradoxes, pitfalls and blind spots open up space and create possibilities for citizen participation in decision-making, but going beyond the EU’s citizenry to encompass those that are subject to governance, that is ‘the governed’. In making that argument I suggest that these normative dimensions of governance can be revealed and underlined by using the discursive resources within governance itself, specifically, at this time, the legitimating discourses of human rights and bioethics, underscored by an emphasis on the EU’s (supra-)stewardship responsibility.

These discourses are key resources for facilitating and powering discussion that generates supplementary knowledge on the paradoxes, pitfalls and blind spots attendant to governance, especially those that present under- or even unacknowledged regulatory failures and ‘societal risks’. The risks and failures gain in importance and might be taken into account in decision-making through their articulation in terms of the legitimating discourses, with support from references to (supra-)stewardship responsibility. That is, through these discourses the failures and risk can be transformed into key ‘institutional risks’, that is risks to the EU’s standing and reputation—and important knowledge that must be factored into decision-making. In short, the risk-based technology governing public health provides a ‘way in’ for participation impelled by the threat that if the

¹⁵ ML Flear and MD Pickersgill, ‘Regulatory or Regulating Publics? The European Union’s Regulation of Emerging Health Technologies and Citizen Participation’ (2013) 21(1) *Medical Law Review* 39.

¹⁶ M Foucault, *The Birth of Biopolitics: Lectures at the Collège de France, 1978–79* (Basingstoke, Palgrave Macmillan, 2008). Cf T Lemke, ‘“The Birth of Biopolitics”: Michel Foucault’s Lecture at the Collège de France on Neo-Liberal Governmentality’ (2001) 30(2) *Economy and Society* 190; W Brown, *Edgework* (Princeton NJ, Princeton University Press, 2005) 39–44. See further: M Dean, *The Signature of Power: Sovereignty, Governmentality and Biopolitics* (London, Sage Publications, 2013).

regulatory failures and ‘societal risks’ it identifies are left unaddressed, they could de-legitimize and undermine the EU’s governance, identity as a security and public health actor and ultimately the project of European integration (since these are part of what public health governance is used to build). In this way participation might politicise and bring out the normative dimensions of the risk-based governing technology, and ensure the EU is held to account for its failures and more fully meets its responsibilities to its citizens.

Before I can make these related arguments over the course of the book, and move from the diagnosis of the current institutionalisation of citizen participation as an underdeveloped technology of governance as ‘the’ key concern to a prescription for its enhancement and with it the quality of governance and its regulatory interventions, it is necessary to elaborate further on these introductory points. In the next section I seek to justify and explain the book’s topic by, first, briefly outlining coverage of public health and the EU’s role in it within legal scholarship and its sub- and most closely related disciplines, and second, introducing the limited consideration and marginal status of citizen participation in them. The third section provides an outline of the theory, concepts and methods—the conceptual approach—deployed in this book to meet its aims and advance its arguments. The final section provides an overview of the book. Over the course of which I further substantiate the initially pessimistic account about citizen participation in governing, but also attempt to provide a basis for optimism about the potential for participation that can propel continued engagement in this project by scholarship and citizens at large.

II. LAW, PUBLIC HEALTH AND PARTICIPATION

A. Law and Public Health: A Very Brief Overview

While the importance of public health seems axiomatic, at least in light of its prominence in media reports, it has hitherto been the subject of limited attention in legal scholarship, which provides the core context for this study and the field in relation to which it articulates most directly. To clarify, in this book I am not trying to determine whether there should be an EU dimension to public health law and governance. That is, I am not interested in determining whether there should be a single and to some extent harmonised ‘EU public health law’ or regime that is produced by the EU’s institutions. Further, I am not trying to determine whether the EU should be engaged in public health. Instead, I examine and reflect critically upon the EU’s public health policy domain as constituted by and through its published documentary record. As explained above in the agenda, this book uses public health as a way of exploring broader concerns related to governing in late modernity and the implications for democratic rule. As such what follows is a schematic overview of law and public health in light of the purpose and scope of the book. I provide only a very brief overview of scholarship on law and public health in order to clarify where it stands at present and to further justify this book

on governing public health. That is followed by an introduction to consideration of citizen participation. Overall this section provides a jumping off point for what follows.

As an initial point, *health* has been described as a state of being ‘that is subject to wide *individual, social and cultural interpretation*; it is produced by the interplay of individual perceptions and social influences’ (emphasis added).¹⁷ The idea of health is therefore highly subjective and intangible. In addition, a wide range of factors influence health, including geography, social and economic conditions and position. The classic medical definition provides that health is the ‘absence of disease’¹⁸—an ‘engineering or mechanical’¹⁹ model of health. The emphasis of this model is on the adequate functioning of the human body, maintaining it and repairing it where necessary. The focus is on how disease impacts upon the human body conceived of as a machine.²⁰ Within this model medical professionals determine who is healthy, and who has access to treatment.²¹

The WHO’s alternative definition is the first explicit and purposefully formulated, and the most widely used and recognised:²² ‘health’ is a ‘state of complete physical, mental and social well-being and not merely the absence of infirmity’.²³ This definition refers to the classic medical definition of health, but goes beyond it to encompass the pre-conditions of health: controls on the quality of food, environmental protection, the provision of public housing and welfare benefits. This is the so-called ‘social model’ of health.²⁴ The definition is clearly ‘messianic in its intent’,²⁵ idealistic and even utopian, in that it focuses on enhancing health rather than treating disease. Health is rendered as something to be worked towards and

¹⁷ LJ Jones, *The Social Context of Health and Health Work* (London, Palgrave Macmillan, 1994) 3.

¹⁸ There appears to be no specific source for this definition. It is however used in several publications without reference to other works. For example, Jones describes the definition as ‘the most pervasive definition of health in the Western World’. Jones, *ibid*, 5.

¹⁹ Jones, n 17 above, 5.

²⁰ T McKeown, *The Role of Medicine* (Oxford, Basil Blackwell, 1979); M Foucault, *The Birth of the Clinic* (London, Tavistock, 1976).

²¹ C Helman, ‘Introduction: The Scope of Medical Anthropology’ in C Helman, *Culture, Health and Illness*, 4th edn (Oxford, Butterworth Heinemann, 2000) 5.

²² RE Spector, *Cultural Diversity in Health and Illness*, 7th edn (London, Prentice Hall, 2008).

²³ World Health Organisation, *Constitution of the World Health Organisation* (Geneva, World Health Organisation, 1948) 14 UNTS 185.

²⁴ The medical model and the social model run parallel in this respect: disease and aging are viewed as processes of the loss of function (in the case of disease this occurs too early; in the case of aging this occurs in due time). Notions of chronic and acute, and progressivity or deterioration are key in both. The medical model and the social model are to be distinguished as follows: the doctor is interested in biological processes within the sick person whereas the sociologist is interested in the way the network of relations around the sick person develops. It has been said that it is not possible to decide what comes first and what is worse, ‘bodily or social loss of function. Such questions of primacy and priority are issues to be fought out in the confrontation between adherents of a “medical model” and a “social model”, in the competition between a well-established medical professional circle and the more recent professional circles of medical sociologists, social psychologists, social workers, and so on’ (A de Swaan, *The Management of Normality: Critical Essays in Health and Welfare* (London, Routledge, 1990) 23–24).

²⁵ J Richman, *Medicine and Health* (London, Longman, 1987) 5.

is 'to be achieved by personal and social change as well as by medical advance'.²⁶ In this understanding health is a public or common concern and it must, therefore, encompass a focus on *public* health.²⁷ Crucially, although the WHO's definition is recent, it helps to highlight how the importance of balancing individual and societal or state interests means that public health has been a topic of enduring importance for law. This is apparent in Gostin's characteristics of public health law: 'Government's responsibility to advance the public's health; Coercion and limits on state power; Government's partners in the public health system; The population perspective; Communities and civic participation; The prevention orientation; Social justice'.²⁸ I return to participation as a characteristic below.²⁹

More important for these introductory remarks is the wide breadth of what is encompassed in law's engagement with public health.³⁰ This is shared by the 2007 report of the Nuffield Council on Bioethics, *Public Health: Ethical Issues*³¹ (Nuffield), which used the term 'stewardship' in order to frame state responsibility for public health and the role of law. The WHO has also used stewardship, going so far as to conflate it with governance. Its *World Health Report 2000* explains how stewardship essentially involves 'setting and enforcing the rules of the game and providing strategic direction for all the different actors involved',³² and it is 'the very essence of good government', with the 'Ultimate'³³ responsibility falling on state governments, described elsewhere as the 'steward of stewards'.³⁴ Human rights and bioethics inform this version of stewardship: 'In addition to *improving overall levels of population health*, [its] objectives are likely to be framed in terms of equity, coverage, access, quality, and patients'³⁵ (emphasis added) rights. Moreover, stewardship 'is ultimately concerned with *oversight* of the entire system, avoiding myopia, tunnel vision and the turning of a blind eye to a system's failings' (emphasis added).³⁶ Broadly speaking national policies do not differ in the aim pursued, 'but rather in the *methods* [or means] adopted in pursuit of them' (emphasis added).³⁷ This responsibility is widely perceived as being fulfilled only by the provision of adequate health and social measures by the state. There is no obligation under the

²⁶ Jones, n 17 above, 6.

²⁷ See further: J Coggon, *What Makes Health Public?* (Cambridge, Cambridge University Press, 2012).

²⁸ LO Gostin, *Public Health Law*, 2nd edn (Berkeley, University of California Press, 2008) xxii.

²⁹ And discussed further in ch 6.

³⁰ Examination of the definition of 'law' in the context of 'health care law' has been provided by J Montgomery, *Health Care Law*, 2nd edn (Oxford, Oxford University Press, 2003) ch 1 'The Scope and Sources of Health Care Law'.

³¹ Nuffield Council, *Public Health: Ethical Issues* (London, Nuffield Council on Bioethics, 2007).

³² 'Message from the Director General, Gro Harlem Brundtland' in World Health Organisation, *World Health Report 2000* (Geneva, World Health Organisation, 2000) viii.

³³ 'Message' *ibid.* Also see: World Health Organisation, *World Health Day: International Health Security: Invest in Health, Build a Safer Future* (Geneva, World Health Organisation, 2007).

³⁴ P Travis and others, 'Towards Better Stewardship: Concepts and Critical Issues' in CIL Murray and DB Evans, *Health Systems Performance Assessment* (Geneva, World Health Organisation, 2003) 289.

³⁵ 'Governance': www.who.int/healthsystems/topics/stewardship/en/index.html.

³⁶ 'Message', n 32 above.

³⁷ TH Marshall, *Social Policy*, 5th edn (London, Hutchinson, 1985) 133.

right to health to provide a comprehensive health care system.³⁸ Nevertheless, the method chosen by many economically advanced countries has been such a system as well as comprehensive public health measures.

However, notwithstanding the WHO's definition of health, references to the international obligations of states in stewardship,³⁹ and growing academic commentary on 'global health law',⁴⁰ public health is arguably only recently becoming a field of specific attention in legal scholarship,⁴¹ but is most often considered as part of wider national 'health law' or 'health care law'. Take Montgomery's definition of the latter: 'It embraces not only the practice of medicine, but also that of non-medical health care professions, the administration of health services *and the law's role in maintaining public health*' (emphasis added).⁴² The focus in the consideration of public health tends to be on the professional–patient relationship in the context of the state's obligations for the protection of public health. Looking a little more widely, recent contributions to law and technology and the cognate discipline of regulation studies have increased attention on public health and transnational actors, but this tends to be in relation to the regulation of technology.⁴³ One notable exception is the work of Brownsword, one of Nuffield's authors, who has built on that report's identification of the transnational dimensions of state responsibility, and the roles of transnational actors, such as around pandemics, terming it 'super-stewardship' and 'a significant item of unfinished business'.⁴⁴

There has also been growing consideration of public health per se rather than dealing with it as part of broader issues in human rights,⁴⁵ seen not just in relation

³⁸ European Social Charter (Revised) (3 May 1996, entered into force 1 July 1999) ETS 163 noted further in ch 2 at n 15 covers only the treatment of illness, not health promotion, and extends only to those unable to purchase care privately. As for the European Convention on Human Rights (4 November 1950, entered into force 3 September 1953) ETS 5, signature states are required to take reasonable steps to protect life under Art 2 on the right to life (*Osman v UK* [1999] 1 FLR 193).

³⁹ See further, ch 6.

⁴⁰ For an overview see: LO Gostin and AL Taylor O'Neill, 'Global Health Law: A Definition and Grand Challenges' (2008) 1(1) *Public Health Ethics* 53. LO Gostin and D Sridhar, 'Global Health and the Law' (2014) 370 *New England Journal of Medicine* 1732. See further: LO Gostin, *Global Health Law* (Boston MA, Harvard University Press, 2014).

⁴¹ Seminally: Gostin, *Public Health Law*, n 28 above. This has been followed by further important works: Coggon, *What Makes Health Public?*, n 27 above.

⁴² Montgomery, *Health Care Law*, n 30 above, 4.

⁴³ Brownsword, n 4 above; R Brownsword and M Goodwin, *Law and Technologies of the Twenty-First Century* (Cambridge, Cambridge University Press, 2012); R Brownsword and H Somsen, 'Law, Innovation and Technology: Before We Fast Forward—A Forum for Debate' (2009) 1 *Law, Innovation and Technology* 1; F Francioni (ed), *Biotechnologies and International Human Rights* (Oxford, Hart Publishing, 2007); T Murphy (ed), *New Technologies and Human Rights* (Oxford, Oxford University Press, 2009).

⁴⁴ R Brownsword, 'So What Does the World Need Now?' in R Brownsword and K Yeung (eds), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Oxford, Hart Publishing, 2008) 47 (this also provides an overview of the term as developed thus far). Developed in: ML Flear (ed), 'Papers from "A Symposium with Professor Roger Brownsword: Super-Stewardship in the Context of Public Health"' (2011) 62(5) *Northern Ireland Legal Quarterly* (Special Issue).

⁴⁵ J Harrington and M Stuttaford (eds), *Global Health and Human Rights* (Abingdon, Routledge, 2010); J Tobin, *The Right to Health in International Law* (Oxford, Oxford University Press, 2012); B Toebes and others (eds), *Health and Human Rights in Europe* (Cambridge, Intersentia, 2012).

to the right to health⁴⁶ or discussion of the implications of public health interventions for human rights, but also as a way to develop legal method.⁴⁷ Nevertheless, where the broader legal literature and regulation studies work considers public health the role of transnational actors receives little attention. And in each the EU receives scant attention⁴⁸—including in discussion of ‘global health law’. Within EU law public health has of course been implicated in different areas.⁴⁹ But the link between the EU and health was made only relatively recently⁵⁰ and it is still the ‘new kid on the block’⁵¹ of EU legal studies, albeit arguably one that is becoming increasingly coherent and displaying particular features.⁵² But within that literature there is little on public health as a field in its own right. Instead public health tends to be seen more as a subset of the broader ‘EU and health’ field in formation or subsumed within the law of other European actors in ‘European law’ as it engages with new health technologies.⁵³ This seems to mirror the situation in medical law, where there is likewise little attention to public health per se except as part of the broader field,⁵⁴ although this is something that is gradually changing.⁵⁵

⁴⁶ The evolution of health as a human right is traced in: B Toebes, ‘*The Right to Health*’ in A Eide and others (eds), *Economic, Cultural and Social Rights* 2nd edn (Kluwer, The Hague, 2001). Initially drawing on Sigerist, Toebes traces the various attempts made to define health in the West, starting in antiquity and moving to the present day in: B Toebes, *The Right to Health as a Human Right in International Law* (Antwerp, Intersentia/Hart Publishing, 1999). See further: HE Sigerist, *Medicine and Human Welfare* (London, Oxford University Press, 1941). Also see: JM Zuniga, SP Marks, LO Gostin (eds), *Advancing the Human Right to Health* (Oxford, Oxford University Press, 2013)

⁴⁷ T Murphy, *Health and Human Rights* (Oxford, Hart Publishing, 2013).

⁴⁸ Within human rights this is surprisingly given the EU is increasingly a human rights organisation, and arguably ‘the’ human rights organisation in Europe, particularly after its Charter of Fundamental Rights gained equal status to the EU Treaties under the Lisbon Treaty 2009.

⁴⁹ Classically as a limitation on the ‘four freedoms’ and as a value to be taken into account in internal market legislation. See further, ch 2.

⁵⁰ Initially in the seminal TK Hervey and JV McHale, *Health Law and the European Union* (Cambridge, Cambridge University Press 2004) (followed-up by the revised and retitled work noted below). Subsequently there has been a lot more attention, see further: SL Greer, TK Hervey, JP MacKenbach and M McKee, ‘Health Law and Policy in the European Union’ (2013) 381(9872) *The Lancet* 1135; TK Hervey, A-M Farrell, S Devaney and T Murphy, ‘The Impacts of European Union Law on the Health Care Sector: Institutional Overview’ (2011) 16(4) *Eurohealth* 5; E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (Cambridge, Cambridge University Press, 2010); M Steffen (ed), *Health Governance in Europe: Issues, Challenges, and Theories* (London, Routledge, 2005). A notable but rare exception: SL Greer and P Kurzer, *European Union Public Health Policy: Regional and Global Trends* (London, Routledge, 2013).

⁵¹ T Hervey, ‘EU Health Law’ in C Barnard and S Peers (eds), *European Union Law* (Oxford, Oxford University Press 2014) 621.

⁵² TK Hervey and JV McHale, *European Union Health Law* (Cambridge, Cambridge University Press, 2015).

⁵³ Flear and others (eds), n 13 above.

⁵⁴ Montgomery, n 30 above, in which public health is considered in ch 2 ‘Public Health Law’; E Jackson, *Medical Law: Text, Cases, and Materials*, 3rd edn (Oxford, Oxford University Press, 2013), in which public health is given little if any specific prominence; JK Mason and GT Laurie, *Law and Medical Ethics*, 9th edn (Oxford, Oxford University Press, 2013) ch 2 ‘Public Health and the Patient-State Relationship’.

⁵⁵ Coggon, *What Makes Health Public?* n 27 above.

Overall, looking across law, its sub-disciplines and regulation studies, current discussion of public health still tends to treat it as part of other issues related to medicine and clinical decision-making, the organisation, delivery and financing of health care services, and questions of liability, and usually as part of wider 'health care law' or 'health law', that is, a subset of this broader field rather than a specific area for attention in and of itself. A key drawback of this organisation of scholarship is a diminution in the importance of 'public health' as an object of study at a time when public health problems seem to only gain in prominence. The general focus also remains on the national level at a time when law, governance and regulation are increasingly transnational or global.⁵⁶ Although this might be understandable given that transnational actors and processes usually operate with and through the national level,⁵⁷ keeping transnational dimensions largely latent reduces and even misses the importance of the circulation of people and things across borders in producing public health problems in the first place as well as the consequent importance of transnational actors in regulation.

There is, therefore, a space and need for a more concerted look at the roles of transnational actors and, given its prominence as a formally accountable actor the EU is a particularly important site in and of itself. In addition to the related limitations in the current scholarship, attention to the transnational sphere, and the EU as an example, is also justified since it is a sphere where the ideas, concepts and rationalities that underpin, orientate and direct law, governance and regulation are produced, (re)circulate from and between other sites, spaces, fora and levels of governance.⁵⁸ In that respect I realise that a more complete picture of EU governance of public health would involve a multi-level consideration of those dynamics and the related range of governance arrangements and regulatory instruments at Member State level, and lower still at the regional level where power is devolved.⁵⁹ Although such an analysis would of course be of much value in providing a fuller picture of the overlapping and interacting sites, spaces and fora that together govern public health, it is unfeasible within the confines of a single book.

Most extant analyses of public health in law and regulation studies also tend to focus on explaining, describing and evaluating current public health regimes and charting transitions between paradigms and eras.⁶⁰ Although these sorts of analysis draw attention to the design of governance and its regulatory interventions,⁶¹

⁵⁶ S Cassese, 'The Globalisation of Law' (2005) 37 *New York University Journal of International Law and Politics* 973; A-M Slaughter, *A New World Order* (Princeton, Princeton University Press, 2004).

⁵⁷ S Sassen, *Territory, Authority, Rights: From Medieval to Global Assemblages* (Princeton NJ, Princeton University Press, 2008).

⁵⁸ See: SL Greer, *The Politics of European Union Health Policies* (Maidenhead, Open University Press, 2009). More generally see, eg: K Armstrong, *Governing Social Inclusion* (Cambridge, Cambridge University Press, 2010).

⁵⁹ See Hooghe and G Marks, *Multilevel Governance and European Integration*, n 12 above.

⁶⁰ Eg see: VK Yadavendu, *Shifting Paradigms in Public Health: From Holism to Individualism* (Springer, 2013).

⁶¹ It is quite a recent development: E Jackson, *Law and the Regulation of Medicines* (Oxford, Hart Publishing, 2012), but with a focus on the UK.

consideration of public health regulation in light of the broader norms, values, rationalities and socio-political imaginaries it is reflective of and within which it is embedded remains largely unexamined—and their link to producing and legitimating socio-political order and projects of rule is even less apparent. Further, although the paradoxes, pitfalls and blind spots attendant to public health governance have been discussed at some length in law and regulation studies, the relation of those problems to and especially production by and through this larger design has received far more attention as key normative concerns in critical theory, bioethics, sociology, STS and anthropology.⁶² Nevertheless, much of the attention in those disciplines, as well as in law and regulation studies looking beyond the national level of governance, has been on the United States (US) regime, global health and the way in which they overlap and relate. The EU and its relations with those other sites has received far less attention.⁶³

B. Citizen Participation

Citizen participation is part of discussions about patient agency vis-à-vis medical decision-making and the shifting paradigms of public health.⁶⁴ Participation is also noted as a key characteristic of Gostin's influential notion of 'public health law':

[M]any forward thinkers urge greater community involvement in public health decision-making so that policy formation becomes a genuinely civic endeavour. Under this view, citizens strive to safeguard their communities through civic participation, open forums, and capacity-building to solve local problems. Public involvement should result in stronger support for health policies and encourage citizens to take a more active role in protecting themselves and the health of their neighbours. Public health authorities, for example, might practice more deliberative forms of democracy, involving closer consultation with consumers and voluntary organisations that represent them (e.g. town meetings and consumer membership of government advisory committees). This kind of deliberative democracy in public health is increasingly evident in government-community partnerships ... (e.g. AIDS action and breast cancer awareness).⁶⁵

Despite such acknowledgement, citizen participation in legal and regulatory decision-making is either a peripheral concern (as with the latter example

⁶² See the literature cited in the discussion in chs 7 and 8 in particular.

⁶³ That is also the case in the growing attention on the EU's growing global role, which although welcome has tended to ignore (public) health as a field in itself. See: M Evans and P Koutrakos, *The International Responsibility of the European Union: European and International Perspectives* (Oxford, Hart Publishing, 2013).

⁶⁴ On the agency of patients in the context of the doctor–patient relationship, see, O O'Neill, *Autonomy and Trust in Bioethics* (Cambridge, Cambridge University Press, 2001) noting at 3: the 'widespread and energetic efforts to respect persons and their autonomy and to improve regulatory structures'. On shifting paradigms see, eg: M Schwab and S L Syme, 'On Paradigms, Community Participation, and the Future of Public Health' (1997) 87(12) *American Journal of Public Health* 2049.

⁶⁵ Gostin, *Public Health Law*, n 28 above, 18.

it is mentioned briefly as part of those wider discussions) or it remains largely untouched in mainstream law and regulation studies engagement with public health, including within human rights.⁶⁶ Indeed, consideration of participation is far more likely in environmental law and governance,⁶⁷ which is unsurprising given the legal innovation of the Aarhus Convention.⁶⁸ Relatedly, there are attempts to integrate citizen concerns in the design of policy, such as through impact assessment, in the context of the environment and other fields, including public health.⁶⁹ Yet even in the field of environmental law there is cause for concern about the nature and extent of the attention given to participation, with Lee observing that ‘Some of the great hope [for participation] ... seems to have waned since the turn of the century, or is certainly less visible in the official discourse around environmental decision-making’.⁷⁰ As I point out below and discuss further in chapter six, in the EU’s official discourse around public health participation is even less visible and is instead underpinned and shaped by a more general approach to participation in science-based regulation.

Key rationales for citizen participation include the input of knowledge and perspectives, policy implementation and legitimation. Whatever the precise rationale, (early) engagement is commonly held to produce better regulation.⁷¹ Indeed, there is a focus on, for example, earlier or ‘upstream’ participation, which is seen as preferable in efforts to reach agreement by, as Mandel explains, bringing ‘together diverse stakeholders [in order] to produce a collaborative governance

⁶⁶ An item for further research in relation to European law’s engagement with new health technologies and in relation to human rights, see respectively: Flear and others (eds), n 13 above; Murphy, *Health and Human Rights*, n 47 above. It is worthwhile nothing that in human rights participation is mentioned in several instruments, eg: Committee on Economic, Social and Cultural Rights, ‘General Comment No 12: The Right to Adequate Food (Art 11)’ (12 May 1999) UN Doc E/C.12/1999/5; Art 28 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (4 April 1997, entered into force 1 December 1999) ETS 164 (often referred to simply as the Oviedo Convention); Art 25 International Covenant on Civil and Political Rights (16 December 1966, entered into force 23 March 1976) 999 UNTS 171. For further discussion, see: H Potts, ‘Participation and the Right to the Highest Attainable Standard of Health’ (Colchester, University of Essex Human Rights Centre, 2009); AE Yamin, ‘Suffering and Powerlessness: The Significance of Participation in Rights-Based Approaches to Health’ (2009) 11(1) *Health and Human Rights: An International Journal* 5.

⁶⁷ See, generally: E Fisher, B Lange and E Scotford, *Environmental Law: Text, Cases, and Materials* (Oxford, Oxford University Press, 2013), especially chs 4, 5 and 13; M Lee, *EU Environmental Law, Governance and Decision-Making*, 2nd edn (Oxford, Hart Publishing, 2013) chs 7 and 8. See further: S Yearley, ‘Bridging the Science-Policy Divide in Urban Air-Quality Management: Evaluating Ways to Make Models More Robust through Public Engagement’ (2006) 24(5) *Environment and Planning C* 701.

⁶⁸ UN Economic Commission for Europe, Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (adopted 25 June 1998, entered into force 30 October 2001) 2161 UNTS 447. Mentioned again in ch 6.

⁶⁹ Impact assessment is discussed further in ch 2 and the implications for participation are taken up in ch 6.

⁷⁰ M Lee, n 67 above, 250.

⁷¹ For discussion, see: R Baldwin, ‘Is Better Regulation Smarter Regulation?’ (2005) *Public Law* 485. Also see: R Baldwin, M Cave and M Lodge, *Understanding Regulation: Theory, Strategy, and Practice*, 2nd edn (Oxford, Oxford University Press, 2013).

system rather than a resource-draining adversarial battle' (emphasis added).⁷² Consequently, there is concern for, as Brownsword puts it, the 'general features to be designed in[to]'⁷³ participation. Although the value of citizen participation is widely acknowledged and enhancing it is urged, much discussion within law and regulation studies including work centred on the EU,⁷⁴ has focused on the appropriate relationship between expert legal and regulatory reasoning and popular or lay understandings,⁷⁵ with particular attention given to the shape and design of procedures for participation. This is perhaps unsurprising in light of liberal accounts where democratic decision-making is delegated to trusted elites wielding scientific and technocratic knowledge and expertise. The focus on participatory procedures is especially apparent in situations where there is little possibility of substantive agreement and participation is essentially used to quell contestation, produce public legitimacy and maintain a functioning economy.⁷⁶

STS has been enduringly critical of the ways in which participation tends to be institutionalised, especially where that has been for instrumental reasons.⁷⁷ Consequently, STS has been especially clear about the importance of reflecting on the use, role and configuration of citizen participation in relation to legal and regulatory decision-making. Indeed, in this discipline a popular view is that participation is a (potential) means of democratising science and technology and related decision-making and producing responsible and responsive innovation.⁷⁸ In that regard the EU's constitutional model has been a site of great hope.⁷⁹ Still, there has been much criticism of the use of citizen participation to merely enrol publics and induce trust in science-based issues and produce acquiescence, rather

⁷² GN Mandel, 'Regulating Emerging Technologies' (2009) 1 *Law, Innovation and Technology* 75.

⁷³ Brownsword, n 4 above, 128. Further discussion at 120–28 includes: D Galligan, 'Citizens' Rights and Participation in the Regulation of Biotechnology' in Francioni (ed), *Biotechnologies and International Human Rights*, n 43 above.

⁷⁴ Notably, participatory rights have received growing attention: J Mendes, *Participation in EU Rule-making: A Rights-Based Approach* (Oxford, Oxford University Press, 2011).

⁷⁵ J Waldron, *Law and Disagreement* (New York NY, Oxford University Press, 1999).

⁷⁶ In this regard Brownsword notes how agreement is frustrated by the 'bioethical triangle' underpinning regulation of new medical and biotechnologies and comprising an empowering human rights perspective, a largely restrictive and disempowering dignitarian perspective and a pragmatic utilitarian perspective. See: R Brownsword, 'Human Dignity, Ethical Pluralism, and the Regulation of Modern Biotechnologies' in Murphy (ed), *New Technologies and Human Rights*, n 43 above.

⁷⁷ R Devon, 'Towards a Social Ethics of Technology: A Research Prospect' (2004) 8 *Techne* 99; S Jasanoff, 'Technologies of Humility: Citizen Participation in Governing Science' (2003) 41 *Minerva* 223; H Nowotny, 'How Many Policy Rooms Are There?' (2007) 32 *Science, Technology & Human Values* 479.

⁷⁸ K Bickerstaff and others, 'Locating Scientific Citizenship: The Institutional Contexts and Cultures of Public Engagement' (2010) 35(4) *Science, Technology & Human Values* 474; S Cunningham-Burley, 'Public Knowledge and Public Trust' (2006) 9 *Community Genetics* 204; R Evans and A Plows, 'Listening Without Prejudice? Re-discovering the Value of the Disinterested Citizen' (2007) 37(6) *Social Studies of Science* 827; MD Pickersgill, 'Research, Engagement and Public Bioethics: Promoting Socially Robust Science' (2011) 37 *Journal of Medical Ethics* 698; T Tegers-Hayden, A Mohr and N Pidgeon, 'Introduction: Engaging with Nanotechnologies—Engaging Differently?' (2007) 1(2) *NanoEthics* 123.

⁷⁹ S Jasanoff, 'Biotechnology and Empire: The Global Power of Seeds and Science' (2006) 21 *OSIRIS* 273.

than ensure a genuine contribution to decision-making.⁸⁰ This might occur, for example, through the use of promissory or anticipatory discourses which seek to talk the future into existence,⁸¹ while at the same time constraining or even eliminating the conditions of possibility for other futures.⁸² Of particular note is criticism of the ‘deficit model’ of citizens in need of education through their participation. A core contribution of STS has been to show how that model undermines participation and is replete with flaws. Among them a point that is taken up in the conceptual approach sketched in the next section, which is that individuals come to know things in different ways, possess different kinds of expertise, and are reflexively aware of limitations in their ability to understand, which they may actively seek to address.⁸³

These insights have recently proven influential within regulation studies.⁸⁴ In particular, work on ‘design-based regulation’⁸⁵ stresses how norms, values, virtues and behavioural options are ‘designed-in’ and ‘designed-out’ of technologies and thereby inhibit or prevent action and undermine human agency.⁸⁶ Of particular note in this regard is Yeung and Dixon-Woods’ work on patient safety. They observe that ‘when rules are embedded in the fabric of design, there is no legal or constitutional obligation on those who identify and design-in the rules to invite *participation from those likely to be affected*, let alone take into account other *stakeholder interests*’ (emphasis added).⁸⁷

⁸⁰ The role of STS in this regard has also been the subject of self-reflection by its scholars: P-B Joly and A Kaufman, ‘Lost in Translation? The Need for “Upstream Engagement” with Nanotechnology on Trial’ (2008) 17(3) *Science as Culture* 225; BE Wynne, ‘Dazzled by the Mirage of Influence? STS-SSK in Multivalent Registers of Relevance’ (2007) 32(4) *Science, Technology & Human Values* 491.

⁸¹ M Fortun, *Promising Genomics: Iceland and deCODE Genetics in a World of Speculation* (Berkeley, University of California Press, 2008); A Hedgecoe and P Martin, ‘The Drugs Don’t Work: Expectations and the Shaping of Pharmacogenetics’ (2003) 33 *Social Studies of Science* 327; MD Pickersgill, ‘Connecting Neuroscience and Law: Anticipatory Discourse and the Role of Sociotechnical Imaginaries’ (2011) 30(1) *New Genetics and Society* 27; N Brown, B Rappert and A Webster (eds), *Contested Futures: A Sociology of Prospective Technoscience* (Aldershot, Ashgate, 2000).

⁸² For discussion of the use of bioethics in this way, see: Hedgecoe and Martin, *ibid*.

⁸³ A Irwin and M Michael, *Science, Social Theory and Public Knowledge* (Maidenhead, Open University Press, 2003); A Kerr, S Cunningham-Burley and A Amos, ‘The New Genetics and Health: Mobilising Lay Expertise’ (1998) 7(1) *Public Understanding of Science* 41; B Wynne, ‘Knowledges in Context’ (1991) 16 *Science, Technology & Human Values* 111; BE Wynne, ‘Misunderstood Misunderstandings: Social Identities and Public Uptake of Science’ (1992) 1 *Public Understanding of Science* 281.

⁸⁴ M Akrich, ‘The De-description of Technical Objects’ in WE Bijker and J Law (eds), *Shaping Technology/Building Society: Studies in Sociotechnical Change* (Cambridge MA, MIT Press, 1992); N Oudshoorn and T Pinch (eds), *How Users Matter: The Co-Construction of Users and Technologies, New Edition* (Cambridge MA, MIT Press, 2005); S Woolgar, ‘Configuring the User: The Case of Usability Trials’ in J Law (ed), *A Sociology of Monsters: Essays on Power, Technology and Domination* (London, Routledge, 1991).

⁸⁵ L Lessig, *Code: And Other Laws of Cyberspace* (New York NY, Basic Books, 1999); R Brownsword, ‘Code, Control and Choice: Why East is East and West is West’ (2005) 25 *Legal Studies* 1.

⁸⁶ Brownsword, n 4 above; K Yeung, ‘Towards an Understanding of Regulation by Design’ in Brownsword and Yeung (eds), *Regulating Technologies*, n 44 above.

⁸⁷ K Yeung and M Dixon-Woods, ‘Design-Based Regulation and Patient Safety: A Regulation Studies Perspective’ (2010) 71(3) *Social Science & Medicine* 613, 617.

Importantly, this may ‘reduce professional and public accountability ... and transfer judgments on the tolerability of risk to unaccountable institutions for which there is little transparency or public accountability’ (emphasis added).⁸⁸

At the same time STS has argued and shown that citizens have the potential to make a substantive contribution towards governing, especially by revealing and underlining the paradoxes, pitfalls and blind spots attendant to it.⁸⁹ The problems attendant to governance and regulation have also been recognised through the widespread use of the aforementioned risk-based governance tool of impact assessment and have of course been acknowledged in law and regulation studies. Still, the potential for participation to contribute knowledge on the problems is (as I have suggested) far less developed in those disciplines. Instead, within legal and regulation studies scholarship there is much attention given to demarcating the boundaries of responsibility and accountability in the event of failure and such matters as defining what ‘failure’ is and when and how it triggers blame. By contrast there is more attention given to the problems attendant to governance as key normative dimensions in cognate disciplines, especially bioethics, sociology, STS and anthropology. A key reason for this might be law/science disciplinary demarcations. These divisions obscure the normative content of scientific and technological knowledge and their material objects, and potentially shield them from engagement by law.⁹⁰

C. Taking Citizen Participation Seriously

The critique provided by STS in particular raises serious doubts about whether, and if so the extent to which, citizen participation is taken seriously in law and regulation studies as an object of study and as more than a procedural means of legitimating decisions and governance more broadly. In making that observation and the related arguments advanced in this book I hope to assist democratisation. Moreover, I seek to identify and push back against the forces at work in late modernity—especially risk-based, medical and/or technical framings of public health problems—that variously shape, constrain and even limit democratic contestation and participation in governing, whether as a consequence of political purpose or through lack of reflection on the undemocratic implications of late modern configurations of power.

The citizen participation I have in mind ought to do more than assist in the mediation of responsibilities and accountabilities and the production of legitimacy. Participation should be about sharing power and benefiting governance and the governed by improving the quality of the regulatory decisions made. This is

⁸⁸ Ibid.

⁸⁹ Discussed in ch 6.

⁹⁰ For discussion, see: T Murphy and N Whitty, ‘Risk and Human Rights in UK Prison Governance’ (2007) 47 *British Journal of Criminology* 798.

particularly important given regulatory failures and the idea that risk, uncertainties and failure are endemic to risk society. In that light, further consideration of citizen participation is not just important as a value in itself or as a technique of legitimation—it could even prove vital in addressing and even forestalling the dangers and threats produced by or not fully tackled by governance and regulation. The conceptual approach adopted to take this study forward is outlined in the next section.

III. GOVERNING IN LATE MODERNITY: THEORY, CONCEPTS AND METHODS

A. Technologies of Governing: Risk, Freedom/Security and Governmentality

To recap, this book aims to bring out how the problems attendant to governance and the potential for citizen participation to reveal and underline them might be better related and developed in ways that are to their mutual gain. This core focus implies a methodological decision about how to view and think about ‘EU law’ and its relations with ‘governance’ and ‘regulation’ for that core purpose. As such the analysis in this book does not look at individual measures of EU (hard) law, judicial decisions interpreting these provisions, soft law, and opportunities for funding (all command, control or steering instruments). Instead, this book adopts a broad brush approach in order to consider the concrete techniques, processes and practices produced by the EU level, their related norms, values and rationalities, and it considers how they are reflective of and embedded within the EU’s socio-political order and project of integration. This approach also brings out how the issues are undergirded by, related to one another, and configured within, the neoliberal conditions of late modernity. In the following I elaborate on these introductory points, trace how they are deployed throughout this book and track them to the subsequent discussion. In doing so I seek to explain how the theory, concepts and methods provide openings and possibilities for citizen participation that can be harnessed in order to enhance it and, in turn, governance and its regulatory interventions.

The analytic perspective used in this book to advance its agenda and related arguments combines insights from critical theory, law and regulation studies, sociology, STS, with anthropology and bioethics. Foucault’s work is especially important to the first of these disciplines, but it has also informed the others. A foundational insight is that the key terms in the initial questions—markets, risk and security, ethics and human rights—can be understood as discourses. For the purposes of this book they are to be found in the EU’s own published documentary record. Attention to discourse is important in that it ‘transmits and produces power; it reinforces it, but also undermines and exposes it, renders it fragile and makes it possible to thwart it’ (emphasis added).⁹¹ In this view power is relational,

⁹¹ M Foucault, *The History of Sexuality: Volume One, The Will to Knowledge* (London, Penguin, 1998) 101.

mutable and double-edged in that it both constrains and creates openings or possibilities for (re)shaping. Further, power operates automatically, often without intention, and with hidden and unforeseen consequences.

Discourses both constitute and help to convey ideas, values and rationalities.⁹² Consequently the way in which they articulate makes them central to framing issues,⁹³ and to producing, organising and utilising knowledge and experience, especially in legal and regulatory decision-making.⁹⁴ Discourses underpin and shape the design of the assemblage of knowledges, scientific and bureaucratic techniques, process and practices—in short, technologies—from a range of national, supranational and global actors and sources. I understand discourses as underpinning and comprising a technology of governing. As explained in the outline of the programmatic level of EU governance provided in the next chapter, this technology is made more specific and gains in importance through its deployment in efforts to produce and legitimate the EU's identity, socio-political order based on an innovative and competitive market economy in order to foster growth, jobs and prosperity, and ultimately the project of European integration.⁹⁵ As part of that the EU has a key role as a public health regulator in its own territory and globally. In short, focusing on the key discourses and their relationships is, therefore, a vital step towards mapping and understanding how public health problems are regulated, revealing the attendant distortions, failures, paradoxes, pitfalls and blind spots, and the limits and possibilities for citizen participation.

A key insight that explains the particular relation between markets, risk and security, and ethics and human rights, and thereby facilitates the first argument of this book, is how liberalism hinges security to markets in a particular way. Security is about regulating the dangers and threats attendant to a particular understanding of freedom as being about optimising the circulation of people and things. As Foucault put it, security provides the conditions of possibility for liberalism's central tenet of freedom, which is understood as 'the possibility of movement, change of place, and processes of circulation of both people and things'.⁹⁶ Freedom is 'one of the facets ... of the deployment of apparatuses of security'.⁹⁷ Security is about

⁹² VA Schmidt, 'Discursive Institutionalism: The Explanatory Power of Ideas and Discourse' (2008) 11 *American Review of Political Science* 303.

⁹³ M Hajer and D Laws, 'Ordering through Discourse' in M Moran, M Rein and RE Goodin (eds), *The Oxford Handbook of Public Policy* (Oxford, Oxford University Press, 2006).

⁹⁴ E Goffman, *Frame Analysis: An Essay on the Organisation of Experience* (Cambridge MA, Harvard University Press, 1974); M Rein and D Schön, 'Problem Setting in Policy Research' in C Weiss (ed), *Using Social Research in Public Policy Making* (Lexington MA, Lexington Books, 1977); DA Snow and others, 'Frame Alignment Process, Micromobilisation and Movement Participation' (1986) 51 *American Sociological Review* 464.

⁹⁵ For discussion of these sorts of connections see: W Brown, *Regulating Aversion: Tolerance in the Age of Identity and Empire* (Princeton NJ, Princeton University Press, 2006); S Jasanoff, *Designs on Nature* (Princeton NJ, Princeton University Press, 2005).

⁹⁶ M Foucault, *Security, Territory, Population: Lectures at the Collège de France, 1977–78* (Basingstoke, Palgrave Macmillan, 2007) 48–49.

⁹⁷ *Ibid.*, 49.

responding ‘to a reality in such a way that ... [it] cancels out the reality to which it responds ... regulates it’.⁹⁸

The discovery of population, the development of statistics to track its size and contours, including measurement of the incidence of disease through epidemiology, for example, valorised this knowledge and the experts producing and interpreting it, and provided the ‘end and instrument of government’ and made it ‘possible to think, reflect, and calculate ... outside the juridical framework of sovereignty’.⁹⁹ This not only made it possible to regulate dangers and threats to public health, but also gave rise to governmentality, which is not limited to law, but extends through its employment and infiltration of a range of imbricating discourses, techniques and elements that regulate everyday life and are constitutive of governance. Throughout this book I examine how the EU level of public health governance is a particular example of the transformation and integration of law and regulation within governmentality.

Especially important in that regard, and an essential link to what follows, is how security becomes understood less in terms of the protection of sovereignty and increasingly in terms of governmentality as being about the optimisation of the health and wealth of (non-state) *populations*. As de Larrinaga and Doucet explain, this is to be achieved through the ‘assessment of threats ... [and it] pays particular attention to the global and transboundary *circulation of threats* to [them]’ (emphasis added).¹⁰⁰ The idea that security is geared towards regulating the *public health* dangers and threats attendant to the circulation of people and things is salient to the EU’s internal market, which is discussed at the outset of chapter two, and referenced throughout the rest of the first part of the book. A final key point is that human rights and ethics are configured in relation to the central relationship between markets and security (and risk), but their central function seems to be the legitimation of governance and its regulatory interventions.

B. Regulating Risk

Thus far I have brought together insights that bring attention to the way in which the technology governing public health functions to optimise the circulation of people and things and tackles the attendant dangers and threats by framing them as risks to be regulated. As explained throughout the first part of the book the perceived risk of public health problems is central to the EU’s governance and the nature and selection of its regulatory responses—and these include interventions within the EU and globally. Governance is in turn reflective of, embedded within and oriented towards the production and legitimation of the EU’s identity,

⁹⁸ Ibid, 47.

⁹⁹ Ibid, 104–05. For application of these insights to the EU, see: W Walters and J Haahr, *Governing Europe: Discourse, Governmentality and European Integration* (Abingdon, Routledge, 2005).

¹⁰⁰ M de Larrinaga and MG Doucet, *Security and Global Governmentality* (Abingdon, Routledge, 2010) 17.

socio-political order and project of rule aimed at European integration. However, risk-based regulation has become more difficult given that risks, uncertainties and failures are increasingly recognised as being endemic to 'risk society'.¹⁰¹ Nevertheless, as Balzacq points out: the '*social design* of a security problem *conditions and legitimates* the *kind of means* used to stop it' and as such it is a 'normative political act' (emphasis added).¹⁰² As I point out as part of the first argument, interventions such as technological and magic bullet medical responses might be favoured by the EU's risk-based technology, in particular because it is reflective of and embedded within a regime that seeks to optimise the circulation of people and things. These sorts of interventions are more often the subject of discussion in sociology, anthropology and bioethics, for example, than law and regulation studies, but are important to the latter two as the key paradoxes, pitfalls and blind spots attendant to the EU's risk-based technology. Moreover, these normative dimensions provide the grounds for the core or overall argument and intervention of this book, which is that citizen participation is vital because it can help to reveal and underline them and enhance the quality of governance and its regulatory interventions.

That overall argument is all the more important for the EU, given how it has met with a crisis of public confidence, trust and legitimacy¹⁰³ in the wake of high profile regulatory failures such as the BSE¹⁰⁴ crisis of the 1990s (as well as ongoing concerns around the inequity of the legal and regulatory arrangements put in place to resolve the economic and financial crisis of the 2000s onwards). As a consequence of this there has been much debate about the shape and design of the regulation of scientific risk and uncertainty and its implementation,¹⁰⁵ which has included a turn to human rights and bioethics.¹⁰⁶ Law and regulation studies, with their focus on decision-making, are, as I have already pointed out, central to this debate, especially given renewed attention to the salience of the context of scientific uncertainty. The production of regulatory failures and risks, and the limited role of citizen participation, both follow (as I shall explain further in chapter six) from the design of governance and its regulatory interventions.

¹⁰¹ U Beck, *Risk Society: Towards a New Modernity* (London, Sage Publications, 1986); U Beck, *World at Risk* (Cambridge, Polity Press, 2009); A Giddens, *The Consequences of Modernity* (Polity Press, Cambridge, 1990); A Giddens, 'Risk Society: The Context of British Politics' in J Franklin (ed), *The Politics of Risk Society* (Cambridge, Polity Press, 1998).

¹⁰² T Balzacq, 'Preface' in *Securitisation Theory: How Security Problems Emerge and Dissolve* (London, Routledge, 2011) xiii. For Foucault influenced securitisation theory in the public health field, see: S Elbe, *Virus Alert: Security, Governmentality, and the AIDS Pandemic* (New York, Columbia University Press, 2009).

¹⁰³ For an overview, see: C Scott, 'Accountability in the Regulatory State' (2000) 27 *Journal of Law and Society* 38 and the references in n 6 above, especially: Scharpf, *Governing in Europe. Effective and Democratic?*; Arnall and Wincott, *Accountability and Legitimacy in the European Union*.

¹⁰⁴ That is, bovine spongiform encephalopathy.

¹⁰⁵ For discussion, see: M Everson and E Vos, 'The Scientification of Politics and the Politicisation of Science' in M Everson and E Vos (eds), *Uncertain Risks Regulated* (Abingdon, Routledge-Cavendish, 2009).

¹⁰⁶ O'Neill, n 64 above, 3, who in addition to noting the 'widespread and energetic efforts to respect persons and their autonomy and to improve regulatory structures', goes on to point out that, 'public trust in medicine, science and biotechnology has seemingly faltered'. See further, the discussion in ch 6.

In terms of design, Brownsword explains how regulators ‘need to tailor their interventions to the perceived risk profile presented by a particular technology’¹⁰⁷—or, indeed, other regulatory targets, such as public health problems (including new technologies as such problems). This involves determining such matters as when risk materialises; the degree of risk (whether it is low or high); the kind of harms or hazards to which risk to public health pertains and the potential for their ranking; and, finally, how risk relates to precaution (whether precaution occurs at risk assessment or somehow operates in risk management).¹⁰⁸ Rare public health problems, such as those emerging well beyond the EU but spreading (in)to it through the circulation of people and things, as well as those produced by new technologies, are especially problematic for the production of a risk profile in that so much is unknown and uncertain, and there is little agreement on a range of issues—including how the related risks ‘should be framed, which methodologies should be adopted, [and] which values prioritised’.¹⁰⁹

Knowledge—its creation, use and deployment—is central to these design-oriented discussions. As noted above, the study of disease through epidemiology and regulation of risk have historically laid the basis for public health governance and its regulatory interventions. This is brought out by Foucault’s idea of power/knowledge, which denotes the way in which changes in knowledge help to provide the basis for the production and exercise of governmental power and control. Knowledge is formulated as encompassing ‘the vast assemblage of persons, theories, projects, experiments and techniques that has become such a central component of government’—it is ‘the “know how” that makes government possible’.¹¹⁰ A major contribution of STS that builds on power/knowledge is that of co-production. Knowledge, including scientific facts,¹¹¹ as well as its ideational and material products, are ‘incorporated into practices of state-making, or of governance more broadly’.¹¹² This underlines the way in which the EU’s risk-based technology for governing public health and its related regulatory interventions have a wider significance, that is, in terms of producing, reflecting and legitimating the EU’s identity, socio-political order and European integration project.

¹⁰⁷ Brownsword, n 4 above, 118.

¹⁰⁸ *Ibid*, 118–19.

¹⁰⁹ *Ibid*, 119–20.

¹¹⁰ N Rose and P Miller, ‘Political Power Beyond the State: Problematics of Government’ (1992) 43(2) *British Journal of Sociology* 172, 178.

¹¹¹ K Knorr Cetina, ‘Laboratory Studies: The Cultural Approach to the Study of Science’ in S Jasanoff and others (eds), *Handbook of Science and Technology Studies* (London, Sage Publications, 1995); B Latour, *Science in Action. How to Follow Scientists and Engineers through Society* (Cambridge MA, Harvard University Press, 1987); M Lynch and S Woolgar (eds), *Representation in Scientific Practice* (Cambridge MA, MIT Press, 1990); A Pickering (ed) *Science as Practice and Culture* (Chicago, University of Chicago Press, 1992).

¹¹² S Jasanoff, ‘The Idiom of Co-Production’ in S Jasanoff (ed), *States of Knowledge: The Co-Production of Science and the Social Order* (London, Routledge, 2004) 3. See, more generally: PK Feyerabend, *Against Method* (London, Verso, 1993); T Kuhn, *The Structure of Scientific Revolutions*, 2nd edn (Chicago, University of Chicago Press, 1970).

In that regard, accountability and legitimacy are, therefore, also key to risk regulation. Foucault's account of governmentality neglected the matter of legitimacy, which is perhaps understandable given the central objective of his work was to decentre the state and sovereignty in analyses of power. However, since the state remains important, even as its functions have been governmentalised and integrated in wider circuits of governing the global, it and state-like organisations like the EU remain the singularly accountable sites of power in late modernity. As such the legitimacy of such organisations and meeting their legitimation needs become vital concerns—as Black points out, the rhetoric of risk is a 'useful *legitimizing* device' (emphasis added).¹¹³ Public perceptions are an important part of legitimation efforts in that, as Power explains, they present a source of 'institutional risk', that is, a risk to the standing and reputation of the institution. Consequently managing that risk entails attempts at governing '*unruly perceptions*' and maintaining the '*production* of legitimacy in the face of these perceptions' (emphasis added).¹¹⁴

These matters become even more important in contexts of uncertainty or non-knowing about, inter alia, the type and scale of risk, such as in relation to the pandemics and other serious cross-border threats to health discussed in chapter five, and where the dominant modes and techniques of scientific and technical knowledge and expertise are undermined even as they remain central to decision-making. Brownsword points out that in these circumstances 'the legitimacy crisis becomes acute'¹¹⁵—and linking back to the discussion above, in this context citizen participation (with the focus on procedures for its facilitation) is seen as a key way of achieving accountability and legitimacy, if not through the contribution of knowledge.¹¹⁶ As discussed in chapter six, citizen participation has become an increasingly important tool or technology for the EU's risk-based governance and regulatory interventions in general and is implicated in the fabrication of the boundaries of responsibility and the legitimation of the regulatory process¹¹⁷ and its outcome that is, helping to foster trust and confidence in the safety of people and things in circulation within and into the internal market.¹¹⁸ As I go on to explain, sensitivity to the 'institutional risk' posed by public perceptions and the wider importance of the legitimation of the EU's risk-based technology are key resources—providing a 'way in'—for enhancing citizen participation in decision-making and with it governance and its regulatory interventions.

¹¹³ J Black, 'The Emergence of Risk-Based Regulation and the New Public Risk Management in the United Kingdom' (2005) *Public Law* 512, 519.

¹¹⁴ M Power, *Organized Uncertainty* (Oxford, Oxford University Press, 2007) 21.

¹¹⁵ Brownsword, n 4 above, 131.

¹¹⁶ On the necessity of public engagement, see: DJ Fiorini, 'Citizen Participation and Environmental Risk: A Survey of Institutional Mechanisms' (1990) 15 *Science, Technology & Human Values* 226.

¹¹⁷ Black, n 113 above; J Black, 'Tensions in the Regulatory State' (2007) *Public Law* 58.

¹¹⁸ Cf G Bache, ML Flear and TK Hervey, 'The Defining Features of the European Union's Approach to Regulating New Health Technologies' in Flear and others (eds), n 13 above.

C. Neoliberalism

A supplementary and key resource for improving the shape and role of citizen participation is provided by an appreciation of the deployment, operation and implications of neoliberalism as that which undergirds EU governance and its regulatory interventions, and how that relates to the production and legitimation of the EU's identity, socio-political order and project of European integration. At the present time, in what is often called late modernity, governmentality and especially the central relationship between markets and security and the prominence of risk regulation, operates within, and is (re)organised by, neoliberal political rationality.¹¹⁹ Recognition of the latter supports the second argument made in this book in particular, while providing the foundations for the subsequent arguments. Neoliberalism increasingly fuses governmentality with technical reason and means-end, or instrumental, market rationality. The latter is actively disseminated through the organisation of governance 'at a distance'¹²⁰ and related concepts of self-managing and sovereign subjects, in order to extend existing power relations and optimise life.¹²¹ As a twist to the understanding of security within governmentality that will become salient to the discussion on preparedness planning in chapter five, and chiming with growing awareness of the importance of 'institutional risk', within neoliberalism there is an increasing focus on the protection of vulnerable *governance*—signalling reflexive governance as an approach—rather than vulnerable populations. Dean points out reflexive governance works by 'securing the mechanisms of *government*. Society itself can be changed, according to this view ... through *transformation of the mechanisms* by which it had previously been governed' (emphasis added).¹²²

More deeply, neoliberalism works to (re)configure several key relationships, such as those between governance and the governed, knowledge and power, sovereignty and territoriality, and power and responsibility. Through a focus on techniques, processes and practices I bring out how EU governance and its regulatory interventions are making use of, and being (re)organised by and within, neoliberalism. As that which undergirds the EU's risk-based technology governing public health, neoliberalism is central to attempts made at not just renegotiating but also more clearly delimiting the boundaries of responsibility and accountability. Further, within neoliberalism knowledge is increasingly made to serve power; and the latter is itself extended, even as governance itself is presented as limited. In effect, as mentioned above, governance is extended in terms of what

¹¹⁹ Described as 'a way of doing things that ... [is] oriented to specific objectives and that ... [reflects] on itself in characteristic ways': N Rose, P O'Malley and M Valverde, 'Governmentality' (2006) 2 *Annual Review of Law Society and Science* 83, 84.

¹²⁰ M Dean, *Governmentality: Power and Rule in Modern Society*, 2nd edn (London, Sage Publications, 2009); H Kemshall, 'Social Policy and Risk' in G Mythen and S Walklate (eds), *Beyond the Risk Society* (Maidenhead, Open University Press, 2006).

¹²¹ R Flynn, 'Health and Risk' in Mythen and Walklate, *ibid*.

¹²² Dean, *Governmentality*, n 120 above, 226.

it covers (from knowledge creation to material interventions), the places where it applies and people enfolded in its operation and in relation to whom it has effects. Neoliberalism also implies the legitimacy needs of formally accountable sites of power, such as the EU, become ever more important as they also tighten their relations with science and technology,¹²³ and citizens engage with this reflexively as a 'knowledge society'.¹²⁴ Through the discussion in the first part of the book these (re)configurations will emerge as the structuring themes of the EU public health policy domain and are important to the subsequent discussion in the second part where they are suggested to open up spaces and possibilities for citizen participation.

A key implication of the operation of neoliberalism that is central to the project pursued in this book and the discursive strategy for enhancing citizen participation put forward in chapter six is the following. As Ong explains, in a move that seeks to efface the normative from governance, and depoliticise and naturalise, its objects 'are recast as non-political and non-ideological problems that need *technical solutions*' (emphasis added).¹²⁵ The effect of depoliticisation serves to, as Brown puts it, remove or mask those phenomena and subjects from comprehension of their '*historical* emergence and from a recognition of the *powers* that produce and contour [them]' (emphasis added).¹²⁶ In other words, the phenomena and subjects produced by the discourses appear to be naturally occurring. Normative matters, including the norms, values and socio-political imaginaries reflected in and underpinning governance, are obscured by the framing of public health problems as matters of risk necessitating technical solutions. This framing renders as natural and non-political both the techniques, processes and practices through which it is operationalised *and* their attendant paradoxes, pitfalls and blind spots, such as those related to the distribution of resources and other benefits and vulnerability. The framing, underpinned by neoliberalism, constrains the space for and frustrates biopolitics as well as citizen participation in decision-making.

Aiding this depoliticisation and naturalisation is the way in which risk individualises and responsabilises through notions of self-management. These work with the focus on the autonomous, rational, 'relentlessly self-interested subject of liberalism'¹²⁷ in law and especially human rights and bioethics, which discursively erases differences between citizens and their attendant disadvantages. Neoliberalism helps to support a number of broader trends in (public) health.

¹²³ Brown, *Regulating Aversion*, n 95 above, 15; Jasanoff, *Designs on Nature*, n 95 above, 5–6.

¹²⁴ D Bell, *The Coming of Post-Industrial Society: A Venture in Social Forecasting* (Harmondsworth, Basic Books, 1976); M Castells, *The Rise of the Network Society (= The Information Age, Vol I)* (Oxford, Blackwell, 1996); K Knorr Cetina, *Epistemic Cultures. How the Sciences Make Knowledge* (Cambridge MA, Harvard University Press, 1999); N Stehr, *Knowledge Societies* (London, Sage Publications, 1994).

¹²⁵ A Ong, *Neoliberalism as Exception: Mutations in Citizenship and Sovereignty* (London, Duke University Press, 2006) 3.

¹²⁶ Brown, *Regulating Aversion*, n 95 above, 15.

¹²⁷ W Brown, *States of Injury* (Oxford, Princeton University Press, 1995) 25, in the aptly titled 'Introduction: Freedom and the Plastic Cage'.

Over 10 years ago Montgomery noted there was a shift 'of emphasis *away* from collective and environmental work, *towards* a concentration on *individual responsibility* and *lifestyle issues*' (emphasis added).¹²⁸ The latter is seen in relation to, say, new diagnostic technologies, which make possible certain discourses on risk for those trying to determine their individual risk of cancer.¹²⁹ The shift towards reflexive governance might help to further obscure the normative content of legal and regulatory decisions, which remains concealed by and within the design of governance and its regulatory interventions. This effect might be abetted by the abovementioned tendency of legal and regulation studies scholarship to not delve deeper into the normative dimensions and consequences of the production, dissemination and wider use of the knowledge that underpins decision-making.

As that which undergirds the risk-based technology governing public health neoliberalism is also central to efforts at producing and legitimating the EU's socio-political order and project of European integration. This implies that the EU's prominence in news media 'status' updates such as those mentioned at the outset, and more detailed information provided online,¹³⁰ is not merely functional as an indispensable adjunct to the EU's core internal market project. Rather, the reports can also be understood as instances of the EU seizing hold of the opportunity to demonstrate its use and 'added value' in the face of 'public health threats'—and even 'emergency'. Indeed, the salience of public health—its centrality to how we live, the universally acknowledged desirability of health,¹³¹ and its place as a core component and focus of formally accountable power and sovereignty—is also useful to the EU's integration project. When viewed from a governmentality perspective the EU's risk-based technology is of use as a support for producing and legitimating the EU's socio-political order and project of European integration, by ensuring it meets public needs and values, and tracks public opinion.¹³²

D. Biopolitics and 'The Governed' as Citizens

The discussion in this book all relates, in one way or another, to the (re)configuration of relations between governance and the governed. Indeed, the sheathing of the normative and political within the technical, the alignment of scientific

¹²⁸ Montgomery, n 30 above, 23. This is part of a trend brought about by three key public health trends: changes in death rates or mortality; developments in the incidence of ill-health or morbidity; linked to that, changes in the understanding of what constitutes 'health' (averred to in discussion of definitions in the previous section and the influence of the WHO's definition).

¹²⁹ A Robertson, 'Biotechnology, Political Rationality and Discourses on Health Risk' (2001) 5 *Health* 293.

¹³⁰ Eg: 'Avian Influenza' ec.europa.eu/dgs/health_consumer/dyna/influenza/; 'Communicable Disease Threats Report (CDTR)' www.ecdc.europa.eu/en/publications/surveillance_reports/communicable-disease-threats-report/Pages/default.aspx.

¹³¹ Richman, *Medicine and Health*, n 25 above.

¹³² See, eg: 'Influenza H1N1' ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/docs/eurobarometer_summary_20100224.pdf. For further discussion, see ch 6.

and technical knowledge and expertise to economic and political power, and the way in which that limits the potential for citizen participation (ie the third argument advanced in this book), when combined with the effects of depoliticisation and naturalisation, reduces and (re)structures the space between the economic and the social in liberalism, which in turn limits the space for biopolitics. As Ong explains, in terms of the relations between governance and the governed, neoliberalism ‘reorganises connections among the governing, the self-governed, and political spaces, optimizing conditions for responding technically and ethically to *globalised uncertainty and threat*’ (emphasis added).¹³³

Nevertheless, as I have already noted, and as described in detail in chapter six and relating to the fourth argument advanced throughout the second part of the book, the governing technology’s framing by risk (made out in the first argument), the (neoliberal) foundations of governance (outlined in making out the book’s second argument) and its paradoxes, pitfalls and blind spots (implicated in making out the first argument), as well as the importance of legitimation and the shaping of public perceptions in that regard, open up space and create possibilities for citizen participation in decision-making in spite of the limits on its current shape and use (the third argument). These normative dimensions can be brought out by citizen participation that uses the discursive resources within governance itself in order to generate supplementary knowledge for decision-making (specifically, the legitimating discourses of human rights, bioethics and developing notions of (supra-)stewardship responsibility for public health). The extension of governance in terms of what it covers (from knowledge creation to material interventions), the places where it applies and the people enfolded in its operation and in relation to whom it has effects, is not without implications for those who come to comprise ‘the governed’.¹³⁴ As I explain in chapter six, in relation to public health governance these include those with underlying medical conditions, limited access to education and economic resources, pregnant women, children and itinerants. Another notable group is non-EU citizens residing in Europe (including undocumented migrants), a group that often has difficulty accessing health services and health insurance and tends to experience more health problems than ‘regular’ EU citizens.

In this light the ‘citizen’ in citizen participation is unsettled and expanded to encompass more than those in possession of formal EU citizenship that is those

¹³³ Ong, *Neoliberalism as Exception*, n 125 above, 14.

¹³⁴ Here I join with scholarship in citizenship studies: ‘the claim that citizenship requires territorially bounded community is under challenge from theorists and activists who propound conceptions of “cosmopolitan citizenship”, “global citizenship”, “transnational citizenship”, “postnational citizenship”, “diasporic citizenship”, and the like—and what we might call, collectively, the “citizenships of globalisation”’. MS Williams, ‘Nonterritorial Boundaries of Citizenship’ in S Benhabib, I Shapiro and D Petranović (eds), *Identities, Affiliations and Allegiances* (Cambridge, Cambridge University Press, 2007) 228.

who are also nationals of an EU Member State.¹³⁵ Importantly, resonating with the Foucauldian understanding of power that is foundational to this book, and recognised in STS (in its critique of the current institutionalisation of participation noted above), as well as in sociology and anthropology in particular, those citizens are endowed with agency. Those that are governed are increasingly (self-) reflexive,¹³⁶ purposive actors who engage in automatic monitoring of social reality. These subjects come to know themselves and relate to others through the prism of different knowledges and biomedical knowledge is foremost in the context of public health.¹³⁷ Through reflection on and application of this knowledge citizen participation might disrupt or destabilise the formal attempts to delineate and distribute responsibilities and accountabilities—and even renegotiate them so as to (re)responsibilise those who make (political) choices over the framing, nature, shape and direction of governance. The chief function of this book is to furnish discursive tools for participation that might (re)frame and (re)shape governance and sketch out some areas for attention by citizens in their attempts to demand and contest decision-making.

IV. OVERVIEW

The insights traced in the previous section are deployed in order to meet the book's aims and advance the related arguments over its two parts. The first part of the book proceeds in a broad brush fashion to trace how risk and security relate to markets, and how ethics and human rights relate to that central relationship, where they can be discerned at all. The next chapter sketches the EU's formal legal competence in the field of public health and situates it within the wider programmatic concerns of the overarching architecture of governance, especially the production and legitimation of the EU's identity, socio-political order based upon a competitive, innovative and optimised market-based economy and project of rule aimed at European integration. Subsequently I sketch the working out of competence through the more specific strategy aimed at consolidating,

¹³⁵ In the EU context see especially Art 9 TEU and Arts 20–24 TFEU (read with Art 18 TFEU on non-discrimination on the basis of nationality), which establish EU citizenship and its rights. Art 20(1) TFEU states 'Citizenship of the Union is hereby established. Every person holding the nationality of a Member State shall be a citizen of the Union. Citizenship of the Union shall be additional to and not replace national citizenship'. For further discussion, see: D Kostakopoulou, 'Ideas, Norms and European Citizenship: Explaining Institutional Change' (2005) 6(2) *Modern Law Review* 233.

¹³⁶ U Beck, *Risk Society: Towards a New Modernity* (London, Sage Publications, 1986); A Giddens, *Modernity and Self-Identity* (Cambridge, Polity Press, 1991). Foucault did not have a theory of reflexivity, but for such an addition to his thinking see: J Butler, *The Psychic Life of Power* (Stanford CA, Stanford University Press, 1997).

¹³⁷ Recognised in terms such as 'biological citizenship': A Petryna, *Life Exposed: Biological Citizens After Chernobyl* (Princeton NJ, Princeton University Press 2002); N Rose and C Novas, 'Biological Citizenship' in A Ong and S Collier (eds), *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems* (Oxford, Blackwell Publishing, 2005). See further, ch 6.

orchestrating and directing the technology governing public health and the policy domain as a whole.

The market-oriented rationale of that strategy is explained and elaborated by reference to its principles and objectives. Of those the principle of putting health in all policies is discussed more extensively for the ways in which it brings out the contours and underpinnings of the domain and its normative orientation and direction. Impact assessment as knowledge-based policy-making and then monitoring, measuring and evaluating as ways of governing through agency and performance are identified as being particularly important governing technologies. After which the growing importance of the EU's role as a security actor and its importance for the production of legitimacy are underlined. Finally, the importance of structured cooperation as the key approach for the EU's strategy is highlighted, and that is followed by discussion of funding through health programmes as a particular way of influencing and regulating national authorities, populations and individuals.

The discussion in chapter two is filled out across chapters three, four and five, which focus on the specific public health problems of, respectively, cancer, HIV/AIDS and finally other pandemics and serious cross-border threats to health. Overall these chapters explain how the various techniques, processes and practices governing the respective problems are aligned to and configured by and within the overarching architecture and its programmatic concerns via the more specific strategy for the public health policy domain. This selection of case studies for the chapters is justified by the research agenda for this book, which focuses on tracing the core contours and underpinnings that are constitutive of the technology governing public health and policy domain.

There are three further reasons for the selection. The first is that the EU's governance of public health is typically organised around specific problems. The second reason for the selection is that these three examples provide a combination of the EU's longstanding and more recent areas of engagement in public health, encompassing communicative and non-communicative diseases, and governing in the face of varying degrees of risk and more recently uncertainty and non-knowing. The selection is therefore quite comprehensive in terms of the types and range of public health risks regulated by EU governance. The final reason for this selection is that the individual case studies are likely to be models for the governance of other public health problems and the regulatory interventions adopted, and in that regard it includes the most important examples (as apparent from a reading of the EU's documentary record). The selection is therefore likely to be extensive enough to permit the breadth and depth of analysis required for the research agenda pursued in this project, which uses public health as a prism through which to examine a cluster of key issues in EU studies and contribute towards 'law and public health'.

Chapter three discusses the EU's approach to cancer, situates it within the wider governance of major and chronic diseases and conditions, and then links the specific EU partnership approach to governing cancer to the overarching architecture

via the public health strategy. Through an analysis of the rationale and objectives of the cancer partnership, its areas and actions for a comprehensive policy response, and finally the stress on steering national responses, knowledge production and governing through the agency and performance of actors are noted as centrally important to the EU's approach. The thrust towards extending and deepening EU involvement at the national level is the final point. Chapters four and five highlight the growing importance of a stronger focus at the EU level on the securitisation of public health, that is, the regulation of the dangers or threats to the circulation of people and things. While the external dimension of EU governance is noted in relation to cancer, it is in relation to these other public health problems that it gains in prominence.

Chapter four examines the EU's governance of HIV/AIDS, touches on and explains its importance by reference to the wider governance of sexually transmitted illnesses and communicable diseases, and again emphasises the securitisation of public health, in particular through an emphasis on prevention and the internal and external dimensions of governance. The discussion again links the EU's approach to HIV/AIDS in its territory and neighbouring countries to the overarching architecture via the public health strategy. The significance of the focus on external governance understood as governing the EU's periphery and beyond is noted as particularly important to the EU's developing identity and security and public health actor. The main contours of the EU's governance are given prominence and noted as including a focus on distributed responsibilities. After which the centrality of prevention and attention to most at risk regions and societal groups and finally knowledge (again) are highlighted.

Chapter five looks at EU level preparedness planning for pandemics (like influenza) and an apparently open-ended cluster of other serious cross-border threats to health. The chapter begins by sketching the very recent genesis of this aspect of public health governance at the EU level. Security, and especially regulation of risk (through preparedness), is again emphasised as a key preoccupation of the internal and external dimensions of EU regulation. The chapter stresses how the focus is, as in relation to HIV/AIDS, on ensuring the operation of the market, that is, the free circulation of people and things within the internal market. Again ethics and human rights seem to be used more as legitimating devices for the security of the free movement market imperative.

The outline of the contours, underpinnings and techniques, processes and practices of the technology governing public health and the policy domain in these chapters comprises the main contribution of the first part of the book, and provides the platform for the second part, which diagnoses citizen participation itself as an underdeveloped technology and therefore 'the' key concern of this book and makes a prescription for enhancing and powering it as a way of improving governance and its regulatory interventions. The diagnosis is made in chapter six, which begins by summarising the findings in the first part of the book, in particular, highlighting the defining features and risk as the dominant framing for the governing technology, but one that is underpinned by and oriented towards market

optimisation understood as being about the circulation of people and things. The chapter identifies the (re)configurations ongoing in governance—those between governance and the governed, knowledge and power, sovereignty and territoriality, and power and responsibility—as the structuring themes of the EU level of the multi-level system of public health governance.

The discussion then moves to make use of these findings by considering the implications of the EU's governance of the public health problems for biopolitics and the role, use and configuration—the institutionalisation—of citizen participation in decision-making. The discussion draws on the previous chapters to describe how the defining features, dominance of risk and the structuring themes undergirding governance open space and provide possibilities for citizen participation in governance. I nominate the legitimating discourses of human rights and bioethics, and the developing notion of (supra-)stewardship responsibility, as the discursive means and strategy for facilitating and powering discussion—for public querying—around framing, distribution and vulnerability that generates supplementary knowledge on the paradoxes, pitfalls and blind spots attendant to governance. I explain how these latter provide a 'way in' for participation impelled by the threat that, if unaddressed, regulatory failures and 'societal risks' could produce 'institutional risks' that undermine and delegitimize the EU's governance, identity as a security and public health actor, socio-political order and project of European integration.

The final two chapters deploy the discursive strategy by using a broad brush approach in order to underline the normative dimensions of the technical through a cluster of related examples. Chapter seven examines the normative dimensions of framing and explains how the focus on risk directed towards economic optimisation produces a distortion of governance priorities and a related preference for technological and medical regulatory interventions. Subsequently, the implications for knowledge production are discussed by reference to the examples of indicators and clinical trials. Throughout the focus is on the implications for distortions in the focus of governance, the distribution of attention and resources and vulnerability. The discussion on clinical trials focuses on their performance abroad for the simple reason that it helps to throw normative concerns into sharper relief.

Chapter eight builds on the discussion in the previous chapter to tease out some of the implications of regulatory interventions in the field of public health with a focus on vulnerability and the consequences for that given the skewing of attention and resources towards magic bullet responses and technological fixes. Pharmaceuticals are the focus of the discussion since, for reasons summarised in chapter six and underlined in chapter eight, they are seemingly the intervention that receives increasing attention and resources within this governance, especially as it relates to the external sphere. Chapters seven and eight underline the importance of citizen participation in querying the techniques, processes and practices of governance itself, including knowledge creation and extending to regulatory interventions.

In chapter nine I overview the key findings, reconsider my initial concern about the current role, use and configuration of citizen participation in light of the foregoing discussion, and explain whether and if so how the mix of pessimism and optimism that prompted the book has changed. Overall, through this book I hope to prompt ongoing critical reflection on the roles and uses of citizen participation in governing and make a case for its continued relevance, both as a value in itself, and for the enhancement of the quality of governance and regulatory interventions.