

# Northern Ireland Legal Quarterly

Volume 62 Number 5

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# An introduction to “A symposium with Professor Roger Brownsword: super-stewardship in the context of public health”

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Stewardship is mentioned in Professor Roger Brownsword’s work on new and innovative technologies as “a significant item of unfinished business”.<sup>1</sup> In recent years, stewardship has arisen in other contexts, most notably the environment and public health.<sup>2</sup> The latter is the immediate context for consideration of stewardship and the development of “super-stewardship” in this special issue. The articles assembled were originally presented in the symposium with Brownsword that was held on 14 November 2009 at the School of Law, University of Sheffield. The articles also engage with the 2007 report of the Nuffield Council on Bioethics, *Public Health: Ethical issues* (Nuffield),<sup>3</sup> which Brownsword co-authored, and occasionally the World Health Organisation’s (WHO) version of stewardship put forward in its *World Health Report 2000*.<sup>4</sup> In the policy world, stewardship is of ongoing relevance given that Nuffield has recently been adopted by the National Institute for Health and Clinical Excellence (NICE),<sup>5</sup> the body that gives guidance and recommendations to the National Health Service on new and existing medicines, treatments and procedures.

More detailed and alternative understandings of stewardship and super-stewardship are provided in the articles, all of them in different ways attesting to the continued salience of the terms. Still, it is useful here to indicate stewardship’s general contours, and I do so by reference to the summary of Nuffield by three of its authors – Baldwin, Brownsword and Schmidt – as follows:

liberal states have responsibilities to look after important needs of people both individually and collectively. Therefore, states are stewards both to individual

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1 R Brownsword, “So what does the world need now? Reflections on regulating technologies” in R Brownsword and K Yeung (eds), *Regulating Technologies: Legal futures, regulatory frames and technological fixes* (Oxford: Hart 2008), p. 47.

2 See further: J Coggon, “What help is a steward? Stewardship, political theory, and public health law and ethics” and S Holm, ‘From steward to Stuart: some problems in deciding for others’, both in this special issue.

3 Nuffield Council on Bioethics, *Public Health: Ethical issues* (London: Nuffield Council on Bioethics 2007).

4 WHO, *World Health Report 2000* (Geneva: WHO 2000).

5 See A Killoran and P White, “NICE public health guidance” (2010) 32(1) *Journal of Public Health* 136. NICE: [www.nice.org.uk/aboutnice/](http://www.nice.org.uk/aboutnice/) (last accessed 5 September 2011).

people, taking account of different needs arising from factors such as age, gender, ethnic background or socio-economic status, and to the population as a whole . . . [T]he notion of stewardship gives expression to the obligation on states to seek to provide conditions that allow people to be healthy, focussing attention, in particular, on reducing health inequalities.<sup>6</sup>

In Nuffield, stewardship is posited on states. Moreover, as elaborated in the collection, Nuffield provides a rights-based approach to incorporate a precautionary way of thinking in public health contexts aimed specifically at the population level. Linking to “super-stewardship”, Nuffield also notes that it is “also reasonable” to apply stewardship at a “*much higher level*”.<sup>7</sup> The obligation of countries to notify others of a serious infectious disease outbreak in accordance with WHO procedures is used as an entry point for consideration of international and supranational responsibilities in the context of public health. The salience on that context is highlighted by inter alia recent pandemic alerts – and the ongoing problem of HIV/AIDS.

A single special issue cannot cover the whole of this emerging field of interest. One way of viewing the collection and its contribution is by highlighting the core contribution of each article. In his keynote article, Brownsword refines and extends his earlier thoughts on the scope and function of stewardship as it is linked to broader concerns on the idea of a “regulatory environment” and “regulatory prudence”. Brownsword’s conception of stewardship contrasts with Nuffield in that the state is not merely fulfilling responsibilities to its citizens, but is transformed into an (aspirant) moral community striving to flourish and develop.<sup>8</sup> This line of thought is extended such that stewardship is conceived as the ongoing responsibilities in relation to the routine running of community life and super-stewardship responsibilities relate to the preservation of the staging or infrastructure for moral community. The article enriches and reinforces the foundations of stewardship and super-stewardship and opens up space for reflection on the meaning and scope of “responsible regulation”.

Complementary criticisms of stewardship and super-stewardship are put forward by Coggon and Holm. For Coggon, stewardship does not provide a basis for robust analysis in public health law and ethics. Rather, stewardship adds little as a label for unsubstantiated normative conclusions or issues of good governance better addressed directly in theory. Coggon argues that stewardship is not a sound basis for policy or critical scholarship, especially since it might obscure rather than expose important normative argument. Still, in a way that resonates with Flear’s article (see below), Coggon acknowledges stewardship’s possible benefits as a public bioethical discourse.

Holm explores stewardship and super-stewardship from a critical philosophical point of view in order to tease out their internal coherence, justification, difference from paternalism, and value in guiding action. Overall, it is argued that Nuffield cannot be differentiated from paternalism and that while Brownsword’s conception of stewardship does contain a justification through reference to the “aspirant moral community”, Nuffield provides no clear justification for stewardship. Holm suggests there is an even weaker justification for super-stewardship. The upshot, then, is that both Holm and Coggon query the wisdom and use of stewardship and super-stewardship.

6 T Baldwin, R Brownsword and H Schmidt, “Stewardship, paternalism and public health: further thoughts” (2009) 2(1) *Public Health Ethics* 113, pp. 115–16.

7 Nuffield Council, *Public Health*, n. 3 above, p. 68 (emphasis added).

8 Cf. R Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: OUP 2008), p. 115.

The articles by Hervey, Murphy and Flear apply stewardship and super-stewardship as tools to highlight and address public health problems and governance in international and supranational settings. Hervey argues that, with some adjustments, stewardship is as applicable to the European Union (EU) as super-stewardship. By drawing on insights from law and streams of European integration theory in particular, Hervey convincingly dismisses arguments against the application of super-stewardship to the EU as a catchy and evocative description of its responsibilities in law and policymaking. She also provides examples of how EU super-stewardship can be discerned and assessed.

Murphy uses Nuffield as a reference point to launch consideration and promote critique of the roles of non-governmental organisations (NGOs) in public health, and especially in relation to HIV/AIDS – and indeed to propose a *revised* Nuffield that engages with the phenomenon she terms “public health *sans frontières*”. Such a report would include attention to and discussion around three particular points: consideration of the relationship between human rights and humanitarianism in the public health arena; the nature, scope and form of the commitment of global human rights NGOs to public health issues; and the particular challenges of *human rights* triage. In extending super-stewardship to NGOs, Murphy highlights a new space in which activists and citizens in general can demand and contest action in public health by NGOs. She stresses that this sort of biopolitics should take place against the background of “global health security” as the context that produces challenges and opportunities for human rights NGOs who work in the field of public health.

Recognising the importance of attuning stewardship to the specifics of the EU’s *sui generis* supranational legal and political order, Flear focuses on its function as public bioethics and reformulates it as “*supra-stewardship*”. Using pandemic planning as a case study, he proposes supra-stewardship as a tool that leverages support from human rights and bioethics and which can be used to facilitate citizen participation in governance around the focal points of framing, distribution, vulnerability and learning. This participation could query the limits of EU responsibility and the production of governance distortions and failures. Flear suggests this could bring out the normative in the technical and contribute important supplementary knowledge to the assemblage brought together, structured by preparedness, and used to govern pandemics.

As Brownsword points out in the conclusion to his article, stewardship and the practical and theoretical work around it are destined to remain items of unfinished business as governance struggles to keep up and connect with its fast-moving technological and societal targets. While this special issue is testament to that observation, it also helps to foster much needed scholarly discussion and critique – and to ensure this field is not unwittingly formed and deployed by and as a legitimating support for governance, but rather opened up, elaborated and contested. The articles provide innovative insights and food for thought on the conception and legal-political practice and potential of stewardship and super-stewardship in national, supranational and international settings.



# Responsible regulation: prudence, precaution and stewardship

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## 1 Introduction

In *Rights, Regulation and the Technological Revolution*,<sup>1</sup> I identified a number of generic challenges that regulators face as they endeavour to put in place the right kind of environment for the development, application and exploitation of emerging technologies – a regulatory environment that is properly geared for risk management and benefit sharing, that is both legitimate and effective, and that is fully connected to its technological targets. In the present paper, I draw out more explicitly three elements of this initial overview, namely: the idea of a “regulatory environment”, the challenge of “regulatory prudence”, and the scope and function of regulatory “stewardship” (together with its link to precautionary reasoning).

First, revisiting my idea of a regulatory environment, I highlight the three key registers in which regulators signal their directions. These comprise: two normative registers, the moral and the prudential, in which regulatees are directed as to how they ought to act if they are to do the right thing relative to, respectively, other-regarding criteria and the criterion of self-interest; and, a non-normative register, where the signal to regulatees is that certain acts are simply not a practical option (indeed, in some instances, performance of these acts is, quite literally impossible). The relevance of these registers and the significance of regulators relying on one register rather than another will become apparent in my discussion of stewardship.

Secondly, I identify regulatory prudence as a distinctive challenge. Essentially, the idea is that regulators (acting as proxies for their regulatees) have a prudential responsibility to ensure that, wherever there is reason to suppose that risks to health, safety and environment might be presented by new technologies, then such risks are expertly assessed and

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1 R Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: OUP 2008).

appropriately managed. Stated shortly, the regulatory environment should ensure that the relevant risks are confined to “acceptable” levels. However, a number of more particular questions can be isolated from this general challenge. One such question is that of “prudential pluralism”. Where individuals arrive at very different prudential judgments as to the acceptability of particular risks (perhaps because they simply have different thresholds of risk, or because they have different valuations of the off-setting benefits), how are regulators to proceed? Is this where responsible regulators should rely on processes of deliberative democracy? Another question concerns the responsibilities that regulators might have to inform and to guide prudential decision-making. For example, where individuals are invited to participate in screening programmes (for various health conditions), there is no guarantee that they will make the “right” prudential decision (in the sense of the decision that best serves their interests); but, if the risk that they take (whichever way they decide) touches and concerns only them, should regulators try (paternalistically) to steer such decisions one way or the other? A further question arises from the state of uncertainty that often accompanies emerging technologies. Even experts cannot agree on the risk (or benefit) profiles of these technologies. Is this an occasion for responsible regulators to embrace a precautionary approach?

Thirdly, I turn to the role of stewardship. Elsewhere, I have introduced this idea in terms of the regulatory state acting for the collective well-being of the community;<sup>2</sup> but, this is compatible with many background philosophies. Narrowing things down somewhat, the basic idea is that community life is staged and that the infrastructure that makes up the staging needs special protection – the staging of public health, promoting the conditions for a healthy population, is a fairly straightforward fit with this image.<sup>3</sup> Following this line of thinking, we can say that, while regulators have ongoing responsibilities in relation to the routine running of community life, they also have stewardship or, let us say, super-stewardship responsibilities for the preservation of the staging (the infrastructure) itself.

Developing these ideas, I suggest that there is a “commons” that provides the staging for all communities of (human) agents—a set of conditions that are generic in the sense that they are essential no matter what particular purposes a community and its (human) agent members might choose to pursue.<sup>4</sup> Communities of (human) agents simply cannot survive without these infrastructural conditions, without the conditions that are conducive to life, well-being, and the opportunity to pursue one’s own plans and purposes. Of course, each community will be distinguished by its particular purposes and, relative to those particular purposes, some infrastructural conditions will be essential (in the way, for example, that the infrastructure of financial services is essential to modern market economies). But we need to distinguish between super-stewardship that is generic in relation to communities of (human) agents and simple stewardship that is contingent. To protect the generic commons is to prevent acts that are not simply imprudent but also, unless we are amoralists, immoral (in the sense that they are damaging to the conditions that are essential for others to sustain their legitimate interest in life); to protect contingent infrastructural conditions is to prevent acts that are, *relative to at least some agents*, imprudent and (again, relative to some lights) immoral.

Arguably, super-stewardship extends beyond the bare conditions of human existence. For, if all agents, simply by virtue of their agency, are rationally committed to a moral way

2 See, R Brownsword, “Rights, responsibility, and stewardship: beyond consent” in H Widdows and C Mullen (eds), *The Governance of Genetic Information* (Cambridge: CUP 2009), p. 99, at p. 117.

3 Cf. R Brownsword, “Public health, private right: constitution and common law” (2006) 7 *Medical Law International* 201; and “Public health, private right and the common law” (2006) 120 *Public Health* 42.

4 For the development of this idea, see R Brownsword, “Friends, Romans, and countrymen: is there a universal right to identity?” (2009) 1 *Law, Innovation and Technology* 223.

of life in general (by which, I mean that they are committed to trying to do the right thing),<sup>5</sup> then regulators need to exercise a super-stewardship responsibility in relation to the essential conditions for moral community. The particular significance of this point is that, insofar as regulators resort to the register of prudence and practicability or possibility, they need to take a hard look at whether this is compatible with maintaining conditions in which regulatees can develop the virtue of doing the right thing for the right reason (as opposed to doing so for reasons relating to prudence, practicability, or possibility). Of course, each moral community will have its own criteria of right action – and, in *Rights, Regulation and the Technological Revolution*, I argued that we should assume a community of rights as our ideal-typical moral community. In a community of rights, the expectation will be that regulators should strive to ensure that public life and private action is rights compatible; and this might imply a layer of rights-specific stewardship. However, the underlying point is that regulators have a super-stewardship responsibility for those conditions that are presupposed by *any kind* of moral community (whether a community of rights, a duty-based community, or a community of consequentialist utilitarians).

Finally, how does precaution fit into this web of ideas? Characteristically, the precautionary principle urges regulators to take protective steps (particularly with regard to environmental concerns) even if the evidence of risk is unclear, even if there is scientific uncertainty, even if we cannot specify the probability of the harm eventuating. As many critics have pointed out, such a one-sided plea for precautionary restraint makes little sense in a routine prudential calculation – for, all things considered, the consequences of precaution might be worse than the consequences of continuation. If precautionary reasoning is to make sense, it must be either modified to fit with intelligent prudential calculation or it must be placed in a special context that is distinct from routine prudential calculation. Where super-stewardship is engaged, the thought occurs that we have precisely such a context. Quite what precaution dictates in such a context remains to be discussed but the idea that, where the super-stewardship jurisdiction is triggered, we need no longer worry about the precise degree of probability of harm has some plausibility – responsible regulators simply do not take any kind of risk with the essential infrastructural conditions.

The paper is in six principal parts. In the next two parts (2 and 3), I elaborate respectively the basic idea of a regulatory environment and the challenge of regulatory prudence. In the three middle sections of the paper (4, 5 and 6), I introduce the particular issues of prudential pluralism, facilitation of individual prudential judgment, and dealing with uncertainty. This leaves super-stewardship to be discussed in the final part of the paper (7).

## 2 The regulatory environment

In this part of the paper, I offer some remarks that are designed to clarify my idea of the regulatory environment. These remarks relate to:

- (i) the basic idea of regulation and the regulatory environment;
- (ii) two framing mistakes that we should avoid;
- (iii) the key regulatory registers employed by regulators;
- (iv) three generations of regulatory environment; and
- (v) the way that the intentions of the regulators play in a regulatory environment.

5 Seminally, see A Gewirth, *Reason and Morality* (Chicago: University of Chicago Press 1978); and see, too, D Beylveled and R Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford: OUP 2001).

### (i) REGULATION AND THE REGULATORY ENVIRONMENT

Generally speaking, the idea of regulation is taken to refer to a sustained, focused and organised attempt to steer conduct. As Julia Black puts it, we think of regulation as:

the sustained and focused attempt to alter the behaviour of others according to standards or goals with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behaviour-modification.<sup>6</sup>

Regulation is thus operationalised through a combination, or cycle, of direction, detection and correction. It follows that, in a regulatory environment, there will be various signals that are intended to direct the conduct of regulatees; there will be various means of monitoring conduct to see whether the directions are being followed; and, where deviation is detected, there will be measures for correction. In such environments, regulators signal whether particular acts are permitted (even required) or prohibited, whether they will be viewed positively, negatively, or neutrally, whether they are incentivised or disincentivised, whether they are likely to be praised or criticised, even whether they are possible or impossible, and so on.<sup>7</sup>

Whilst some environments are regulated in a top-down law-like fashion (with regulators clearly distinguishable from regulatees), others are more bottom-up, more self-regulatory, and more reliant on “governance” than hard law. Moreover, while some regulatory environments are reasonably stable and well-formed, others are unstable, overlapping, conflictual, and so on.

### (ii) TWO FRAMING MISTAKES

For lawyers, it is natural to centre attempts to understand the social world in distinctively *legal* types of regulation. For lawyers, it is law that makes the world go round; and it is puzzling that sociologists, whose business it really is to understand the social world, appear to have such little interest in the law. With this focus on law, we need to be careful – and, above all, it is lawyers who need to be careful – to avoid two framing mistakes with regard to the idea of a regulatory environment.

First, there is *the mistake of legal exclusivity* – which makes the assumption that the only signals in the regulatory environment are formal legal signals. One of the key points about the regulatory environment is that we may find regulators employing a range of mechanisms or modalities that are designed to channel the conduct of their regulatees. Some of these modalities may well be legal. It is not that regulatory environments never feature legal signals; and, in many instances, it will be the legal signals that have the highest profile. Nevertheless, the regulatory repertoire goes well beyond legal signals. Seminally, Lawrence Lessig has identified the following four regulatory modalities: namely, the law, social norms, the market and architecture (or code).<sup>8</sup> So, for example:

The government may want citizens to wear seatbelts more often. It could pass a law to require the wearing of seatbelts (law regulating behavior directly). Or it could fund public education campaigns to create a stigma against those who do not wear seatbelts (law regulating social norms as a means to regulating

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6 J Black, “What is regulatory innovation?” in J Black, M Lodge and M Thatcher (eds), *Regulatory Innovation* (Cheltenham: Edward Elgar 2005), p. 1, at p. 11.

7 Cf. R Brownsword and H Somsen, “Law, innovation and technology: before we fast forward – a forum for debate” (2009) 1 *Law, Innovation and Technology* 1.

8 L Lessig, *Code and Other Laws of Cyberspace* (New York: Basic Books 1999), ch. 7; and L Lessig, “The law of the horse: what cyberlaw might teach” (1999) 113 *Harvard Law Review* 501, pp. 507–14.

behavior). Or it could subsidize insurance companies to offer reduced rates to seatbelt wearers (law regulating the market as a way of regulating behavior). Finally, the law could mandate automatic seatbelts, or ignition-locking systems (changing the code of the automobile as a means of regulating belting behavior). Each action might be said to have some effect on seatbelt use; each has some cost. The question for the government is how to get the most seatbelt use for the least cost.<sup>9</sup>

The significance of these different modalities is not just that there is more than law in the regulatory mix; for, once the modality moves away from law and social norms, to market, architecture and code, the signal to regulatees can change from being normative to non-normative in character.

This takes us to the second framing mistake, *the mistake of normative exclusivity* – which makes the assumption that the only signals in the regulatory environment are normative (that is, signals that prescribe what ought, or ought not, to be done). Again, laws are normative, as of course are social norms. Market signals might also speak to what ought (or ought not) to be done, not so much as a matter of respect for others but simply what ought (or ought not) to be done in one's own interest. For example, where a "green" tax is added to the price of larger cars or to fuel, we might reason that we ought to drive a smaller car because larger cars are expensive and put a strain on our personal finances. However, if the price of larger cars is increased beyond our means, our reasoning shifts from the normative mode to the non-normative mode of practicability – it is not so much that, as a matter of self-interest, we ought not to buy a large car but that we simply cannot (afford to) do so. When the regulatory modality is that of architecture or code, or the like, we might well find that the signal is one of (non-normative) practicability or possibility. However, as with market signals, there might be elements of both normativity and non-normativity – witness, for example, Mireille Hildebrandt's important distinction between "regulative" (normative) and "constitutive" (non-normative) technological features.<sup>10</sup> So, for example, if a car is equipped with sensors that can detect alcohol in the driver, it might be designed to respond normatively (by advising that it is not safe for the driver to proceed) or non-normatively (by immobilising the car).

Given that the regulatory environment sets the context for the operation of the law, it is important that we frame our inquiries in the most helpful way. For example, if we are to make informed choices about the right kind of legal intervention, especially about the effectiveness of the intervention, we need to know what other signals are in play in the regulatory environment. Moreover, as the non-normative elements of the regulatory environment gain in importance, we need to address the values of legality (and the rule of law) that we take to be central to civilised social ordering.<sup>11</sup>

### (iii) THREE REGULATORY REGISTERS

We can tighten our grip on the significance of the different regulatory modalities by identifying the key registers that regulators employ to engage the practical reason of regulatees. There are three such registers as follows:

- (i) the moral register: here regulators signal that some act, x, categorically ought or ought not to be done relative to standards of right action (as in retributive

<sup>9</sup> Lessig, *Code*, n. 8 above, pp. 93–4.

<sup>10</sup> M Hildebrandt, "Legal and technological normativity: more (and less) than twin sisters" (2008) 12(3) *TECHNE* 169.

<sup>11</sup> Compare M Hildebrandt and B-J Koops, "The challenges of ambient law and legal protection in the profiling era" (2010) 73 *Modern Law Review* 428.

articulations of the criminal law where the emphasis is on the moral nature of the offence); or

- (ii) the prudential register: here regulators signal that some act, x, ought or ought not to be done relative to the prudential interests of regulatees (as in deterrence-driven articulations of the criminal law where the emphasis is on the sanction that will be visited on offenders); or
- (iii) the register of practicability or possibility: here regulators signal that it is not reasonably practicable to do some act, x, or even that x simply cannot be done – in which case, regulatees reason, not that x ought not to be done, but that x cannot be done (either realistically or literally).

In an exclusively moral environment, the primary normative signal (in the sense of the reason for the norm) is always moral; but the secondary signal, depending upon the nature of the sanction, might be more prudential. In traditional criminal law environments, the signals are more complex. Whilst the primary normative signal to regulatees can be either moral (the particular act should not be done because this would be immoral, or (in Millian liberal orders) the act would be harmful to others) or paternalistically prudential (the act should not be done because it is contrary to the interests of the regulatee), the secondary signal represented by the deterrent threat of punishment is prudential.<sup>12</sup>

Where there is an increasing reliance on regulatory technologies (for example, CCTV, DNA-profiling, radio frequency identification tracking and monitoring devices, and so on)<sup>13</sup> the strength and significance of the moral signal fades. First, the dominant signal to regulatees tends to be a prudential one, accentuating that the doing of a particular act is contrary to the interests of regulatees (because they will be detected and punished); and, then, in a later drift, the signal becomes that an act is either not practicable (such as trying to board an aircraft for an international flight without going through the security scans) or simply not possible.<sup>14</sup> Where the signal is that a particular act is no longer a possible option, regulatee compliance is, so to speak, fully determined.

#### (iv) THREE GENERATIONS OF REGULATORY ENVIRONMENT

From time to time, my colleague Karen Yeung helpfully reminds me that (as I had once written)<sup>15</sup> techno-regulatory strategies might focus on products, places, or persons. Thus, regulators might specify certain safety, or privacy-enhancing, or copyright-protecting features to be designed into products; or they might specify certain architectural features to improve safety (as in the layout of roads), or to facilitate transparency (think about the Bundestag building in Berlin), or adversarial political debate (think about the layout of the House of Commons at Westminster); or, in some future world, they might specify that only those human embryos that have acceptable genetic profiles should be implanted for reproductive purposes.

If we shuffle these ideas, we can imagine three ideal-typical generations of regulatory environment. In a first-generation regulatory environment, regulators would rely exclusively on normative signals. In a second-generation regulatory environment, regulators would rely

12 Compare A Norrie, “Citizenship, authoritarianism and the changing shape of the criminal law” in B McSherry, A Norrie and S Bronitt (eds), *Regulating Deviance* (Oxford: Hart 2009), p. 13; and L Zedner, “Fixing the future? The pre-emptive turn in criminal justice”, *ibid.* p. 35.

13 Cf. M A Rothstein and M K Talbot, “The expanding use of DNA in law enforcement: what role for privacy?” (2006) 34 *Journal of Law, Medicine and Ethics* 153, pp. 160–1.

14 Cf. B-J Koops, “Technology and the crime society: rethinking legal protection” (2009) 1 *Law, Innovation and Technology* 93.

15 See R Brownsword, “Code, control, and choice: why east is east and west is west” (2005) 25 *Legal Studies* 1, p. 12.

on both (first generation) normative signals and second-generation design of products and places. Where regulators rely on such a design strategy, the signal might no longer be normative; instead, the design features signal what is practicable or possible (in the way that the smart car is immobilised on sensing drink or drugs in the driver). Finally, in a third-generation regulatory environment, regulators would go beyond traditional normative signals and design of products and places by incorporating the regulatory design within regulatees themselves (for example, by means of pharmacological intervention, or neurosurgery, or by controlling their genetic coding). Where design is embedded in regulatees in such a way that it channels their behaviour, it is likely to be much less apparent to regulatees than they are being regulated – if the design is reliable, regulatees will simply behave (like products or, for that matter, robots) in accordance with their specification.

#### (v) DESIGN AND INTENTIONALITY

Finally, there is the matter of regulatory intention and effect. If we are to hold regulators to account, then the paradigm case is one in which they have self-consciously put in place a range of signals that are intended to direct or channel behaviour in a particular way. In such a case, the regulatory environment is purposively produced. However, designs might have regulatory effects even though such effects are not ones that the regulators (designers) intended. So, for example, there has been a long-running debate about whether the design of Robert Moses' bridges on the New York parkways was intended to have the (racially discriminatory) effect of making it more difficult for the poor, mainly black, population to reach the beaches on Long Island.<sup>16</sup> From the point of view of prospective beach-users, it made little difference whether the bridges had been designed with this intent – in practice, the bridges had the regulative effect of making the beaches more difficult to access. Nevertheless, if we are to hold regulators (designers) to account, is it not the case that their intentions remain important?

The paradigm is one in which regulators have certain channelling purposes, and they put in place a rule framework or a design that is intended to have a particular effect. In such a case, it is perfectly fair to ask regulators to justify both their purposes and the instruments (the rules or the designs) that they have adopted. However, even the best-laid regulatory plans can go awry and, as is all too well known, a common problem with regulatory interventions is that they generate unintended effects.<sup>17</sup> Clearly, when regulators are held to account, they must answer for both the intended and the unintended effects of the regulatory environments that they have put in place.

Having said this, the case of the New York parkway bridges might seem rather different. In defence of the bridge designers, it might be argued that there was no regulatory plan as such, simply an attempt to strengthen the bridges. To be sure, in practice, the newly constructed bridges might have had a regulative impact, but this was an unintended effect of the design. Once upon a time, such a defence might have been adequate; but, nowadays, regulators will not get off the hook quite so easily. For, as it becomes increasingly clear that design can matter (potentially, having both negative and positive effects), so it is no longer acceptable for regulators to plead a lack of intent, or attention, with regard to such technical details. While inattention may lead to regulatory environments that are detrimental to, say, the health or the privacy of regulatees, smart regulatory action can have the opposite impact (for

16 See N Manders-Huits and J van den Hoven, "The need for a value-sensitive design of communication infrastructures" in P Sollie and M Düwell (eds), *Evaluating New Technologies* (Dordrecht: Springer 2009), p. 51, at p. 54.

17 For a helpful overview, see S Biegel, *Beyond Our Control?* (Cambridge MA: MIT Press 2003); and, for some particular cases, see C R Sunstein, "Paradoxes of the regulatory state" (1990) 57 *University of Chicago Law Review* 407.

example, by requiring or encouraging architects and technologists to default to health-promoting or privacy-enhancing designs).<sup>18</sup> In short, although the paradigmatic regulatory environment is the product of intentional design, regulators need to answer for both the intended and the unintended channelling effects of their actions as well as for their omissions.

#### (vi) LOOKING AHEAD

There are a number of ways in which this elaboration of the features of a regulatory environment might assist our understanding of the operation of law. Moreover, there are important pointers to what we should be looking for as regulation becomes less transparent and more reliant on design. However, for present purposes, the particular significance of this discussion will become clear when we turn, later in the paper, to the stewardship responsibilities of regulators.

### 3 The challenge of regulatory prudence

One of the first concerns for any community will be whether a novel technology is safe, whether it presents any risk to human health or safety, or to the environment (the integrity of which is, of course, essential for human health and well-being). There is nothing noble about such concerns; they are entirely self-serving prudential concerns; but, because these are concerns that are common to all humans with the instinct for survival, they are not controversial in themselves. To some extent, individuals can take their own protective measures – for example, an individual who is worried about the safety of mobile phones might decline to use one, or use it only in emergencies, or use it only as a hand-held device operating well away from one's head – but there are limits to how far such protective steps can be taken. Where individuals are employed in workplaces that are equipped with machines, where getting from A to B involves an encounter with road traffic, and so on, it is not reasonably practicable to conduct one's life in a way that maintains a safe distance from industrial and transport technologies. Accordingly, it falls to regulators to protect the public against technologies that give rise to safety concerns; and the challenge of regulatory prudence is essentially one of reducing risk to an acceptable level.

In her excellent account of the way that regulators have responded to emerging technologies, Susan Brenner has suggested that regulators have tended to focus on two forms of harmful use, defective implementation and (intentional) misuse.<sup>19</sup> In the case of defective implementation, the technology was not being used in a way that was intended to be hazardous; nevertheless, safety issues arose and regulators needed to address them. Regulatory responses can vary, one from the other, and across time. Consider, for example, the case of the bicycle. According to Brenner:

Legislators at first simply banned bicycles from major thoroughfares, including sidewalks. These early enactments were at least ostensibly based on public safety considerations. As the North Carolina Supreme Court explained in 1887, regulations prohibiting the use of bicycles on public roads were a valid exercise of the police power of the state because the evidence before the court showed “that the use of the bicycle on the road materially interfered with the exercise of the rights and safety of others in the lawful use of their carriages and horses in passing over the road.”<sup>20</sup>

18 See e.g. Manders-Huits and van den Hoven, “The need”, n. 16 above; and P-P Verbeek, “The moral relevance of technological artifacts” in Sollie and Düwell, *Evaluating New Technologies*, n. 16 above, p. 63.

19 S W Brenner, *Law in an Era of “Smart” Technology* (New York: OUP 2007).

20 Ibid. pp. 36–7.

Over time, though, the regulatory response to bicycles mellowed so that, by the end of the nineteenth century, bicycle users were being treated on much the same footing as other road users. This meant that there needed to be some rules of the road – for example, in 1897, New York’s traffic code “established a speed limit of eight miles per hour and required cyclists to give pedestrians the right of way”; it also “forbade cyclists from coasting on city streets”, although at that time opposition from cyclists blocked moves to require the fixing of brakes on bicycles.<sup>21</sup> With modern technology, brakes are as much a part of the design of the bicycle as are the pedals, and “[m]odern statutes regulate various aspects of cycling, such as limiting how many people can ride a bicycle at one time, specifying how bicycles are to be operated, and requiring helmets for operators and lamps for cycles being operated after dark”.<sup>22</sup> Indeed, one might see in modern regulatory measures, a concern not only for the safety of pedestrians and other road users but also a (paternalistic) concern for the safety of the cyclist – such concerns being reflected in an array of measures for safe design and safe implementation.

Moving on from bicycles, what are the prudential concerns that are generated by today’s technologies? Some of these technologies, like their predecessors, give rise to straightforward safety concerns but, with others, the concerns relate much more to the health of persons and the protection of the environment. In part, this might be because, in the twenty-first century, following bovine spongiform encephalopathy, thalidomide, contaminated blood products, Chernobyl, and a host of similar causes célèbres, there is a much greater sensitivity to the ways in which our health is affected by the food, drugs and technologies of our time, as well as an awareness of the way in which the cumulative use of technologies can be environmentally damaging.<sup>23</sup>

In one respect, however, we might think that the safety concerns relating to the technologies of the twenty-first century are rather different to earlier regulatory experiences. Today, the following three factors are at work:

- (i) for the most part, and in most places, citizens are eager to embrace the benefits of new technologies (they are largely technophiles);
- (ii) at the same time, however, citizens are highly risk-averse; and,
- (iii) there is a great deal of uncertainty surrounding both the benefits and, particularly, the risks of new technologies – for example, there is uncertainty about the impact of genetically modified organisms on the environment; there is uncertainty about whether unfixed nanoparticles might be the new asbestos; there is uncertainty about both the benefits and the risks associated with synthetic biology, and so on.

The interaction between these factors sets up a number of tensions and regulatory dilemmas. For example, how are the risks to be balanced against the benefits? And, when scientists are unable to assure citizens as to the safety of particular technologies, how should regulators proceed? If zero risk is not an option, then the challenge of prudence is one of finding the level at which risk is judged to be acceptable. But how is acceptability to be judged when both risks and benefits are viewed differently from one person to another, as well as being assessed quite differently by experts?

In such a contested context – and, moreover, in a context of rapid social and technological change – what are the requirements of responsible regulation? I suggest that regulatory prudence presents three major challenges: first, to find an acceptable way of

21 Brenner, *Law in an Era*, n. 19 above, p. 39.

22 Ibid.

23 See e.g. G Little, “BSE and the regulation of risk” (2001) 64 *Modern Law Review* 730.

dealing with prudential pluralism; secondly, to decide how far there is a responsibility to facilitate informed prudential decision-making by individuals (or even to steer decisions more directly); and, thirdly, to find an adequate way of handling scientific uncertainty. In the next three parts of the paper, we can begin to think through these particular challenges.

#### 4 Responsible regulation I: dealing with prudential pluralism

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

To see what precisely the issue is in relation to prudential pluralism, our first step is to clarify the nature of a prudential judgment (as against an ethical judgment); then, we can assess the appropriateness of deliberative democracy, both in principle and in practice, as a responsible regulatory response to prudential pluralism.

##### (i) PRUDENTIAL PLURALISM

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

As against a prudential judgment (where A judges only what is in A’s own interest), an “ethical” judgment involves judging what is in the legitimate interests of all affected “parties”, both oneself and others. To act ethically is to try to do the right thing, not just relative to one’s own interests but relative to the legitimate interests of both oneself and others. In practice, there will often be a convergence between a prudential judgment that takes into account the judging party’s longer-term self-interest and an ethical judgment – as a result of which it might be difficult, at times, to detect whether an act that gives weight to the interests of others is motivated by prudential or ethical reasons. In principle, however, the difference between a prudential and an ethical judgment – and, concomitantly, the difference between a prudential and an ethical plurality – is clear.

As we have said, where agents are each invited to make their own prudential judgment about a matter, there are likely to be a number of different judgments made. For example, whereas agent A might be persuaded that it is in his interest to drink a glass of claret each day, judging that the anticipated benefits outweigh the costs, agent B might value the benefits and calculate the costs differently, leading to the judgment that prudence does not dictate such consumption. Of course, the way in which these prudential judgments come out might have a practical impact on those who are involved in the wine industry but the

prudential pluralism that exists between A and B does not, as yet, invite regulatory attention. However, once the prudential preferences of A and B in relation to some particular matter x are no longer compatible, then regulators have to lay out the ground rules – regulators have to decide whether to prohibit or permit x; and, where they decide to permit x, they have to decide on what terms x is to be permitted.

Suppose, for example, that regulators are pressed to set a framework for the safe research and development of synthetic biology or the safe application of nanomedicine. This is not usually understood as a demand for zero risk but that regulators should set standards that manage the risk at an acceptable level.<sup>24</sup> However, what constitutes an acceptable risk will depend upon how the costs and benefits are calculated. While agent A, who is highly risk averse, may judge, prudentially, that synthetic biology should be prohibited or, at least, subjected to a moratorium, agent B, who is a biotechnological entrepreneur, might take a radically different view. The views of A and B, it must be emphasised, are not the least bit noble; it is purely and simply a matter of A and B making judgments that each calculates to be self-serving; A, in making his prudential judgment, takes no account of B's preferences or interests; and B, in making her prudential judgment, takes no account of A's preferences or interests.

### (ii) DELIBERATIVE DEMOCRACY IN PRINCIPLE

Where a regulatory position needs to be taken, how should regulators respond to a prudential plurality? In a democracy, there is a reasonable expectation that there will be a process of public engagement before a position is taken. Before settling upon a legal framework, there needs to be a process that ascertains public opinion, that seeks out a reasonable position, and then that adopts a regulatory position that reflects a reasonable view about an acceptable level of risk.

When Professor Amy Gutmann was appointed to chair the (US) Presidential Commission for the Study of Bioethical Issues (and first tasked to report on the implications of synthetic biology), she declared that it was her intention to champion informed debate in the spirit of deliberative democracy.<sup>25</sup> According to Professor Gutmann, deliberative democracy, in contrast to “sound-bite democracy”, is about engaging the public:

Deliberative democracy is about . . . listening to competing points of view, considering opposing arguments and coming to a decision that ideally finds common ground – or at least respects competing points of view.<sup>26</sup>

On the face of it, this is a promising strategy, not only for handling ethical pluralism but also for dealing with prudential pluralism. For deliberative democracy, as elaborated by Professor Gutmann,<sup>27</sup> decrees that all freely expressed views are to be heard and that, so long as they are not wholly unreasonable, they are to be accorded equal consideration. At the end of the process, differences should have been minimised and regulators should be in a position to act on reasons that are at least acceptable to all persons who are committed to fair terms for political and social cooperation. To be sure, this does not quite guarantee

24 Cf. e.g. the European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Nanomedicine* (Opinion No 21, 2007), para. 4.2.3: “risk management actions should be aimed at identifying the ‘acceptable risk’ threshold with regard to the values at stake – and respect for the human body is undoubtedly one of the values deserving the highest legal protection”.

25 See, M Wadman, “Bioethics gets an airing”, *Nature*, 7 July 2010, available at [www.nature.com/news/2010/070710/full/news.2010.340.html](http://www.nature.com/news/2010/070710/full/news.2010.340.html).

26 *Ibid.*

27 See A Gutmann and D Thompson, *Why Deliberative Democracy?* (Princeton: Princeton UP 2004).

that the eventual outcome will attract everyone's vote; but, because the decision in question will be supported by acceptable reasons, reasonable people should respect it. Moreover, it is characteristic of Professor Gutmann's version of deliberative democracy that debates can be re-opened; decisions are, thus, reviewable, which means that the time might still come for today's dissenting views. In this way, scientific research and the development of associated technologies can proceed leaving pluralistic societies to settle their differences in a civilised way.<sup>28</sup>

### (iii) DELIBERATIVE DEMOCRACY IN ACTION

Even if deliberative democracy seems like an appropriate regulatory response to prudential pluralism, and even if we can assume that the purposes that underlie the engagement of the public are in the best sense democratic (and not merely an attempt to "educate" the public in a way that "legitimizes" emerging technologies),<sup>29</sup> this is far from being a straightforward exercise in public consultation and debate.<sup>30</sup> For example, how are researchers to cope with what can be extremely variable levels of public understanding of the technology,<sup>31</sup> how are they to distil attitudes towards a particular technology from a medley of predispositions (to science, technology, commerce, and so on); and how are they to overcome the public's suspicion of stakeholders in the technology?<sup>32</sup>

How might these obstacles be overcome? In the influential report by the Royal Society and the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and uncertainties*,<sup>33</sup> it is recommended that: dialogue and engagement should occur early, and before critical decisions about the technology become irreversible or "locked in"; dialogue should be designed around clear and specific objectives; the sponsors should publicly commit to taking account of the outcome of the engagement process; dialogue should be properly integrated with other related processes of technology assessment; and resourcing for the dialogue should be adequate.<sup>34</sup> Even with attention to these matters, however, there

28 In its ensuing report (see the Presidential Commission for the Study of Bioethical Issues, *New Directions: The ethics of synthetic biology and emerging technologies* (Washington, December 2010)), the commission identifies five key principles (namely, public beneficence, responsible stewardship, intellectual freedom and responsibility, democratic deliberation, and justice and fairness). The "principle of responsible stewardship rejects two extreme approaches: an extreme action-oriented [proactionary] approach that pursues technological progress without limits or due regard for public or environmental safety, and an extreme precautionary approach that blocks technological progress until all possible risks are known and neutralized" (p. 26). Instead, as a middle way between proaction and precaution, the commission advocates "the development of agile, measured oversight mechanisms" (ibid.). In other words, "[r]esponsible stewardship calls for *prudent vigilance*, establishing processes for assessing likely benefits along with safety and security risks both before and after projects are undertaken" (p. 27) (original emphasis). For further elaboration of prudent vigilance as an articulation of responsible stewardship, eschewing both extreme proaction and precaution, see ibid. pp. 123–4.

29 For a critical commentary on EU governance in this regard, see M L Flear and A Vakulenko, "A human rights perspective on citizen participation in the EU's governance of new technologies" (2010) 10 *Human Rights Law Review* 661.

30 Cf. e.g. International Risk Governance Council (IRGC), *Risk Governance of Synthetic Biology* (Geneva: IRGC 2009); and S Davies, P Macnaghten and M Kearnes (eds), *Reconfiguring Responsibility: Lessons for public policy (Part 1 of the report on Deepening Debate on Nanotechnology)* (Durham: Durham University 2009).

31 Synthetic biology is just such a case in point: see the findings in Royal Academy of Engineering, *Synthetic Biology: Public dialogue on synthetic biology* (London: Royal Academy of Engineering, June 2009).

32 See R Sheldon, N Cleghorn, C Penfold, A Brown and T Newmark, *Exploring Attitudes to GM Food* (London: Social Science Research Unit, Food Standards Agency, 24 November 2009); and, S Jasanoff, *Designs on Nature* (Princeton: Princeton UP 2005), p. 129 (for a somewhat negative assessment of the public debate on genetically modified foods in the UK).

33 Royal Society Policy document 19/04 (London: July 2004).

34 Ibid. para. 38.

might be doubts about how fully the public is engaged; and, of course, it is difficult to immunise a citizens' jury against the influence of the media.

Assuming, though, that the public can be adequately engaged, their prudential calculations are likely to be varied and, concomitantly, their preferred regulatory responses will be at different points of the spectrum from outright prohibition to simple permission or even promotion. Still, in a democracy, this is the stuff of preferences and politics; decisions that are made today can be revised tomorrow; and, while this might not be the ideal way of accommodating the variety of self-interested views, it is a civilised way of living with pluralism. Accordingly, even if the realisation of deliberative democracy is challenging, it appeals as the right way to deal with prudential pluralism.<sup>35</sup>

### 5 Responsible regulation II: facilitating (and steering) individual prudential calculation

In the easy case, where agents can make their personal prudential calculations without this raising any problems of incompatibility, is there any reason for responsible regulators to act? Should they simply leave agents to their own prudential devices; or, where there is a risk that ill-informed decisions might be made, should regulators take steps to educate and inform the parties; and, where the decisions concern, for example, the longer-term well-being of agents, should regulators tilt the decision-making context in a way that they (the regulators) think will serve such longer-term interests?

We can speak briefly to the responsibility to educate and inform; and then we can turn to the setting of defaults that “nudge” agents towards particular decisions (or actions).<sup>36</sup>

#### (i) INFORMING

If the question concerns a matter about which there is little reliable information, then we might expect regulators to take steps to ensure that the public is properly informed. In other words, regulators should take reasonable steps to ensure that, if there is to be a plurality, it is at least based on a correct understanding of the respective risks and benefits. However, this runs into at least two complications.

First, the reason why the information lacks clarity might be because the experts themselves broadcast mixed messages. Provided that regulators summarise the differences in an intelligible way, this is as much as can be done to facilitate *informed* prudential decision-making. Beyond this, however, we might want regulators to turn their attention to the environment in which research is conducted. If the reason that the expert community is divided is that there is a lack of integrity, then responsible regulators have more work to do.<sup>37</sup>

Secondly, in some cases – for example, where healthcare professionals want to steer agents towards a particular test, screen or procedure – there might be a tension between the professional paternalistic judgment as to what is in an agent's best interest and the agent's

35 See R Brownsword, “Regulating the life sciences, pluralism, and the limits of deliberative democracy” (2010) 22 *SALJ* 801.

36 See, R H Thaler and C R Sunstein, *Nudge: Improving decisions about health, wealth, and happiness* (New Haven: Yale UP 2008).

37 Cf. e.g. O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: CUP 2002), p. 120: “There are cases of outright fraud that go beyond disingenuous communication and evasion: scientists, biotech companies and journalists all sometimes misreport and exaggerate the significance of new discoveries; scientific misconduct and fraud sometimes arise from competition for grants, results and glory; peddlers of untried and untested remedies sometimes prey on desperate people. Sporadic deception can be found almost anywhere: among scientists tempted to falsify experimental data; among government agencies tempted to keep worrying medical or scientific facts confidential; among journalists tempted to exaggerate and sensationalise biomedical ‘stories’; among campaigning groups eager to persuade the public of their views.”

own prudential judgment. Unless we think that regulators should be aiding and abetting professional paternalism, there is a responsibility to ensure that the information is framed and presented in the way that facilitates *autonomous* prudential decision-making.<sup>38</sup>

However, no one should be under any illusions about how tricky this is. Those who are providing the information have to decide what to include and what to omit, what to highlight in the foreground and what to relegate to the background as well as judging what is common ground, what is controversial, and what is plain crazy.<sup>39</sup> This is not to say that informers should abandon their attempts to put prudential decision-makers in the picture as impartially as they can; but, where the picture is contested, there is no neutral presentation.

## (ii) NUDGING

Suppose that a screening programme for a particular condition, for example, for prostate cancer, is adopted. We assume that the target male population will be invited to take the appropriate test – that is, we assume this because this is the way that screening programmes are usually rolled out. However, this is just one of a number of possible default positions for a screening programme. For example, the default might be:

- D1 general notice of the screening programme is given; but no one is specifically invited to participate; the onus is on men to request the test (general notice opt-in); or,
- D2 target males are personally notified about the screening programme but it is left to individuals to request the test (personal notice opt-in); or
- D3 target males are personally notified about the screening programme, they are given an appointment for the test and they are expected to take the test unless they expressly indicate otherwise (personal notice opt-out).

No doubt these defaults can be finessed in various ways. However, the point is that, although target males have the option in all cases of taking or not taking the test, D3 steers much more strongly towards the test than D1; and, human nature being what it is, it is likely that the take-up rate under D1 will be low in contrast with a high take-up rate under D3.

Where it is simply not possible to operate without a default position, the question arises whether regulators should self-consciously endeavour to “nudge” regulatees towards acts or lifestyles that regulators judge to be in the longer-term interest of regulatees. This was a strategy, a simple kind of stewardship, that appealed to the Nuffield Council on Bioethics (the Council) in its report on the ethics of public health.<sup>40</sup>

In this report, the Council takes as its guiding standard Millian liberal principles modified by a principle of state stewardship.<sup>41</sup> While the liberal principles resist the idea that coercion may be legitimately applied against an agent unless their conduct creates a clear and present threat of harm to others, stewardship extends the range of legitimate state intervention (although, according to the Council, coercive measures should be treated as a last resort). The resulting stewardship model holds that legitimate public health interventions should:

38 See, for discussion, R Brownsword and J Earnshaw, “Controversy: The ethics of screening for abdominal aortic aneurysm” (2010) *Journal of Medical Ethics* 827.

39 Cf. e.g. A Stirling, “‘Opening up’ and ‘closing down’: power, participation, and pluralism in the social appraisal of technology” (2008) 33 *Science, Technology, and Human Values* 262.

40 Nuffield Council on Bioethics, *Public Health: Ethical issues* (London: Nuffield Council on Bioethics, November 2007).

41 *Ibid.* ch. 2.

- aim to reduce the risks of ill health that people might impose on each other;
- aim to reduce causes of ill health by regulations that ensure environmental conditions that sustain good health, such as the provision of clean air and water, safe food and decent housing;
- pay special attention to the health of children and other vulnerable people;
- promote health not only by providing information and advice, but also with programmes to help people to overcome addictions and other unhealthy behaviours;
- aim to ensure that it is easy for people to lead a healthy life, for example, by providing convenient and safe opportunities for exercise;
- ensure that people have appropriate access to medical services; and
- aim to reduce unfair health inequalities.<sup>42</sup>

Although the legitimacy of these interventions is not predicated on obtaining each individual's informed consent, the Council recognises that, wherever possible, it is better to respect personal choice and individual consent, as well as avoid coercive measures. Accordingly, the stewardship version of liberalism specifies that public health programmes should:

- not attempt to coerce adults to lead healthy lives;
- minimise interventions that are introduced without the individual consent of those affected, or without procedural justice arrangements (such as democratic decision-making procedures) which provide adequate mandate; and
- seek to minimise interventions that are perceived as unduly intrusive and in conflict with important personal values.<sup>43</sup>

Some of these extensions of Mill are relatively easy cases for stewardship – for example, interventions that address the care of children, that provide information about the risks to health associated with certain foods, drinks, or lifestyles, that offer facilities that are designed to help to overcome addiction, and the like.<sup>44</sup> Few, too, would question the state's responsibility for securing the basic environmental conditions that are essential for public health. However, this aspect of the state's responsibility is given a subtle twist once we extend it to a self-conscious staging of everyday circumstances so that they are defaulted in a way that is conducive to public health. Nevertheless, provided that the default setting (say, for walking or using stairs) co-exists with alternatives (say, for riding or using lifts or escalators), this seems to keep faith with Millian liberal principles while exercising stewardship in a way that tilts conditions towards public health.<sup>45</sup>

42 Nuffield Council on Bioethics, *Public Health*, n. 40 above, para. 2.44.

43 Ibid. These constraints are open to a number of interpretations. In a community of rights, they would be expressed in a more focused, rights-respecting way.

44 See, further, T Baldwin, R Brownsword and H Schmidt, "Stewardship, paternalism and public health: further thoughts" (2009) *Public Health Ethics* 1.

45 More controversially, the Council also relies on stewardship to reduce unfair health inequalities. Clearly, any manifesto that aspires to equalise the conditions of public health or to eliminate unfairness in access to health resources is open to interpretation. However, insofar as these extensions relate closely to the conditions that are judged to be essential for any prospect of agency, this seems to me to be entirely defensible relative to the broad commitments of a community of rights.

While it is arguable that setting the defaults in a way that is paternalistic, but that still gives agents an opt-out possibility, is compatible with respect for individual autonomy,<sup>46</sup> is this an appropriate exercise of *prudential* regulatory responsibility? What if regulatees prefer different defaults? I have already said that regulators need to be sensitive to the effects of their designs (in this case defaults) and these paternalistic defaults might well display a well-intended public health sensitivity. However, sensitivity is not enough; regulators need to be aware of their regulatees' preferences as well as rendering the defaults transparent. In other words, autonomy with a tilt or a nudge is all very well, but responsible prudential regulation needs to display the standard public law virtues of due process and transparency before it prioritises paternalism over general preferences.<sup>47</sup>

### 6 Responsible regulation III: dealing with uncertainty

With emerging technologies, there are many matters about which there can be uncertainty. So far as prudential risk/benefit calculations are concerned, the four key points of potential uncertainty relate to: (i) the nature of the possible harms; (ii) the likelihood of the harms eventuating; (iii) the nature of the possible benefits; and (iv) the likelihood of the benefits eventuating. Where the uncertainty relates to the type or likelihood of harm, one view is that responsible regulation implies a precautionary approach. Of course, much has been written about the precautionary principle, much of it critical and dismissive, and some might share Gary Marchant and Douglas Sylvester's judgment that the principle is "an overly-simplistic and under-defined concept that seeks to circumvent the hard choices that must be faced in making any risk management decision".<sup>48</sup>

Despite this kind of criticism, the view persists that responsible regulation displays both prudence and, in some cases, precaution. As the Appellate Body at the World Trade Organisation remarked in the *Hormones* dispute, "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g., life-terminating, damage to human health are concerned."<sup>49</sup> Moreover, the principle has a foothold in many regulatory regimes, as highlighted by Annex II of the European Commission's communication on the precautionary principle,<sup>50</sup> in which the leading occurrences of the principle in international law are listed. What, then should we make of this?

First, although Principle 15 of the Rio Declaration in 1992, enjoining states to take measures to prevent serious and irreversible damage to the environment even if there is a "lack of full scientific certainty", is the most commonly cited expression of the principle, it has no authoritative formulation as such. If, as Neil Manson has suggested, all versions of the principle specify a particular "damage" condition, a particular "knowledge" condition, and a particular "remedial" condition,<sup>51</sup> each of which can be specified in many different ways, then there are (at least) dozens of possible formulations of the principle. It is essential, therefore, to try to put the principle in its most defensible form.

46 Cf. the idea of "libertarian paternalism" elaborated by C Sunstein (with R Thaler) in *Laws of Fear* (Cambridge: CUP 2005), ch. 8.

47 Regulators also need to take care that a nudge does not become so strong that opt-out is no longer a realistic option. When nudges shade into something stronger, the regulatory register changes from normative to non-normative, from ought to can (or cannot).

48 G E Marchant and D J Sylvester, "Transnational models for regulation of nanotechnology" (2006) 34 *Journal of Law, Medicine and Ethics* 714, p. 722.

49 EC Measures Concerning Meat and Meat Products (Hormones), Report of the Appellate Body WT/DS26/AB/R, WT/DS48/AB/R, 16 January 1998, para. 124.

50 COM(2000) 1, Brussels, 2 February 2000.

51 N Manson, "Formulating the precautionary principle" (2002) 24 *Environmental Ethics* 263.

Secondly, it is important to clarify whether the principle is intended to knock out a poor excuse for inaction (namely a lack of scientific certainty) or to insist upon precautionary action (scientific uncertainty notwithstanding). Whereas the Rio Declaration reads as though it is pushing for action, some articulations – particularly those that focus on specifying the threshold conditions for intervention – imply some resistance to action;<sup>52</sup> and yet others present the principle as being broadly enabling but without disclosing any obvious bias either towards or against intervention.<sup>53</sup> If, as René von Schomberg argues, the modest (but radical) function of the principle is to resist political actors using or abusing “a persistent dissent among scientists as a reason (or excuse) for not taking action at all”,<sup>54</sup> precaution is clearly in line with regulatory responsibility; for it surely would be irresponsible if regulators routinely refused to interfere until the expert community achieved consensus (for example, until there was full scientific agreement that smoking tobacco causes lung cancer and heart disease).

Thirdly, it follows that the more controversial versions of the principle will be those that advocate regulatory action, scientific uncertainty notwithstanding. To simplify, let us suppose that the nature of the uncertainty concerns the likelihood of activity *x* causing harm *y*. Some experts put the likelihood higher than others; but, of course, the range of difference and where it lies on the scale of probability could be almost infinitely variable. For example,

- (i) everyone puts the likelihood as higher than 50/50, but the difference ranges from 60/40 to 90/10; or
- (ii) everyone agrees that the likelihood is lower than 50/50, but the difference ranges from 40/60 to 10/90; or
- (iii) while some put the likelihood as higher than 50/50, others put it as lower than 50/50, with the difference ranging from 90/10 to 10/90.

Other things being equal, it would be irresponsible not to take precautionary action in the first of these scenarios (because, although there is some uncertainty, the experts agree that it is more likely than not that *x* causes *y*); but, the case for precautionary action is much less clear in the other cases unless *x* can be given up with no loss of benefit (or unless the culture in the community is particularly risk-averse).

Fourthly, this last point cues in the objection that it cannot be responsible or rational to introduce a regulatory prohibition on *x* (which might or might not be causing *y*) without taking into account the cost of giving up *x* (or, the loss of benefit associated with *x*).<sup>55</sup> Without doubt, in a prudential calculation (which is what we are taking this to be), the loss of benefit must be weighed. Accordingly, even in the scenario where the experts agree that it is more likely than not that *x* causes *y*, it would not be prudent to sacrifice *x* without weighing the costs of doing so. This means that the prudential calculation is complex (the

52 See e.g. *Pfizer* [2002] ECR II-3305, para. 143: “a preventive measure cannot properly be based on a purely hypothetical approach to risk, founded on mere conjecture which has not been scientifically verified”. So, mere conjecture and hypothesis will not suffice. Moreover, the underlying science must be consistent with principles of “excellence, transparency and independence” (para. 172).

53 Cf. e.g. the Nuffield Council on Bioethics, *Genetically Modified Crops: The ethical and social issues* (London: Nuffield Council on Bioethics 1999), p. 162, where the principle is expressed as permitting the imposition of restrictions “on otherwise legitimate commercial activities, if there is a risk, even if not yet a scientifically demonstrated risk, of environmental damage”.

54 R von Schomberg, “The precautionary principle and its normative challenges” in E Fisher, J Jones and R von Schomberg (eds), *Implementing the Precautionary Principle: Perspectives and prospects* (Cheltenham: Edward Elgar 2006), p. 19, at p. 23.

55 See Sunstein, *Laws of Fear*, n. 46 above.

certain loss of x against the likely prevention of y); but the critics are surely correct in holding that it is not responsible to try to avoid this complexity by simply taking the precautionary option.

Fifthly, can we imagine a scenario in which precaution is automatically privileged despite (i) there being uncertainty about the likelihood of x causing y and (ii) the loss of benefit if x is given up? In other words, is there any room in a world of prudent and responsible regulation for a pure precautionary intervention? Cass Sunstein, having been perhaps the sternest critics of a one-eyed precautionary principle,<sup>56</sup> has sought a more plausible version of the principle by putting it in the context of possible catastrophic harm (in other words, where y represents a catastrophic loss).<sup>57</sup> Some of the worst-case (or catastrophic) scenarios that Sunstein hypothesises are ones in which the likelihood of x causing y is *known*. However, he also discusses some scenarios in which the likelihood of x causing y is not known, in which there is *uncertainty*. It is in this latter kind of scenario that regulators might appeal to a special form of precautionary principle. For Sunstein, the best formulation is on the following lines:

In deciding whether to eliminate the worst-case scenario under circumstances of uncertainty, regulators should consider the losses imposed by eliminating that scenario, and the size of the difference between the worst-case scenario under one course of action and the worst-case scenario under alternative courses of action. If the worst-case scenario under one course of action is much worse than the worst-case scenario under another course of action, and if it is not extraordinarily burdensome to take the course of action that eliminates the worst-case scenario, regulators should take that course of action. But if the worst-case scenario under one course of action is not much worse than the worst-case scenario under another course of action, and if it is extraordinarily burdensome to take the course of action that eliminates the worst-case scenario, regulators should not take that course of action.<sup>58</sup>

Rightly, Sunstein concedes, that this is “too vague” to operate as a decision rule.<sup>59</sup> For instance, what would make one worst-case scenario so much worse than another? Would the difference be self-evident? What would make a cost “extraordinarily burdensome”? Still, it puts down a marker for precaution under conditions of uncertainty: if regulators cannot rule out the possibility of catastrophe, they should consider taking steps (that are not disproportionate) to avert that possibility.

This seems to me to be on the right track. However, rather than putting this generally in terms of catastrophic harm, I suggest that the relevant harm is to the generic infrastructure for human existence (the agency commons). Faced with the possibility of such catastrophic harm (for example, if there is reason to fear that particle accelerators might provoke a “strangelet” disaster that reduces the planet to a tiny inert hyperdense sphere), regulators surely have a prudential responsibility to act – if only by temporarily suspending the suspect activity x. Yet, some question the rationality of such a precautionary intervention. For example, Fritz Allhoff, Patrick Lin, and Daniel Moore argue:<sup>60</sup>

First, it allows extremely low probabilities to derail entire activities . . . Second, these low probabilities – which nevertheless establish *possibility* – could be

56 Sunstein, *Laws of Fear*, n. 46 above.

57 Cf. C. R. Sunstein, *Worst-Case Scenarios* (Cambridge MA: Harvard UP 2007), esp. ch. 3.

58 *Ibid.* pp. 167–8.

59 *Ibid.* p. 168.

60 F. Allhoff, P. Lin and D. Moore, *What is Nanotechnology and Why Does It Matter?* (Chichester: Wiley-Blackwell 2010), p. 91.

effectively impossible to reduce to zero . . . the precautionary approach . . . becomes paralysing. Third, this is simply irrational . . . it is completely irrational to allow remote risks to entirely preclude our consideration of the associative benefits for some course of action.

But this stretches the context (of possible, yet uncertain, harm to the infrastructure) in which the proposed precautionary principle is to be applied, that is, a context in which the point is that we cannot say that the probability of catastrophe is “extremely low”; and nor can we assume that the risk is “remote”. Even with this correction, however, is it a fair objection that precautionary super-stewardship is productive of paralysis as well as irrational in foregoing the associative benefits?

I suggest that this objection is misconceived. If regulators know that an activity is harmful to the infrastructure, it would be the height of irresponsibility not to intervene. Quite simply, if the infrastructure is harmed, there will be no beneficial (superstructural) activities to paralyse or derail. If, however, regulators are not certain that an activity is harmful to the infrastructure, *but they cannot rule out such a possibility*, then the question is whether they should be granted a jurisdiction to intervene. This might be an exceptional scenario but this is precisely what pure precautionary reasoning involves. In other words, in its purest form, quite different to simple or complex prudential reasoning that involves balancing likely harms and benefits, there is a special (and probably very limited) version of the precautionary principle holding that the protection of the infrastructural conditions is so important that, where the possibility of activity x causing harm to infrastructural condition y cannot be ruled out, x should be restrained even though this involves a loss of benefit – at any rate, this special principle holds unless the benefit that is lost also relates to the maintenance of the infrastructure. In this scenario, prior to taking such restraining action (rather like a court issuing an interlocutory injunction), regulators need not attempt to estimate more precisely the likelihood of x causing harm to y, and nor need they attempt to weigh the loss of a beneficial activity (x) against the possible protection of the infrastructure.

It is with this idea of regulators acting to protect the generic infrastructural conditions that we get to the notion of super-stewardship.

## 7 Super-stewardship

For any human community, it is imperative that the generic infrastructural conditions are properly protected. This is the first responsibility of regulators. There is a sense in which the tragedy of the commons is far more serious than a tragedy of the anti-commons. But, of course, a tragedy of the anti-commons is extremely serious; and regulators need to be thinking not only about protecting the essential infrastructure but also setting an environment that enables humans to flourish in their transactions and interactions. For a community with moral aspirations, what this particularly means is that the regulatory environment must leave space for moral development; and, to recall our earlier discussion, this means that reliance on prudential signals and design fixes should not leave regulatees unable to do the right thing for the right reason. Accordingly, in an aspirant moral community, we can think of regulators having a super-stewardship responsibility for the protection and preservation of the essential infrastructural conditions as well as for the generic conditions that are conducive to any kind of moral life.

Let me conclude, then, with some short remarks about regulatory super-stewardship, the agency commons and the conditions for moral community.

(i) REGULATORY SUPER-STEWARDSHIP AND THE AGENCY COMMONS

The regulatory environment comprises signals and steering mechanisms that are intended to direct the actions, transactions and interactions of regulatees. However, this already presupposes a stage on which such activities are viable; it presupposes an infrastructure. The general idea of an infrastructure as the underlying foundation for a system is reasonably settled; and the conventional wisdom is that infrastructures in this sense are found in transportation and communication systems, as well as being constituted by basic public services such as sewers, water and energy.<sup>61</sup> By way of illustration, consider the regulatory environment for a railway system. That environment regulates the movement of rolling stock on the tracks and the conduct of passengers who are carried on the trains. It is an environment that is, literally, thick with regulatory signals. It is also an environment where we find non-normative design replacing (largely for reasons of safety<sup>62</sup> but also to inhibit free-riding) traditional normative signals. None of this is viable, however, without a supportive infrastructure, without a track.

Now, we can draw a distinction between those infrastructural features that are generic and, thus, essential for any human activity and those that are specific to particular activities. While the railway infrastructure is necessary for a railway transport system, it is not generic. It is not even generic in the context of transport systems because waterways and road traffic, for example, can function perfectly well in the absence of a railway infrastructure; and it is certainly not generic in the broader sense of being essential for any kind of activity to be viable. What, then, might be candidates for the generic infrastructure in this broader and most fundamental sense?

One thing that humans must have before they are capable of acting, transacting or interacting in the purposive (goal-directed) way that we associate with agency is a minimal level of health and well-being. For humans whose basic health and well-being is under threat, there is little prospect of actualising their agency – it is akin to the train system being paralysed by damage to the tracks. Immediately, this gives rise to two difficult questions. First, what are the elements that are relevant to an agent's basic health and well-being? And, secondly, where do we draw the line between the generic infrastructure, specific infrastructures and activities on these infrastructures?

Turning to the first of these questions, let us suppose that we have a rough sense of what it means to say that a human enjoys basic health and well-being. Rather than asking what factors are conducive to such a condition, we can readily identify the kind of factors that are antithetical to such a condition. For example, we can point to problems with food security and clean water, to environmental pollution, and to the prevalence of disease. Sadly, chronic conditions of this kind can be found in many parts of the world and, following a natural disaster, we will often see some of these conditions in an acute form. In these cases, we can say that the infrastructure is deficient or, in the case of an emergency, that it has collapsed.

This leads to the second question. How do we draw the line between the generic infrastructure, specific infrastructures and activities on these infrastructures? In the light of what we have already said, I suggest that it is not too difficult to distinguish between generic and specific infrastructures. To return to railway systems, their specific infrastructures are important and valued; they enhance agency but they are not essential to it. Human agency does not presuppose railway tracks, roads, or any other kind of transport

61 Cf. B M Frischmann, "An economic theory of infrastructure and commons management" (2005) 89 *Minnesota Law Review* 917, pp. 923ff.

62 Cf. J Wolff, "Five types of risky situation" (2010) 2 *Law Innovation and Technology* 150.

infrastructure. These are not part of the *generic* infrastructure. We might say much the same about the infrastructural elements of a modern information technology system. Cybercrime is particularly serious when it strikes at these infrastructural elements; and, for those communities that increasingly transact and interact online, this is an extremely serious matter.<sup>63</sup> Nevertheless, this is not part of the *generic* infrastructure. Having said that, it is much less clear how we should distinguish between infrastructures and activities that take place on those infrastructures. An agent's basic health and well-being can be harmed by the isolated act of another human, by some inhibiting situational threat (such as that of terrorism), or by deficient living conditions. What makes a feature generically infrastructural is that it strikes at the general possibility of agency, irrespective of the agent and of an agent's particular purposes, rather than the particular occurrent prospects of the agent. Or, to put this another way, there first has to be infrastructure and then there can be activity: while there can be infrastructure without activity, there can be no activity without infrastructure.

If we think about the regulatory environment in this kind of way, we can begin to distinguish between those parts of the environment that are designed to secure the infrastructural conditions and those parts that are intended to direct the conduct of regulatees as they act, transact and interact on the infrastructure. Inevitably, there will be cases that are clearer than others: for example, it is clear that, while deficient living conditions are infrastructural, an isolated assault is not; and, depending on the scale and intensity of the threat, we might find it more difficult to classify terrorism. At all events, it is arguable that four major regulatory implications follow from this.

First, while the former part of the regulatory environment should apply to securing the generic infrastructure for agency itself, the latter (the regulation of agents' on-stage interactions and transactions) can be more tuned to local cultural commitments and preferences. To put this in cosmopolitan terms, while all regulators share a responsibility for securing the essential infrastructural conditions, within each community of rights there is room for some (legitimate) variation in the regulation of local activities.<sup>64</sup>

Secondly, if the infrastructure is to be secured, this implies a considerable degree of international co-ordination and shared responsibility. Moreover, because politics tends to operate with short-term horizons, it also implies that the regulatory stewards have some independence from the political branch.

Thirdly, as I have indicated in the previous part of the paper, a form of pure precautionary reasoning might be acceptable in defence of the infrastructure.<sup>65</sup> According to such reasoning, where the regulatory stewards cannot rule out the possibility that some activity threatens the infrastructure, then they may in good faith apply protective measures even though such measures involve some sacrifice of a valued activity. This reasoning, it should be emphasised, assumes an active employment of precaution. It is not simply that a

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63 Following the devastating DDoS (distributed denial of service) attacks on Estonia in 2007, the question of the vulnerability of critical information infrastructures in Europe rapidly moved up the political agenda: see, House of Lords European Union Committee, *Protecting Europe Against Large-Scale Cyber-Attacks* (Fifth Report, Session 2009–2010).

64 For further discussion, see R Brownsword, "Regulatory cosmopolitanism: clubs, commons, and questions of coherence", TILT Working Papers, No 018/2010 (University of Tilburg 2010).

65 Cf. D Beylveid and R Brownsword, "Complex technology, complex calculations: uses and abuses of precautionary reasoning in law" in Düwell and Sollie (eds), *Evaluating New Technologies*, n. 16 above, p. 175.

lack of full scientific certainty is no reason (or excuse) for inaction – rather, where the harm concerns the infrastructure, there is a need to initiate preventive and protective action.<sup>66</sup>

Fourthly, for communities that have moral aspirations or that value their individual autonomy, it is important that the regulatory environment does not design out the opportunities for acting freely or doing the right thing. Nevertheless, where the regulatory stewards are acting to protect the infrastructure, a resort to designed-in solutions may be more readily justified.

Let us think about how this might play in the context of public health biobanking, for which many societies now have a passion. According to the Ethics and Governance Framework, version 3.0 (October 2007) for UK Biobank,<sup>67</sup> the Biobank

... will serve as the steward of the resource, maintaining and building it for the public good in accordance with its purpose. This implies both the judicious protecting and sharing of the resource. It also extends to the careful management of any transfer of parts or all of the database or sample collection.

Given that the purpose of projects such as UK Biobank is to improve our understanding of the interactions between genetic profiles, physical environments and lifestyles, and their impact on the health of individuals (as well as the health of larger populations), how does stewardship (with an infrastructural focus) fit in? Do we see any resulting improvement in our understanding as relating to the generic infrastructure or simply to agents' activities on an already secured infrastructure? Do we understand more about how to set the *stage* (the infrastructure), or is it the *performance* (the activity) that we understand how to improve? For, to the extent that it is infrastructural, the stewardship jurisdiction may be invoked with all that this entails for the character of the regulatory environment. However, we need to be careful – and nowhere more so than in a community of rights, where agents value the opportunity to choose their own lifestyle. Even if there is a public health concern about, let us say, obesity, as Inez de Beaufort has provocatively asked, why shouldn't those who have a sweet tooth carry on eating “queen of puddings, sticky toffee puddings, and knickerbocker glories”?<sup>68</sup>

In the light of these remarks, imagine that, 50 years from now, Biobank research has yielded important findings about the causes of major diseases. Equipped with this understanding, the state is in a position to make effective interventions that will reduce the incidence of disease. What would the community make of the following kinds of public-health directed measures that are proposed by the state? First, with a range of key genetic markers now identified, and with techniques such as pre-implantation genetic diagnosis now wholly reliable and sophisticated, what if the state proposes that any embryos that carry a relevant marker should not be used? We should recall that such screening already takes place for markers associated with a predisposition to cancer; so why not also for markers associated with, say, obesity or addiction? Or, what if a similar approach is taken to pre-natal testing, so that a fetus with the relevant marker is recommended for abortion (or is required to be aborted)? Secondly, what if products (such as tobacco and alcohol) that are judged to be contrary to public health are prohibited? Or, again, what if certain lifestyles are treated in the same way? Thirdly, what if the physical environment is designed in ways that are not

66 Cf. E Fisher, J Jones and R von Schomberg, “Implementing the precautionary principle: perspectives and prospects” in Fisher et al., *Implementing the Precautionary Principle*, n. 54 above; and E Fisher, *Risk Regulation and Administrative Constitutionalism* (Oxford: Hart 2007).

67 [www.ukbiobank.ac.uk/docs/EGF20082.pdf](http://www.ukbiobank.ac.uk/docs/EGF20082.pdf).

68 Whose Potbelly Is It Anyway? public lecture, hosted by the Nuffield Council on Bioethics, delivered at the Royal Society, London, 26 April 2010.

simply conducive to health but that present agents with no option other than the healthy one? What if the only way to get from A to B is to walk or to use the stairs? In short, how far, in a community of rights, will it be accepted that the state as steward for public health can not only set the stage in the right (health-promoting) way but may also act as gatekeeper for who is admitted to the community and then as a monitor of individual lifestyles?<sup>69</sup>

These are difficult questions. However, we should not despair. If a community of rights can (and should) debate questions concerning the regulation of activities (of acts, interactions and transactions), so it can (and should) debate its best understanding of the distinction between infrastructure and activity – and, concomitantly, its understanding of the regulatory competence that follows from this distinction. Of course, whilst there is some comfort in these remarks, we should not be complacent: it is no use initiating such a debate in 50 years' time; this is a debate that must start now.

### (ii) THE CONDITIONS FOR MORAL COMMUNITY

Just as there is a generic infrastructure for agency *simpliciter* (irrespective of whether agents are moralists or amoral prudentialists), so there are generic conditions for the moral life (for all moral agents, irrespective of their particular moral credos). In both cases, regulators have super-stewardship responsibilities.

The generic conditions for moral life obtain irrespective of particular substantive moral codes. In other words, these are the conditions that all moralists, whether utilitarian, Kantian, Gewirthian, Rawlsian, or whatever, would agree to be essential for there to be the possibility of moral community and personal moral development. If, as I assume, one of these conditions is that there must be the possibility of individuals acting in a morally guided way, doing the right thing for the right reason, then this bears on the way that regulators regulate. Each moral community, with its own criteria of right action, will have its own view about the legitimacy of particular regulatory standards and purposes; but the communities will be united in agreeing that regulators should not displace moral signals in a way that distorts the regulatory environment. Where prudential signals displace moral signals, it remains possible for regulatees to do the right thing for the right reason – it is just that the moral signal is no longer in the foreground. However, when normative signals are displaced by non-normative signals of practicability and possibility, regulatees can find themselves in a position where the only thing that they can do is the right thing – or, at any rate, the thing that the regulators have approved by their design.

There is a great deal of work to be done in clarifying, both as a matter of principle and as matter of practice, how far moral communities can afford the moral signals to fade in their regulatory environments. I have said already that it might be legitimate to rely on design in order to protect the essential infrastructure. However, this is exceptional and the real question is about the legitimacy and effect of using a technical fix in relation to a routine activity. Unless we categorically rule out the use of design as a regulatory strategy, the default position seems to be that such a regulatory strategy is legitimate unless it goes beyond a point (possibly a tipping point) at which the opportunity for moral development is lost. However, this gives little specific guidance. How might we begin to specify the ground rules for responsible regulation in this context? For example, is it responsible (and legitimate) to resort to design when this is a safety feature that is intended to reduce defective implementation (unintentional harm) rather than acts of intentional harm? Or, should it be acts of intentional harm that are the first priority for a technical fix? Then,

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69 Cf. Thaler and Sunstein, *Nudge*, n. 36 above.

does it matter whether the design is in products, places or people? These are all challenging questions.<sup>70</sup>

Even if we can draft some guiding principles for the appropriate use of the non-normative regulatory register, there is still the question of how, in practice, regulators can be kept in line. Given that politicians are likely to be tempted to deploy regulatory strategies that “work”, there will need to be independent procedures for review. Accordingly, within each aspirant moral community, there will need to be local procedures to hold regulators to account, and to challenge particular interventions, whenever regulatory reliance on design departs from guiding principles or raises questions about the sustainability of moral community.

## 8 Conclusion

In this paper, I have referred from time to time to questions of health and I should conclude with a large health warning. In *Rights, Regulation and the Technological Revolution*, I said that, even such a long book did little more than scratch the surface, that in all areas there was unfinished business. Having been gently chided for entering such caveats, I hesitate to repeat them.<sup>71</sup> Nevertheless, although I have tried to take things forward in this present essay, I am all too aware that, with each elaboration, further questions arise. For example, the idea of the regulatory environment has no obvious limits. Where does it start and where, precisely, does it finish? In what circumstances and for what purposes is it permissible to rely on non-normative regulatory strategies? The line between prudential and moral reasoning is tricky (particularly where prudential preference maximisation merges into a regulatory script for utilitarian reasoning). The idea of pure precautionary reasoning (let alone moral precautionary reasoning)<sup>72</sup> invites much further analysis, as does the concept of the essential infrastructure upon which it draws. Stewardship, whether super or standard, needs to be handled very carefully and, in some cases, it might seem like a hostage to fortune.<sup>73</sup> Is it responsible to embrace such an idea, to contemplate such a regulatory jurisdiction?

We should also remember that, although responsible regulation might start with safety concerns, it certainly does not end there. As Maria Lee<sup>74</sup> has observed:

The proper regulation of controversial technologies . . . is complex and contested. Difficult questions about the safety of these technologies, for the environment and for human health, resonate at the highest political level. There is also however *another* politics of regulation: whilst environmental and human safety are important, complex and political, so may be, for example, the way a

70 The best place to start thinking about these issues is K Yeung, “Towards an understanding of regulation by design” in R Brownsword and K Yeung (eds), *Regulating Technologies* (Oxford: Hart 2008), p. 79. For more recent reflections, see K Yeung, “Can we employ design-based regulation while avoiding Brave New World?” (2011) 3 *Law, Innovation and Technology* 1; and R Brownsword, “Lost in translation: legality, regulatory margins, and technological management” (2011) 25 *Berkeley Technology Law Journal* (forthcoming).

71 See D Morgan, “Technology in the age of anxiety: the moral economy of regulation” (2009) 29 *Legal Studies* 492, which sparks off so many thoughts that it succeeds only in persuading me that the caveats were undoubtedly required.

72 Compare the idea of “procautionary” reasoning in R Brownsword, “Nanoethics: old wine, new bottles?” (2009) 32 *European Journal of Consumer Policy* 355.

73 In this respect, we should note Han Somsen’s cautionary remarks: see, H Somsen, “Cloning Trojan Horses: precautionary regulation of reproductive technologies” in Brownsword and Yeung (eds), *Regulating Technologies*, n. 70 above, p. 221.

74 M Lee, “Beyond safety? The broadening scope of risk regulation” (2009) 62 *Current Legal Problems* 242.

technology distributes risk and benefit; the social and political arrangements a technology might favour; and the real purposes of the technology.<sup>75</sup>

Beyond the politics of risk regulation, there are, indeed, difficult questions of equity and ethics that remind us that responsible regulators will aspire to set legitimate standards as well as to set about the regulatory enterprise in the right kind of way. So, this really is work in progress. Moreover, with the constant acceleration in emerging technologies, coupled with changing social attitudes, this is in all probability how the work, both practical and theoretical, is destined to remain.<sup>76</sup>

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75 Lee, “Beyond safety?”, n. 74 above, p. 243.

76 O Bekou and T Murphy surely put their finger on it when they remark in a recent editorial introduction to a special issue on human rights and new technologies that “negotiating the mix of hope, hype, fear and quotidian use that surrounds new technologies is not going to be easy – either for individuals or groups, or indeed for regulators”: see (2010) 10 *Human Rights Law Review* 597. For earlier reflections on the relationship between human rights and new technologies, see T Murphy (ed.), *New Technologies and Human Rights* (Oxford: OUP 2009) and “Technology, tools, and toxic expectations: post-publication notes on New Technologies and Human Rights” (2009) 1 *Law, Innovation and Technology* 181.



# What help is a steward? Stewardship, political theory and public health law and ethics

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## 1 Introduction

Public health law, on almost any estimation, represents an enormously broad field. Some commentators would seek to limit its scope, for example by claiming that it refers solely to the competence of the government's public health department,<sup>1</sup> or even by declaring only a narrow competence of all of government to deal with health issues.<sup>2</sup> However, it is hard to find non-arbitrary means of avoiding the much wider definitions that account for all socio-political responsibility for health; not simply health *care* or the policy of departments of health, but all practical manifestations of responsibility for health held by “the state, in collaboration with its partners”.<sup>3</sup> It is therefore becoming a received wisdom that the concerns of scholars in (public) health law and ethics cannot be addressed simply

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\* Institute for Science, Ethics and Innovation, School of Law, University of Manchester: email john.coggon@manchester.ac.uk. I am grateful for feedback from audiences who heard earlier drafts of this paper at the following conferences: A Symposium with Professor Roger Brownsword: Super-stewardship in the Context of Public Health, School of Law, University of Sheffield, 14 November, 2009; The David C.Thomasma International Bioethics Retreat, Institut d'Études Politiques de Paris, 21–25 June 2010; Medical law section at the annual conference of the Society of Legal Scholars, University of Southampton, 13–16 September 2010. For feedback on earlier drafts, I am grateful to Soren Holm and Sheelagh McGuinness. Responsibility for any errors is my own. Finally, thanks to the British Academy postdoctoral fellowship scheme and the Wellcome Strategic Programme in the *Human Body, its Scope, Limits and Future* for their support during the development of this paper.

- 1 M Rothstein, “Rethinking the meaning of public health” (2002) 30 *Journal of Law, Medicine and Ethics* 144–9. For further discussion, see also D Goldberg, “In support of a broad model of public health: disparities, social epidemiology and public health causation” (2009) 2(1) *Public Health Ethics* 70–83, and M Rothstein, “The limits of public health: a response” (2009) 2(1) *Public Health Ethics* 84–8.
- 2 R Epstein, “In defense of the ‘old’ public health” (2004) 69(4) *Brooklyn Law Review* 1421–70; R Epstein, “Let the shoemaker stick to his last: a defense of the ‘old’ public health” (2003) 46(3) *Perspectives in Biology and Medicine* S138–59. See also L Gostin and M Gregg Bloche, “The politics of public health: a response to Epstein” (2003) 46(3) *Perspectives in Biology and Medicine* S160–75.
- 3 The phrase is taken from Larry Gostin's celebrated definition of public health law: “Public health law is the study of the legal powers and duties of the state, in collaboration with its partners . . . to ensure the conditions for people to be healthy . . . and of the limitations on the power of the state to constrain for the common good the autonomy, privacy, liberty, proprietary, and other legally protected interests of individuals.” See L O Gostin, *Public Health Law: Power, duty, restraint* 2nd edn (Berkeley: University of California Press 2008), p. 4.

by reference to, or analysis of, medicine and health care.<sup>4</sup> A natural upshot of this is that theorists are forced (of course, some may already anyway choose to do this)<sup>5</sup> to consider wholesale political theories when grounding their analyses: it is impossible to identify or evaluate a “public health problem” without having an idea of the role of the state and the reasons how and why a given health-related issue is a public one and properly subject to policy.<sup>6</sup> It is for this reason that we increasingly find in the literature distinct evaluative measures for analysis of public health matters. Included in the wide array of proposed models are accounts based in feminism,<sup>7</sup> contractarianism,<sup>8</sup> luck egalitarianism,<sup>9</sup> communitarian civic virtue,<sup>10</sup> capabilities or functionings,<sup>11</sup> small state libertarianism,<sup>12</sup> and Millian political liberalism.<sup>13</sup> As part of this journal’s special issue on “super-stewardship” and the related work of Roger Brownsword, my purpose in the current paper is to provide a critical examination of the stewardship model as applied in regard to public health. I evaluate it both as a concept to assist analyses of public health issues, and as something designed to help guide political decision-makers in issues concerning health.

The essay begins with two foundational sections: the first briefly gives the analytic context, exploring the contention that political theory is the relevant start point in the public health studies to which stewardship is directed; the second explores the idea of stewardship itself as it has been employed in relation to public health. This groundwork allows me then to build a substantive critique of stewardship, which demonstrates strong reasons to doubt it as a useful or robust theory. Although I do not address super-stewardship explicitly, it should be clear that the claims that I make in what follows apply to it too.<sup>14</sup> I consider arguments about the relationship between stewardship and political theory more widely, and question quite what it adds to understandings of political obligation. This permits examination of the crucial question: what do we gain by appealing to stewardship in debates on public health? I focus particularly on the World Health Organisation’s (WHO) *World Health Report 2000*<sup>15</sup> and the Nuffield Council on Bioethics’ report *Public Health: Ethical issues*,<sup>16</sup> which give great prominence to stewardship, and the recent work of

4 This is perhaps most starkly represented in the shift in focus from Norman Daniels’ seminal work *Just Health Care* (Cambridge: CUP 1985) to his *Just Health: Meeting health needs fairly* (Cambridge: CUP 2008). See, especially, the introduction to the latter.

5 Including Roger Brownsword, whose work is considered in the current essay.

6 See the discussion in J Coggon, “Commentary – Public health, responsibility and English law: are there such things as no smoke without ire or needless clean needles?” (2009) 17(1) *Medical Law Review* 127–39.

7 F Baylis, N Kenny and S Sherwin, “A relational account of public health ethics” (2008) 1(3) *Public Health Ethics* 196–209.

8 Daniels, *Just Health*, n. 4 above.

9 S Segall, *Health, Luck, and Justice* (Princeton and Oxford: Princeton UP 2010).

10 B Jennings, “Public health and civic republicanism” in A Dawson and M Verweij (eds), *Ethics, Prevention, and Public Health* (Oxford: OUP 2007).

11 M Powers and R Faden, *Social Justice: The moral foundations of public health and health policy* (Oxford: OUP 2006); J Wolff and A de-Shalit, *Disadvantage* (Oxford: OUP 2007).

12 Epstein, “In defense of the ‘old’ public health”, n. 2 above.

13 J Coggon, *What Makes Health Public? A critical evaluation of moral, legal, and political claims in public health* (Cambridge: CUP 2012).

14 See also the criticisms in S Holm, “From steward to Stuart: some problems in deciding for others”, in the current issue of this journal.

15 WHO, *World Health Report 2000* (Geneva: WHO 2000).

16 Nuffield Council on Bioethics, *Public Health: Ethical issues* (London: Nuffield Council on Bioethics 2007). The Nuffield Council describes itself as “an independent body that examines and reports on ethical issues in biology and medicine”, [www.nuffieldbioethics.org/about](http://www.nuffieldbioethics.org/about) (last accessed 5 January 2011).

Roger Brownsword, which also claims a role for stewardship.<sup>17</sup> Finally, I consider the relationship between stewardship and paternalism. This last part comes against a backdrop of concerns about “nanny-statism” and positions of cynicism and scepticism towards state regulation of health issues.<sup>18</sup>

The conclusion to the analysis is that stewardship offers little in the development of robust analysis in public health law and ethics. It either provides a label for normative conclusions that are unsubstantiated, in which case we need to see a theory rather than a politically attractive term, or it speaks to issues of good governance that are anyway entailed in a theory, in which case little or nothing is gained by an added reference to stewardship. Whilst I acknowledge stewardship’s possible benefits for public ethical discourse, I urge caution against its adoption in analysis, particularly where it obscures rather than exposes important normative argument, and I suggest that it is not a sound reference point as the basis of policy or critical scholarship.

## 2 Public health and politics

Public health law and ethics are developing as subjects of increasing prominence and importance.<sup>19</sup> Roger Brownsword’s work stands amongst the most significant contributions, offering a rich marriage of concern for coherent moral theory and a deep understanding of law and regulation.<sup>20</sup> A large part of that work has been directed to questions in bioethics; at issues relating to rights, liberties and responsibility in regard to health and health decision-making. It is useful, therefore, to introduce the current essay with some brief general reflections on the nature of normative analysis of law and policy in relation to public health.<sup>21</sup>

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- 17 In particular, see D Beylvel and R Brownsword, “Principle, proceduralism, and precaution in a community of rights” (2006) 19(2) *Ratio Juris* 141–68; R Brownsword, “So what does the world need now? Reflections on regulating technologies,” in R Brownsword and K Yeung (eds), *Regulating Technologies: Legal futures, regulatory frames and technological fixes* (Oxford: Hart 2008); R Brownsword, “Rights, responsibility and stewardship: beyond consent” in H Widdows and C Mullen (eds), *The Governance of Genetic Information: Who decides?* (Cambridge: CUP 2009).
- 18 See e.g. the reception of the Nuffield report in *The Times*: D Rose, “No to the nanny state, but yes to telling us all what to do through ‘stewardship’”, *The Times* (London), 13 November 2007; D Rose, “Higher alcohol tax and no smoking at home – beware of the new nanny state”, *The Times* (London), 13 November 2007.
- 19 See especially D E Beauchamp and B Steinbock (eds), *New Ethics for the Public’s Health* (New York: OUP 1999); N Kass, “An ethics framework for public health” (2001) 91(11) *American Journal of Public Health* 1776–82; A Thompson, A Robertson and R Upshur, “Public health ethics: towards a research agenda” (2003) 9(2) *Acta Bioethica* 157–63; B Jennings, “Frameworks for ethics in public health” (2003) 9(2) *Acta Bioethica* 165–76; S Anand, F Peter and A Sen (eds), *Public Health, Ethics, and Equity* (Oxford: OUP 2004); M Boylan (ed.), *Public Health Policy and Ethics* (Dordrecht: Kluwer Academic Publishers 2004); R Bayer, L O Gostin, B Jennings and B Steinbock (eds), *Public Health Ethics: Theory, policy, and practice* (Oxford: OUP 2006); A Dawson and M Verweij (eds), *Ethics, Prevention, and Public Health* (Oxford: OUP 2007); Gostin, *Public Health Law*, n. 3 above; K Syrett and O Quick, “Pedagogical promise and problems: Teaching public health law” (2009) 123(3) *Public Health* 222–31; L O Gostin, *Public Health Law and Ethics: A reader* 2nd edn (Berkeley: University of California Press 2010); M Freeman, *The Ethics of Public Health*, vols I and II (Farnham: Ashgate 2010).
- 20 The key books explicating Brownsword’s jurisprudential position are D Beylvel and R Brownsword, *Law as a Moral Judgment* (London: Sweet & Maxwell 1986); D Beylvel and R Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford: OUP 2001); D Beylvel and R Brownsword, *Consent in the Law* (Oxford and Portland OR: Hart 2007). The enormous body of work he has produced looks at health-related issues, and much else besides.
- 21 These ideas are explored in much greater depth in Coggon, *What Makes Health Public?*, n. 13 above. See also J Coggon, “Assisted dying and the context of debate: ‘medical law’ versus ‘end-of-life law’” (2010) 18(4) *Medical Law Review* 541–63; J Coggon, “Confrontations in ‘genetics’: rationalities, challenges, and methodological responses” (2011) 20(1) *Cambridge Quarterly of Healthcare Ethics* 46–55.

A hallmark of much medico-legal scholarship is the prominence given to moral theory.<sup>22</sup> Yet, as the focus has moved beyond the doctor/patient relationship, and wider disciplines such as “healthcare law”, “health law”, and “public health law” have developed, it has become apparent that often the more pertinent school of normative inquiry is political rather than moral philosophy. Thus, whilst theorists may seek to derive normative conclusions, for example, from Kantian moral theory – or, as in Brownsword’s work, that of Alan Gewirth – they recognise the need for some “meta-theory”; a bridge between what morality “says” and the proper scope and manner of legal regulation, be it coercive or otherwise. Although a good deal of focus is directed to understanding the *moral* rights and wrongs of a given scenario, practical philosophical discussion often falls on the public policy implications of troublesome normative questions. Analysts want to know what freedoms and duties *citizens* should have; what responsibilities *the state* has to structure its institutions and its health-related policy; what the limits are to *professional obligations*; and so on. It is trite to note that there need be no direct correlation between moral and legal obligation: we may have legal rights that are morally uninteresting, or be legally free to do things that are in contravention of many accounts of morality.<sup>23</sup> And a commitment to morality does not demand a complete matching of moral and legal obligations. Brownsword, who is not a legal positivist, argues that when it comes to regulation it is better that people are not always forced to do right as this forestalls their potential to learn and choose to act as responsible moral agents.<sup>24</sup> So, whilst (indeed because) he is a committed and consistent advocate for Gewirthian moral theory,<sup>25</sup> his analyses of law and regulation assume a commitment to related but different concerns than just ensuring that moral right be done. Rather than simply direct arguments at moral agents to assist their moral deliberations, his position speaks to the state, and assists understandings of the proper scope, reach and ends of law and regulation. To be clear from the start, this is part of what he describes as the state’s stewardship role within a system of Gewirthian rights. And such analysis is an exercise in political philosophy.

Likewise, regardless of putatively “private” interactions, for example, between doctor and patient, whatever “public health” might mean, it necessarily gives rise to political ideas. Any normative analysis of a public, or of matters being public, presents questions in politics. It is for this reason that works in public health law and ethics position themselves (wittingly or otherwise) in the field of political philosophy.<sup>26</sup> This is true regardless of where a theorist happens to sit on the political spectrum. Concepts of the state and legal rights and responsibilities are always at least in the background, if not presented as central concepts. The Nuffield Council on Bioethics’ report on ethics and public health makes this point starkly. Under the heading “Ethical issues – *The context of the debate?*” it says:

Public health measures raise complex questions about the relationship between the state and individuals and organisations that are affected by its policies. They also raise questions about the duties that individuals have towards each other. A substantial body of literature in political philosophy examines these relationships of duties and entitlements . . .<sup>27</sup>

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22 K Veitch, *The Jurisdiction of Medical Law* (Aldershot: Ashgate 2007).

23 Seminally, on the separation of law and morality see H L A Hart, *Law, Liberty, and Morality* (Stanford: Stanford UP 1963).

24 See e.g. R Brownsword, “So what does the world need now?”, n. 17 above, pp. 40–1, and the discussion in section 5, below.

25 A Gewirth, *Reason and Morality* (Chicago: University of Chicago Press 1978).

26 See Coggon, *What Makes Health Public?*, n. 13 above, chs 7 and 8.

27 Nuffield Council, *Public Health*, n. 16 above, p. xv.

The report explicitly contrasts political philosophy and the bioethics literature, and suggests that this latter body of scholarship is not equally pertinent to evaluations of public health. Instead it states that: “The central issue in public health is the extent to which it is acceptable for the state to establish policies that will influence population health.”<sup>28</sup> In order to understand this, the report takes for granted the existence of a state, and considers its possible manifestation from extremes of libertarianism to extremes of collectivism.<sup>29</sup> Along this spectrum are increasingly invasive roles for government, with the mandate of political institutions deriving from distinct political philosophical positions; for example, libertarian “natural rights”, social contract models, or systems directed to protect collective welfare. The authors of the report purport to position themselves some way along the spectrum, claiming that their position can be characterised by the concept of stewardship. They seek to distinguish this from the liberalism of John Stuart Mill,<sup>30</sup> and urge that it provides a happier balance between too much individualism at an indifferent extreme of minimal state responsibility, and too much meddling at an extreme of nanny-statism. The following section gives an account of stewardship as it has been developed in relation to public health.

### 3 Stewardship in public health

The concept of stewardship is establishing a place in academic public health law and ethics, and in public policy. It is important to note and distinguish the independent existence of robust theological concepts of stewardship, which assume significance in environmental ethics. In that context, stewardship represents the idea that humanity is steward over the earth; rather than meaning the world is ours to do with as we please, it gives expression to the principle that we must be responsible stewards of God’s creation. As Robert Lannan puts it, “human beings are given the dual responsibilities of serving as stewards over the environment, and as agents acting on God’s behalf in the ongoing process of creation and redemption”.<sup>31</sup> In this sense, humankind is under an obligation to ensure the protection and perfection of itself and its environment. Beyond environmental ethics, it should be noted too that theological arguments about stewardship have been invoked in relation to medical ethics,<sup>32</sup> and non-theological notions of stewardship have also been advanced in relation to medical ethics, medical resource allocation decisions and good medical practice.<sup>33</sup> In the current essay, I do not seek to address any of these uses of stewardship, and in particular would emphasise the irrelevance of what follows to theological concepts of stewardship and environmental ethics. My focus is on the new incarnations of stewardship, which may be attributed to the WHO, and which have since found champions within the Nuffield Council on Bioethics and the King’s Fund,<sup>34</sup> and in the academic work

28 Nuffield Council, *Public Health*, n. 16 above, p. xvi.

29 See *ibid.* ch. 2.

30 J S Mill, *On Liberty*, E Alexander (ed.) (Peterborough, Canada: Broadview 1999).

31 R W Lannan, “Catholic tradition, and the new Catholic theology and social teaching on the environment” (1999) 39(4) *Catholic Lawyer* 353–88, pp. 365–6. See also B Waters, “Christian theological resources for environmental ethics” (1995) 4(8) *Biodiversity and Conservation* 849–56.

32 See e.g. R L Sevensky, “The religious foundations of health care: a conceptual approach” (1983) 9(3) *Journal of Medical Ethics* 165–9.

33 See e.g. D C Thomasma, “Stewardship of the aged: meeting the ethical challenge of ageism” (1999) 8 *Cambridge Quarterly of Healthcare Ethics* 148–59.

34 The King’s Fund describes itself as a body that “seeks to understand how the health system in England can be improved” and “shape policy, transform services and bring about behaviour change”, [www.kingsfund.org.uk/about\\_us/](http://www.kingsfund.org.uk/about_us/) (last accessed 5 January 2011).

of Roger Brownsword. As I will show, these accounts of stewardship present themselves with an incompleteness, superficiality, or superfluity that renders them problematic.

In the literature relating to public health, stewardship has been given as the basis of governmental responsibility for the health of the population. The principal source is the WHO's *World Health Report 2000*.<sup>35</sup> The WHO defines stewardship in, amongst others, the following ways:

The careful and responsible management of the well-being of the population – stewardship – is the very essence of good government. The health of people is always a national priority: government responsibility for it is continuous and permanent.<sup>36</sup>

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.<sup>37</sup>

[Drawing from the dictionary definition]: *the careful and responsible management of something entrusted to one's care*. People entrust both their bodies and their money to the health system, which has a responsibility to protect the former and use the latter wisely and well . . . A large part of stewardship consists of regulation, whether undertaken by the government or by private bodies which regulate their members, often under general rules determined by government. But the concept embraces more than just regulation, and when properly conducted has a pervasive influence on all the workings of the system.<sup>38</sup>

Governments should be the “stewards” of their national resources, maintaining and improving them for the benefit of their populations. In health, this means being ultimately responsible for the careful management of their citizens' well-being. Stewardship in health is the very essence of good government. For every country it means establishing the best and fairest health system possible. The health of the people must always be a national priority: government responsibility for it is continuous and permanent. Ministries of health must take on a large part of the stewardship of health systems.

Health policy and strategies need to cover the private provision of services and private financing, as well as state funding and activities. Only in this way can health systems as a whole be oriented towards achieving goals that are in the public interest. Stewardship encompasses the tasks of defining the vision and direction of health policy, exerting influence through regulation and advocacy, and collecting and using information. At the international level, stewardship means influencing global research and production to meet health goals. It also means providing an evidence base to guide countries' efforts to improve the performance of their health systems.<sup>39</sup>

In a King's Fund report, written by Karen Jochelson and entitled *Nanny or Steward? The role of government in public health*, stewardship is described as follows:

Legislation brings about changes that individuals on their own cannot, and sets new standards for the public good. Rather than condemning such activity as nanny statism, it might be more appropriate to view it as a form of “stewardship”. Stewardship implies that government has a responsibility for protecting national health, and to serve in the public interest and for the public good. It suggests a

35 WHO, *World Health Report 2000*, n 15 above.

36 *Ibid.* p. x.

37 *Ibid.* p. xi.

38 *Ibid.* p. 45.

39 *Ibid.* p. 118.

protective function, where individuals are protected from harm by others and sometimes from themselves. Stewardship implies that paternalistic government is acceptable under certain conditions, and the debate should focus both on defining these conditions and the likely benefits.<sup>40</sup>

Finally, the Nuffield Council on Bioethics, in its report *Public Health: Ethical Issues*, presents stewardship in the following way:

The concept of “stewardship” is intended to convey that liberal states have a duty to look after important needs of people individually and collectively. It emphasises the obligation of states to provide conditions that allow people to be healthy and, in particular, to take measures to reduce health inequalities. The stewardship-guided state recognises that a primary asset of a nation is its health: higher levels of health are associated with greater overall well-being and productivity.<sup>41</sup>

The Nuffield Council report does not provide a clear explanation of stewardship’s normative foundations. It does, however, offer some claims about the concept as a political framework. Most notably, it gives an account of Millian liberalism, which echoes readings found in much of the bioethics literature more than it does some interpretations or developments of the ideas expressed in *On Liberty*.<sup>42</sup> The report suggests that sometimes Mill’s liberalism is to be recommended and incorporated in the model it advances, but that, on occasion, Millian liberalism is to be set aside because it fails to address important concerns. These concerns are stated rather than clearly derived from an explicated political theory. Although there is no obvious means of mediating between the demands of its articulation of Millian liberalism and the alternative concerns, it does list “the core characteristics that public health programmes carried out by a stewardship-guided state should have”:<sup>43</sup>

*Concerning goals, public health programmes should:*

- aim to reduce the risks of ill health that people might impose on each other;
- aim to reduce causes of ill health by regulations that ensure environmental conditions that sustain good health, such as the provision of clean air and water, safe food and decent housing;
- pay special attention to the health of children and other vulnerable people;
- promote health not only by providing information and advice, but also with programmes to help people to overcome addictions and other unhealthy behaviours;
- aim to ensure that it is easy for people to lead a healthy life, for example by providing convenient and safe opportunities for exercise;
- ensure that people have appropriate access to medical services; and
- aim to reduce unfair health inequalities.

*In terms of constraints, such programmes should:*

- not attempt to coerce adults to lead healthy lives;
- minimise interventions that are introduced without the individual consent of those affected, or without procedural justice arrangements (such as democratic decision-making procedures) which provide adequate mandate; and

40 K Jochelson, *Nanny or Steward? The role of government in public health* (London: King’s Fund 2005), p. 1 (reference omitted).

41 Nuffield Council, *Public Health*, n. 16 above, pp. xvi—xvii.

42 See J Coggon, “Harmful rights-doing? The perceived problem of liberal paradigms and public health” (2008) 34(11) *Journal of Medical Ethics* 798–801.

43 Nuffield Council, *Public Health*, n. 16 above, p. 26.

- seek to minimise interventions that are perceived as unduly intrusive and in conflict with important personal values.<sup>44</sup>

It is not obvious from the Nuffield report's explanations quite why Millian liberalism cannot itself be read to accommodate these goals.<sup>45</sup> More problematically, the picture it presents of stewardship attaches to *conclusions* about the state's role rather than to reasons for accepting certain things to be the state's function. The report offers the following understanding of "the liberal", who apparently would accept the conclusions:

The liberal agrees with the libertarian that the protection of individual freedom constrains the state's authority. Nonetheless, the liberal rejects the libertarian thesis that legitimate state power is restricted to protection of these freedoms, and agrees with the social contract version of collectivism that the state's power may rightly be used to advance the welfare of its citizens.<sup>46</sup>

There thus seems to be a sense in which the concept of stewardship will only appeal to those who already accept it: libertarians, for example, will not be convinced to change their minds simply because "the liberal" disagrees with them.<sup>47</sup> And there does not seem to be any argument provided to persuade them otherwise.

In its various presentations, then, stewardship is a concept whose normative basis is opaque, but whose implications have a degree of clarity. Some readers may not find it terribly illuminating. It tells us that the state (and probably in all three cases given above this should be read as the liberal-democratic state) exists for the good of citizens. Perhaps the most controversial aspect of the concept is the claim that health should be singled out as a particularly strong priority.

Having levelled these criticisms, it is important to acknowledge that an immediate response might be that they miss the point about the nature of the documents from which the definitions are drawn. Reports aimed at the public, governments, or other policymakers are necessarily *not* sources of philosophically robust normative theory. Jonathan Montgomery, who was a member of the working group on the Nuffield Council report, makes a forceful and convincing argument against critics (including me),<sup>48</sup> urging acceptance of the distinction between "public ethics" and scholarly works in ethics.<sup>49</sup> Montgomery stresses two particularly strong reasons why it would be unreasonable to expect in reports, such as those of the Nuffield Council, the nature and quality of argument that one would find in an academic work. First, there is the distinct collaborative nature of committees that "do" public ethics. Montgomery explains the necessary processes of compromise and the formal and political constraints that committees face. Regarding

44 Nuffield Council, *Public Health*, n. 16 above, p. 26.

45 See Coggon, "Harmful rights-doing?", n. 42 above.

46 Nuffield Council, *Public Health*, n. 16 above, p. 14.

47 Thus, an account such as Robert Nozick's would remain unaffected by the claims made in the Nuffield report because they do not answer for the breach of the rights whose existence Nozick asserts: R Nozick, *Anarchy, State, and Utopia* (Oxford: Blackwell 1974). This criticism applies *mutatis mutandis* to any alternative political ideology.

48 In part Montgomery's paper is a response to a paper of mine that is critical of the report for not providing a stronger theoretical position. In my paper, I suggest the liberalism of Joseph Raz is an example of the type of political theory that the Nuffield Council might have adopted, instead of the unclear concept of stewardship: see Coggon, "Harmful rights-doing?", n. 42 above. Two other members of the working party are co-authors with the working party's secretary of another paper that responds to my argument: T Baldwin, R Brownsword and H Schmidt, "Stewardship, paternalism and public health: further thoughts" (2009) 2(1) *Public Health Ethics* 113–16. This article is considered below.

49 J Montgomery, "Reflections on the nature of 'public ethics'" (in progress). I am grateful to Professor Montgomery for sharing with me an early draft of this paper, and for discussions we have had on this issue.

compromise, he notes that final formulations may be agreed upon even if they are reached by different committee members for different reasons. Second, regarding audience, he notes the need to account for and respond to the prevalent policy climate, to express ideas in a way that tracks well the prevailing discourse, and to consider the different addressees the reports will have, including a non-expert public.

Montgomery offers sound reasons to accept the working party's wisdom in selecting a catchy label such as "stewardship", even where it might seem a simplistic substitute for substantive academic argument: "Such a summary is necessary to facilitate debate in a media context that favours dramatic images and soundbites over subtle and protracted arguments."<sup>50</sup> Rhetoric, in short, is crucial to public impact, and academic critics of concepts presented in public documents must remain sympathetic to the real politics of public discourse about ethics. Expectations must be set against the contexts of the process, form and purpose of reports, such as those considered directly above. To quote Montgomery once more:

It is entirely right for academic work to draw attention to the shortcomings of pronouncements in order to test and refine them. However, it is also appropriate to note that the context of public communication introduces different aspects to the challenge of doing ethics. "Public ethics" needs to pay more attention to the way in which its contribution will be understood than writing for academic colleagues because the audience does not share the same technical vocabulary or canons of interpretation that the community of scholars has developed.<sup>51</sup>

Accepting Montgomery's position, I remain committed to a critical wariness of stewardship and consider it important to express my views for two reasons. First is what may be called a "real world objection". Ideas taken to be subsumed within the label "stewardship" are geared to affecting people in real life. Ideological stances are being sold to governments on the back of supposedly sound intellectual argument. In the case of the Nuffield Council, for example, there is the tangible and reasonable sense that the report is academically rigorous, given that its authors are highly noted academic figures.<sup>52</sup> This quite properly gives a sheen to the claims made in the report, and allows other bodies – such as the National Institute for Health and Clinical Excellence (NICE)<sup>53</sup> – to cite it as an authoritative statement, and introduce it directly as a defensible normative basis for the policy recommendations that NICE makes, and which are acted upon by government. Given this, it is crucial to expose weaknesses in, and problems with, the concept.

My second concern relates to scholarship. The concept of stewardship is taking hold in some academic circles,<sup>54</sup> and this heightens the demand for careful scrutiny. Politicians may find appeal in attractive names without too much concern about substance. In the usage of Jochelson, considered above, "steward" over "nanny" seems to be better packaging. But scholars, in contrast, need to know what they are dealing with before they go and embrace a supposedly new concept. If regulatory theorists and other academics take for granted the

50 Montgomery, "Reflections", n. 49 above.

51 Ibid.

52 The working group, listed at p. ix of the report, includes, amongst others, esteemed professors of philosophy, law, health economics and primary care.

53 See A Killoran and P White, "NICE public health guidance" (2010) 32(1) *Journal of Public Health* 136–7. NICE works independently of government, basing its decisions on the best available expert evidence, to give guidance and recommendations to the National Health Service on new and existing medicines, treatments and procedures, and the treatment and care of people with specific diseases and conditions: see further [www.nice.org.uk/aboutnice/](http://www.nice.org.uk/aboutnice/) (last accessed 19 January 2011).

54 Note, for example, its employment in other papers at the conference where the current paper was first presented: "A Symposium with Professor Brownsword", n\* above.

soundness of stewardship, and carry it into their analyses, they risk producing scholarship whose normative foundations are to be doubted. I will therefore continue in this section by exploring in greater detail stewardship in public health.

Readers unfamiliar with dominant theories in medical ethics might be interested to learn that part of the reason that a “repackaging” exercise for political liberalism was considered necessary lies in the current state of the field of bioethical scholarship. Conceptions of autonomy and liberty are often grossly impoverished, ill-conceived, or ill-equipped to deal satisfactorily with the sorts of social problems they are supposed to resolve.<sup>55</sup> Conceptual caricatures, for example, of Mill’s treatise *On Liberty*, dominate the literature, and doubt is cast on the original’s capacity to serve as a sound piece of political theory. In the face of a near hegemony of unrefined concepts of “individual autonomy”, theorists and policy-advisers sense a need for a conceptual sea-change.<sup>56</sup> Whilst in some cases the suggested reforms are excellent, it is important to accept the need for rigour in response to problems of hyper-atomisation or hyper-individualism. I have elsewhere explored the difficulties with responses to this individualism that rest heavily on normative constructs of “public health”.<sup>57</sup> My concerns about stewardship are similar. It is not satisfactory to be told simply that public health demands that society be structured in such-and-such a manner, as if public health has the “authority” or “jurisdiction” straightforwardly to do that. Equally, there is no value or strength in being told that the steward state, as described in the passages above, straightforwardly and compellingly “means” that society ought to be regulated in a particular way. It cannot do this, especially when it is a concept that is presented as an incompletely articulated theory.

To find more substantial meaning, therefore, and to try to discern the reasons for embracing stewardship, I turn to Richard Saltman and Odile Ferroussier-Davis, who have provided perhaps the most useful exploration of the concept in the light of the WHO report. Saltman and Ferroussier-Davis allude, in essence, to a governmental *need* to be freed from various constraints, which may be categorised as follows:

1. what the authors label “traditional theories”, which focus “on inherent limitations of state organization and behaviour”;
2. economic theories that posit that “civil servants never serve the state, but instead pursue only their own rational self-interest”;
3. disagreements over the role and function of civil servants;
4. and, in their words “[m]ost significantly”, the constraint (one imagines that it is a constraint) of the need to make populations healthier.<sup>58</sup>

Effectively, Saltman and Ferroussier-Davis suggest that there is a certain end point that states should aim towards, and they consider stewardship to be the best means to reach it. This attitude is reflected in the other literature on stewardship in health policy. It seems to be based on something approximating the following reasoning:

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55 See M Brazier, “Do no harm: do patients have responsibilities too?” (2006) 65(2) *Cambridge Law Journal* 397–422.

56 See W Gaylin and B Jennings, *The Perversion of Autonomy: Coercion and constraints in a liberal society* 2nd edn (Washington DC: Georgetown UP 2003); B Jennings, “Public health and liberty: beyond the Millian paradigm” (2009) 2(2) *Public Health Ethics* 123–34.

57 J Coggon, “Does public health have a personality (and if so, does it matter if you don’t like it)?” (2010) 19(2) *Cambridge Quarterly of Healthcare Ethics* 235–48.

58 R B Saltman and O Ferroussier-Davis, “The concept of stewardship in health policy” (2000) 78(6) *Bulletin of the World Health Organization* 732–9, p. 732.

1. we know what are attractive ends: people generally are in better health, social determinants of health inequalities are reduced, etc;
2. we know that we fail in reaching these ends as a logical upshot of prevalent norms in political philosophy; so
3. we need a new theory that tells us that the attractive ends are good and lets us reach them – and it is best labelled “stewardship”.

Saltman and Ferroussier-Davis describe the history of stewardship as a normative concept, drawn first from theological perspectives, and latterly from environmental ethics. This has led to discussions in political theory where we move:

[B]eyond solely process-based notions of the state as an efficient agent to substantive-based ones in which the state is an ethically motivated representative of the popular will and the common interest.<sup>59</sup>

They also say that stewardship is to be distinguished from the technocratic nature of the European welfare state, which is unable to be “simultaneously ethical and efficient”.<sup>60</sup> In short:

The positive dimensions of stewardship are predominantly tied to its potential for improving policy outcomes. The core contention is that while focusing the policy process on traditional principal–agent relationships can create an efficient state, it is possible to create a state that is not only efficient but good by emphasizing normative, ethically oriented expectations of stewardship. Stewardship, at its best, could provide an organizing principle for power in society transcending economics to base itself on the common interest.<sup>61</sup>

Stewardship is seen as a communitarian, pluralist, contractarian, democratic theory of the state. Yet little theorising has been done on the back of stewardship: *it* tells us nothing new. I would note that the final sentence in the quoted passage could as well have read “Politics, at its best . . .”. We might also be wary of observations such as the following:

A stewardship approach based in developing the collective health commons fits well with the sense of mission that has traditionally been the central motivation of health care providers. For physicians, this mission-oriented framework lies at the core of the Hippocratic oath. The notion of stewardship, if properly developed, is also consistent with an evidence-based health policy framework.

Surely the authors are correct, but the dice are doubly loaded here. First, it is less a happy coincidence and more a pre-ordained certainty that stewardship will present the same drivers as the so-called “mission” in public health if we hold that it is *based* on that same mission. Second, we are told that the “notion” of stewardship is yet to be developed, but that we already know that it is consistent with these worthy things. In other words, if in practice it fails to provide an efficient and good state, it is only because it has been wrongly developed.

To conclude this section, it is evident that within the public health literature stewardship is best seen as a means of packaging a set of conclusions rather than as a means of coming to them. This is a profound weakness, and leaves us in need of a defensible theory. The potential influence of documents that endorse stewardship is considerable. Its advocates seek to distinguish it, prescriptively guide, and yet the concept awaits substantive conceptual content. In the following section, I will develop this point by examining the employment of stewardship in the Nuffield report and in the scholarly work of Roger Brownsword.

59 Saltman and Ferroussier-Davis, “The concept of stewardship”, n. 58 above, *ibid.* p. 734.

60 *Ibid.* pp. 734–5.

61 *Ibid.* p. 735.

#### 4 What does stewardship add to public health law and ethics?

We have seen how stewardship is defined in public health documents, and noted its popularity amongst policy bodies: on the international stage, WHO; nationally, NICE. It has also been embraced by bodies that offer ethical advice to policymakers, such as the Nuffield Council and the King's Fund. And within academe, it has been brought into works discussing public health questions, most influentially in the recent scholarship of figures including Roger Brownsword. Having considered the concept as it features in various public sources, my focus in the remainder of this paper is on the concept as presented in the Nuffield Council's report on public health ethics, and in Brownsword's academic work. It is interesting to begin by distinguishing the problems each has. In the case of the Nuffield report, stewardship is problematic because of the superficiality with which it is presented. In Brownsword's independent work, the problem by contrast is not superficiality, but superfluity. Where he discusses stewardship, he is referring to functions of the state that are already comprised in his wider theoretical position. Whilst there is no intrinsic problem with his description of the stewardship role of regulators, stewardship itself is not a basis of regulatory justification. Rather, state responsibilities are a logical upshot of his already clearly articulated theory.

In a defence of the Nuffield report, Tom Baldwin, Roger Brownsword and Harald Schmidt say that stewardship:

[I]n its shortest form can be understood as stating that governments have a responsibility to promote, protect and preserve the infrastructural conditions that are essential to community life.<sup>62</sup>

This iteration is interesting for two reasons. First, because it betrays the issue at the core of my concern: stewardship is a statement, not a theory. Indeed, in concession to this line of criticism, they also say that:

[T]he stewardship model does not claim to be the heart of a comprehensive moral theory, nor does it attempt to be the last word on the question of "what is a robust normative theory for public health ethics?"<sup>63</sup>

Their iteration is interesting, second, because what stewardship states is pretty much the central point of philosophical inquiry into normativity and liberal political obligation.<sup>64</sup> It does not seem peculiar to advocates of stewardship, unless they are identified so blandly and widely that their title becomes redundant, that they should be concerned with governments having to sustain community life.<sup>65</sup> As explained here, stewardship is at most an aspect of a wider political philosophy, but there can be no doubting that all manner of inquiry on the political spectrum described in the report relates to the morally defensible

62 Baldwin et al., "Stewardship", n. 48 above, p. 116.

63 Ibid. p. 116.

64 Thomas McPherson, for example, says: "Politics is concerned with the State and with our relations to the State and its to us – in the liberal tradition with how to achieve peace and security and our interests, and with how to achieve 'more commodious living?'" T McPherson, *Political Obligation* (London: Routledge & Kegan Paul 1967), p. 76. Regardless of whether a reader is convinced by McPherson's analytic separation of moral and political obligation, this categorisation must be widely acceptable.

65 It should be noted that some may object to my characterisation here. Tristram Engelhardt, for example, argues that community and society are separate concepts. His point seems to be directed at communitarian theories that treat political society and moral community as the same thing: H T Engelhardt, "Health care reform: a study in moral malfeasance" (1994) 19(5) *Journal of Medicine and Philosophy* 501–16, pp. 509–10. My use of community does not entail a commitment to such a view (i.e. a conflation of moral and political community), and relates rather to the community that is associated through a shared political authority. In this sense, even narrow libertarian models that would only protect people's "basic rights" concern themselves with sustaining community.

maintenance of community life. As far as the Nuffield Council report goes, the overarching philosophy is not clearly articulated, and this makes it very hard to assess either its coherence, or the role of stewardship within it. As seen in the previous section, it provides little more than a list of putatively important things, with no means of gaining substantial insight into how important each is, what ought to be done to prioritise them, or how to mediate conflicts between them and *other* important things.

I am therefore sceptical of the supposed force in the language found in the report. For example, at para. 2.41:

The concept of stewardship means that liberal states have responsibilities to look after important needs of people both individually and collectively. Therefore, they are stewards both to individual people, taking account of different needs arising from factors such as age, gender, ethnic background or socio-economic status, and to the population as [a] whole, including both citizens of the state, and those that do not have citizen status, but fall under its jurisdiction. In our view, the notion of stewardship gives expression to the obligation on states to seek to provide conditions that allow people to be healthy, especially in relation to reducing health inequalities.

It is not unsympathetic academic rigour to note that stewardship does not, and cannot, *mean* anything that tells states what to do, especially as it is presented here. If, as the report says, it gives expression to an obligation of states, it is that obligation and not the expression of it that means that states must do x or refrain from doing y. Unfortunately, I do not find in the Nuffield report sufficient presentation of the basis of this political obligation. Rather, there is a nice word that we are told summarises some apparently appealing conclusions. It is easy to see why this might be attractive to governments and policymakers, but it is not enough to support arguments in favour of general or special obligations.

By interesting contrast, in the case of Brownsword's work this criticism is not applicable. Drawing faithfully from the moral philosophy of Alan Gewirth, Brownsword describes in careful detail the normative foundations of legal rights and responsibilities, their relation to concepts such as dignity and human rights, and the attendant role of the state. But here again we find the problem with stewardship doing no work. Brownsword takes it as analytically true that the state should do good. But this analytic truth undermines any need to appeal to stewardship. To gain content to the theory we need only look to Gewirth (or Brownsword's interpretation of Gewirth). Put another way, the state learns of its obligations from a proper interpretation of Gewirthian theory, not from stewardship. The force of reasons for seeking to draw from stewardship is nullified entirely if we accept the view that is taken *ex ante* by Brownsword. He considers and dismisses the concern that:

[L]icens[ing] the state to intervene on the grounds that the act in question might be damaging to rights-holders or *might* be damaging to the community is to put a considerable trust in both the sound judgment and the good faith of the state.<sup>66</sup>

His dismissal comes because:

In a *community of rights* . . . it is an analytical truth that . . . the state simply will not act in bad faith or in a way that is clearly incompatible with the community's rights or commitments.<sup>67</sup>

66 Brownsword, "Rights, responsibility and stewardship", n. 17 above, p. 119.

67 *Ibid.*

The upshot is that the state is already a steward rather than in a position where it has to *assume* the stewardship role. It is naturally benevolent, and thus stewardship tells it nothing that it does not already know.

As noted above, there is nothing intrinsically objectionable with Brownsword's using the stewardship metaphor: the important thing – providing a normative theory – is clear and present in his work. His appeals to a state having stewardship functions are well captured in Christopher McMahon's observation that "political society is a peculiarly human phenomenon".<sup>68</sup> In moral communities, or in "aspirant moral communities",<sup>69</sup> state regulation is needed to overcome "co-ordination problems", to provide needed certainty, and to maintain the community's commitment to morality.<sup>70</sup> Again to quote McMahon, the "*raison d'être* of political society is to overcome the mutual frustration of moral purposes which ensues when autonomous moral agents follow their own conceptions of the public good".<sup>71</sup> Thus, I do not doubt the importance of the stewardship function presented by Brownsword, but describe it as superfluous in the sense that it offers nothing foundational to a normative political theory, and would be entailed within Brownsword's theory (and other normative political theories), regardless of the use of the stewardship label. Brownsword is right that states must take seriously their stewardship responsibilities. Equally, it is important that the content of these be explored by academics, policy advisers and policymakers. However, whilst there is general agreement that a "state stewardship role" exists, there is radical disagreement about its basis and the means of understanding its content. This latter is achieved through normative analysis. The specifics of having a normative position should not be sidestepped by reference to general agreement about states having a stewardship function. The important aspects of Brownsword's analysis are found in the Gewirthian theory, and it is to that and not the label "stewardship" that theorists should trace political obligation if they agree with Brownsword. In other words, people could agree that stewardship roles are needed whilst fully rejecting Gewirthian morality and thus, potentially, the sorts of substantive roles that Brownsword describes. This is not to claim that political decision-making requires everyone to agree on the same conclusion for the same reasons.<sup>72</sup> But it is to say that reasons are needed, and those are not found in stewardship. At most, it presents a general term for a generally accepted view of part of the state's role. So, describing the state as having a "stewardship responsibility"<sup>73</sup> is not problematic, but talking about "the stewardship version of liberalism" is.<sup>74</sup> It is widely accepted that states have stewardship roles, but this wide agreement is not reducible to a single understanding of liberalism.

In summary, there is good reason to believe that stewardship as it is employed in the public health law and ethics literature offers nothing, and possibly obscures a great deal. The Nuffield report provides an example of stewardship being used in a superficial manner. Rather than provide reasons in support of an ethical foundation for public health policy, stewardship is simply given as a title to encapsulate a commitment to conclusions whose support is not articulated. Readers are invited to accept stewardship because they (should) agree with the list of priorities articulated in the report. But stewardship offers nothing new

68 C McMahon, "Autonomy and authority" (1987) 16(4) *Philosophy and Public Affairs* 303–28, p. 325.

69 Brownsword, "Rights, responsibility and stewardship", n. 17 above, p. 122.

70 Beyleveld and Brownsword, "Principle, proceduralism, and precaution", n. 17 above; Brownsword, "Rights, responsibility and stewardship", n. 17 above, p. 120.

71 McMahon, "Autonomy and authority," n. 68 above, p. 325.

72 See C Sunstein, *Legal Reasoning and Political Conflict* (Oxford: OUP 1998).

73 E.g. Brownsword, "Rights, responsibility and stewardship", n. 17 above, p. 124.

74 *Ibid.* p. 118. This description is given in reference to stewardship as presented in the Nuffield report.

and, of course, if readers already agree about the state's obligations then they are not afforded further insight by the label. Instead, they are given a label that they can further employ in their own analyses, and possibly in claim of greater "jurisdiction".<sup>75</sup> In contrast with this, Brownsword's use of stewardship provides an example of its being used superfluously. Brownsword's prior normative commitments and analytic givens already spell out the foundation, nature and scope of political obligation. In this case, it is just not clear what is gained by reference to stewardship. At most, reference to stewardship serves as a reminder that the state has certain paternalist and co-ordination roles. Whilst it is not objectionable for these to be labelled "stewardship", the interesting and important normative work comes from the prior theory. In Brownsword's work, that theory is the principle of generic consistency, and his understanding of the state's roles and obligations is derived from that, not from stewardship. Having reached these conclusions, I will consider one more issue: whether stewardship can meaningfully be said to present a distinct understanding to state paternalism.

### 5 Stewardship and paternalism

We have seen that part of the attraction of the term stewardship is its rhetorical appeal. It allows the repackaging of ideas that might otherwise be labelled nanny statist or imply undue paternalism. The Nuffield report, however, seeks to distinguish stewardship and paternalism, probably because the latter is something of a dirty word in much of the bioethical literature. Although there are overlaps, there is an important conceptual distinction between paternalism and stewardship. Unlike paternalism, stewardship presents itself as (part of) a political theory, even where its advocates hold that it is not a complete normative theory. Stewardship permits (demands even) paternalism. Paternalism by contrast does not permit paternalism, or anything else. Rather, it is an instance of something that may be permissible given a background theory (such as stewardship would purport to be). Although a definition of paternalism may contain normative criteria – such as person A, or state A, acts to further the interests of person B – *ex ante* we know nothing of the instances in which it is valid; we just know what it is. Stewardship, by contrast, is supposed to help assessments of the instances when paternalism may be justified. Stewardship requires a normative defence, whereas paternalism in the abstract just offers something whose application in any instance would warrant normative justification. This point has been made by Angus Dawson and Marcel Verweij,<sup>76</sup> who say:

First, paternalism is a concept, not a normative position. Usually . . . the term paternalism is used to describe specific types of action, performed for specific reasons. It is not a model, theory or view in any sense . . . Second, whilst, paternalistic actions may involve coercion, it seems a category mistake to claim [as the Nuffield report does] that paternalism supports coercion . . .<sup>77</sup>

Baldwin, Brownsword and Schmidt respond that Dawson and Verweij's criticism is invalid because it works from a different understanding of paternalism to that employed in the Nuffield report, which follows Gerald Dworkin, saying:

[P]aternalism is: "interference of a state or an individual with another person, against their will, and justified by a claim that the person interfered with will be better off or protected from harm".<sup>78</sup>

75 See e.g. the perspectives in L Marks, S Cave and D J Hunter, "Public health governance: views of key stakeholders" (2010) 124 *Public Health* 55–9.

76 A Dawson and M Verweij, "The steward of the Millian state" (2008) 1(3) *Public Health Ethics* 193–5.

77 *Ibid.* p. 194.

78 Baldwin et al., "Stewardship", n. 48 above, p. 115.

In this sense, it might seem that paternalism is itself both the concept and the background theory, i.e. it contains its own justificatory criteria. However, we may not be convinced that this provides a defence against Dawson and Verweij's point. This becomes clearer if we consider more of Baldwin, Brownsword and Schmidt's argument. They say:

[I]t is correct that actions that fall under the concept provided by Dworkin may be motivated by the *intention* of "wanting to do good for another person". But it would be a mistake to reduce paternalism to this one sense. It is not uncommon that what is perceived to be good for another person by one party is enforced against that person's will, and it is precisely this overriding of 'individuals' wills that makes acts of paternalism problematic – irrespective of whether or not they are supported by a comprehensive normative theory.<sup>79</sup>

This reasoning is troublesome because in being asked to accept stewardship we are invited to agree that at times – i.e. when there is a comprehensive normative theory that supports it – paternalist measures are acceptable. Acts of paternalism are of necessity non-problematic if they are supported by a comprehensive normative theory. For an analyst such as Robert Paul Wolff, paternalism – indeed any political obligation – is necessarily unjustifiable.<sup>80</sup> But for an analyst who supports a comprehensive theory that "deproblematises" paternalism, there is no concern. And stewardship is intended to represent a view that paternalism is not always problematic. Nevertheless, Baldwin, Brownsword and Schmidt go on to say:

The Council hence stands by the view that Dworkin's characterisation is an appropriate one. Equally it stands by the view that what is needed is an approach that endorses qualified paternalism that goes beyond both libertarian paternalism and the restrictive liberalism that is based on simple Millian accounts. This is what has been set out as the stewardship model.<sup>81</sup>

Despite this claim, it seems more accurate to say that the Nuffield Council is not endorsing a "qualified paternalism"; rather, it is attempting to articulate the instances when paternalism is justified. That requires a sound normative model, and, as shown above, it is not provided by stewardship.

As these problems combine, there is little left to recommend stewardship. To understand when, why, and how political obligation is legitimate, we need a substantial theory. Even so, the idea has gained appeal for regulators and those working in regulatory theory and, before concluding, I would like to explore a point made by Brownsword. In this there is reference, albeit tacit, to a problem that is noted in various ways in different works that consider paternalism: the sometimes absent rational self within each of us that can be replaced by the irrational, perhaps compulsive or selfish self. In discussion of regulators considering the employment of new technologies that would make people behave better, Brownsword discusses the issue as follows:

In a community of rights, agents will face more than one kind of moral dilemma. One kind of dilemma will be that in which the agent is striving to do the right thing but it is not clear what action is required; for example, this is the dilemma of an agent who is not sure whether the right thing to do is to tell the truth or to tell a white lie, whether to respect a confidence or to inform another of a risk, and so on. However, it is another kind of dilemma that is relevant to our thinking about the impact and import of design-based regulation. This is the dilemma of an agent who believes that the morally required action is x (say,

79 Baldwin et al., "Stewardship", n. 48 above, p. 115.

80 R P Wolff, *In Defense of Anarchism* (with a new preface) (Berkeley: University of California Press 1998).

81 Baldwin et al., "Stewardship", n. 48 above, p. 115, reference omitted.

keeping a promise) but who is inclined, for reasons of non-moral self-interest, to do not-x (say, breaking the promise in order to make financial gain). As Kantians would put it, this is the case of an agent whose will is in conflict, the autonomous moral will being contested by the heteronomous will of inclination and desire. More prosaically, we can identify the following four key elements in this conflicted situation:

- (a) the agent is aware that doing x is the morally required action;
- (b) however, the agent is inclined, or desires, to do not-x;
- (c) this conflict arises in circumstances where a choice between doing x and doing not-x presents itself to the agent as a real practical issue; and
- (d) the circumstances also allow, in practice, for the doing of not-x

In principle, regulators might target any one of these elements in order to design around or design out the difficulty. The question is whether, in a community of rights, anything rides on which element of the situation regulators target.

Assuming that the agent is aware that doing x is morally required, then when an agent might be tempted to defect, regulators might seek to reinforce the agent's moral resolve against defection.<sup>82</sup>

So, here we see an expression of the apparent attraction to regulators of overriding people's ostensible choices when they are wrongful. However, and notwithstanding the foreseeable breaches of morality, Brownsword does not consider this to be a good idea. He goes on to argue:

To be sure, if the regulatory intervention makes it so easy for agents to do the right thing that they experience no resistance to doing that thing, then there is no element of overcoming and there is a risk that agents lose the sense that they face a choice (between right and wrong).<sup>83</sup>

I agree with Brownsword here. But we might note that the reason for being reluctant to interfere with people's freedom to make mistakes – to harm their own or others' interests – is based entirely on a paternalistic rationale; it is good for them to be able to choose to be good. In other words, in a political system the “steward” is *always* looking over our shoulder, whether it is being coercive for our good or permissive for our good. Where the reluctance to interfere is justified by paternalistic concerns, we are still witnessing paternalism, albeit “passive paternalism”. Contemplated decision-making at a state level leads to policy whether that policy manifests itself positively or negatively. In the words of the Nuffield Council: “Any policy, including a policy to ‘do nothing’, implies value judgements about what is or is not good for people, and requires justification.”<sup>84</sup> This seems to me to support a claim that even in a libertarian system the state is still to be characterised as a steward – i.e. it assumes a “stewardship role” – and it supports a view that paternalism is inevitable within the political schemes advanced by stewardship's advocates. The background paternalism that may take a passive form, and the fact that a good state will concern itself with the interests of its citizens, drives evaluations of measures, systems and policies. The question is, does talking about stewardship add anything to those evaluations? I have argued that it does not.

82 R Brownsword, “So what does the world need now?”, n. 17 above, p. 40.

83 Ibid. p. 41.

84 Nuffield Council, *Public Health*, n. 16 above, p. xvi. Recall also the statement from the WHO report, quoted above, that “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.” WHO, *World Health Report 2000*, n. 15 above, p. xi.

## 6 Conclusions

In considering stewardship in public health law and ethics, we are often confronted with a point that theorists seek to draw from public health as a science: namely, that we should take a “population perspective” in our analysis.<sup>85</sup> As I have stated elsewhere,<sup>86</sup> the simultaneous banality and profundity of this message is interesting. When we are dealing with political communities, we necessarily take a “population approach”; we are addressing the regulation of populations by definition! More profoundly though, we see that if a normative theory fails to allow for a population perspective, it will fail as a theory applicable in public health analysis, and in legal and political theory more generally. This point applies as strongly to the most minimal state libertarianism as it does to the most stringent forms of communitarianism: in all cases our perspective is on populations. The dispute then is about how populations are best served; by minimal intervention and sharing of concerns, or by greater state interference and wider sharing of responsibilities.

Analysts and regulators have good reasons for looking at alternative conceptions of the state, but the way it is presented in the context of stewardship either begs the question (“we know this is good; let’s find out what it means”) or else it adds nothing to an already complete social theory (e.g. Brownsword’s preferred jurisprudential model). Of course, people come up with theories and concepts, and these need names. My point is not that no concept of stewardship could be useful in political philosophy. But it is hard to see – especially in the public health literature – how stewardship distinguishes itself from many well understood brands of political liberalism or concepts entailed therein, either in its grounds, or in the claims it makes. The use of stewardship at most is as a means of packaging ideas nicely. I am sceptical of its potential to provide salient reasons for rethinking political philosophy, and am wary of its potential to have its claims overstated in pursuit of ends whose justifications remain to be argued. The insight that a normatively defensible liberal state will assume a stewardship role in some of its regulatory activity is important, and worth stating *if* the point will otherwise be missed. But stewardship as a political theory or framework is not an important basic reference point for regulatory theorists or public policy-makers. It is a cause of great concern if a neat label becomes accepted as a substitute for clear and robust arguments about political obligation.

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85 See G Rose, “Sick individuals and sick populations” (1985) 14 *International Journal of Epidemiology* 32–8; M Verweij and A Dawson, “The meaning of ‘public’ in ‘public health’” in Dawson and Verweij, *Ethics, Prevention, and Public Health*, n. 10 above; W Parmet, *Populations, Public Health, and the Law* (Washington DC: Georgetown UP 2009).

86 See Coggon, *What Makes Health Public?*, n. 13 above, pp. 146–7.

# From steward to Stuart: some problems in deciding for others

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The purpose of this paper is to explore the concepts of state stewardship and international super-stewardship in public health from a critical philosophical point of view. Stewardship has recently been presented as an alternative to paternalism and the “nanny state” in the field of public health. It is therefore of interest to explore whether the concepts and models of stewardship that are proposed 1) are internally coherent, 2) are based on a sound justification, 3) really differ from a reasonably sophisticated account of paternalism, and 4) can be action-guiding in practice. By the term “critical philosophical”, I mean that the analysis presented here is not a narrowly legal one and, in the few instances where legal material is used, it teases out the arguments in a non-jurisdiction specific way.

The paper falls into three sections. The first explores the origins of stewardship discourse in general and how the concept of stewardship entered discussions about public health. It examines why stewardship discourse has been successful, but does not provide an in-depth analysis of the social, legal and political conditions that allowed stewardship discourse to emerge and that are now facilitating its circulation. The second section outlines two particularly influential concepts of stewardship: one put forward by the Nuffield Council on Bioethics in its report on *Public Health: Ethical issues*,<sup>2</sup> and one put forward by Roger Brownsword who was a member of the group drafting the Nuffield report.<sup>3</sup> Based on the exposition of these two concepts a number of issues critical to the usefulness of stewardship as a tool in the formulation and justification of public health policy are then analysed and critically discussed. The first of these is whether stewardship can be differentiated from paternalism in public health. It is argued that the Nuffield Council concept of stewardship cannot be differentiated in this instance, if the paternalism we are envisaging is a sophisticated kind in a modern democracy. Secondly, the question is

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  - 2 Nuffield Council on Bioethics, *Public Health: Ethical issues* (London: Nuffield Council on Bioethics 2007). As a member of the Nuffield Council on Bioethics when the report was published, I have signed up to the report, although as will become evident not necessarily to the minutiae of its argument.
  - 3 And later defending it against critics, see T Baldwin, R Brownsword and H Schmidt, “Stewardship, paternalism and public health: further thoughts” (2009) 2 *Public Health Ethics* 113. Brownsword’s own conception of stewardship is laid out in most detail in R Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: OUP 2008).

addressed of whether the state having a role as steward of public health can be justified. It is argued that, whereas Brownsword's concept of stewardship does contain such a justification, through the device of the "aspirant moral community", the Nuffield Council concept provides no clear justification for state stewardship. The third and final section of this paper extends this critical analysis of state stewardship to international super-stewardship in the public health arena. It is argued that the justification for super-stewardship in public health is even weaker than for state stewardship.

### Stewardship then and now

According to the *Oxford English Dictionary* the term "steward" has 13 distinct meanings,<sup>4</sup> the original but now obsolete one being: "An official who controls the domestic affairs of a household, supervising the service of his master's table, directing the domestics, and regulating household expenditure; a major-domo." Another and for our present purposes more relevant usage that entered the English language very soon after the first one is: "One who manages the affairs of an estate on behalf of his employer."

The historically most famous and successful stewards are probably the Stuart family who from the position of stewards of the royal house of Scotland in a few generations managed to elevate themselves to the position of kings of Scotland as "the Stewarts" and later of England and Scotland as "the Stuarts". They moved from being the trusted servants of the ruler to become rulers themselves and the later Stuarts attempted to transform the English–Scottish political system into an absolute monarchy, supported by political theorists such as Sir Robert Filmer.<sup>5</sup> The steward-to-Stuart transition thus exemplifies one of the risks inherent in stewardship, i.e. the shift from being steward of another's interests and affairs to being the master.

The concept of stewardship entered philosophy via moral theology and considerations of man's relationship to nature. In Genesis 1:28–30, God gives man dominion over the earth and all living things:

And God blessed them, and God said unto them, Be fruitful, and multiply, and replenish the earth, and subdue it: and have dominion over the fish of the sea, and over the fowl of the air, and over every living thing that moveth upon the earth.

And God said, Behold, I have given you every herb bearing seed, which is upon the face of all the earth, and every tree, in the which is the fruit of a tree yielding seed; to you it shall be for meat.

And to every beast of the earth, and to every fowl of the air, and to every thing that creepeth upon the earth, wherein there is life, I have given every green herb for meat: and it was so."<sup>6</sup>

The traditional interpretation of these verses is, understandably, that man is placed by God in a position of power over the earth and that the earth is there to be exploited by man for his own benefit. The nature and extent of this power was traditionally understood to be unlimited. But, in the latter half of the twentieth century, dissatisfaction with this traditional interpretation grew and one of the prominent re-interpretations reconceptualised man's role in terms of stewardship. Man is not the ruler and the owner of the earth, but he is God's steward and must treat the earth responsibly. This theological re-orientation

4 *Oxford English Dictionary Online* [www.oed.com](http://www.oed.com) (last accessed 11 January 2011).

5 R Filmer, *Patriarcha: Or the natural rights of kings* (originally published posthumously 1680). Available at [www.constitution.org/eng/patriarcha.htm](http://www.constitution.org/eng/patriarcha.htm) (last accessed 10 January 2011).

6 Genesis 1:28–30, King James' Bible.

happened as a response to increasing environmental concerns in society. It is not the case that theologians were the first to discover or develop an environmental ethics taking account of modern environmental concerns, but, prior to these theological developments, the environmental concerns and the proper response to them had not been conceptualised in terms of stewardship. This theological development of the environmental stewardship idea and its influence on environmental ethics in general is traced and discussed in detail in the contributions in a recent comprehensive assessment of environmental stewardship discourse.<sup>7</sup> The exact details of this theological conception of stewardship need not detain us here, but from moral theology it was adopted by some non-religious environmental philosophers and ethicists. And it is primarily from environmental ethics that stewardship has found its way into thinking about public health. Here, it has gained prominence partly because of its alleged potential to justify some coercive public health actions without resorting to paternalistic justifications and partly because the phrase “the stewardship state” is more pleasing to the ear and the populace than the nanny state.<sup>8</sup> Whether stewardship discourse will in time come to dominate public health discourse is a complicated question that is outside the scope of this paper. It is, however, important to note that if it does come to dominate it will not be as a direct result of any greater philosophical coherence or better justification than other competing concepts and ideas. If stewardship wins this contest it will be – with phrasing borrowed from Ashcroft’s insightful discussion of a possible convergence of human rights and bioethics – not due to intellectual necessity but due to concrete historical and political contingencies.<sup>9</sup>

In the reformulation of the stewardship concept as non-theological, two quite distinct versions emerged: one where stewardship is still seen as stewardship on behalf of someone who is absent or unable to express interests and desires (e.g. future generations or “Nature”) but who its final beneficiary; and another where stewardship is uncoupled from any particular beneficiary and is merely describing a certain mode of or attitude towards decision-making.<sup>10</sup> As will become apparent, these two concepts can easily be elided, but it is important to keep them apart.

Two other strands of stewardship discourse have also influenced the concepts of stewardship applied to public health.

In the business ethics and management theory literature, “stewardship theory” has been proposed as an alternative to “agent theory” or “agency theory”.<sup>11</sup> In agent theory, those who act on behalf of others are supposed to be exclusively self-interested. An agent’s only aim is to pursue his or her own interests and it is only if an agency relationship can be put in place that aligns the agent’s interests with the interests of those whom he or she is acting for (the principals) that the agent can be expected to act in their interests. Agent theory applies this description to both public and private agents and thus claims that it also applies to state bureaucrats, including presumably, those responsible for public health. In stewardship theory, the person acting is conceptualised quite differently:

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7 R J Berry (ed.), *Environmental Stewardship* (London: T&T Clark 2006).

8 K Jochelson, “Nanny or steward? The role of government in public health” (2006) 120 *Public Health* 1149; K Calman, “Beyond the ‘nanny state’: stewardship and public health” (2008) 123 *Public Health* e6. For the view that stewardship rhetoric signifies a dangerous move from the “nanny” to the “bully”, state see P Basham, “From the nanny state to the bully state” (2010) 62 *IPA Review* 24.

9 R E Ashcroft, “Could human rights supersede bioethics?” (2010) 10 *Human Rights Law Review* 639.

10 Berry, *Environmental Stewardship*, n. 7 above.

11 P Block, *Stewardship: Choosing service over self-interest* (San Francisco: Berrett-Koehler 1993); J H Davis, F D Schoorman and L Donaldson, “Toward a stewardship theory of management” (1997) 22 *Academy of Management Review* 20.

In stewardship theory, the model of man is based on a steward whose behavior is ordered such that pro-organizational, collectivistic behaviors have higher utility than individualistic, self-serving behaviors. Given a choice between self-serving behaviour and pro-organizational behaviour, a steward's behavior will not depart from the interests of his or her organization. A steward will not substitute or trade self-serving behaviors for cooperative behaviors. Thus, even where the interests of the steward and the principal are not aligned, the steward places higher value on cooperation than defection (terms found in game theory). Because the steward perceives greater utility in cooperative behaviour and behaves accordingly, his or her behaviour can be considered rational.<sup>12</sup>

The steward is thus distinguished from the mere agent by identifying with the goals of the organisation in which he or she works. Whether a steward will act in an ethical manner therefore depends upon whether the goals of the organisation are ethical.

Finally, the World Health Organization (WHO) proposed in 2000 that stewardship should be the basis for the state's role in directing the health-care system and providing health care.<sup>13</sup> This proposal is explicitly based in stewardship theory as just described. According to the WHO, state stewardship in relation to the health system amounts to responsible management of the well-being of the population:

Ultimate responsibility for the performance of a country's health system lies with government. The careful and responsible management of the well-being of the population – stewardship – is the very essence of good government. The health of people is always a national priority: government responsibility for it is continuous and permanent.<sup>14</sup>

And the stewardship function is primarily discharged by oversight:

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.<sup>15</sup>

A 2002 technical report provides further, more concrete, guidance concerning how the WHO thinks the stewardship function should be operationalised. This report makes it clear that the WHO sees stewardship as a high-level function of government:

WHO is attempting to identify a small number of core domains/sub-functions that collectively are thought to constitute effective health system stewardship that leads to better outcomes . . .

Who are stewards trying to influence, and how? They are aiming at influencing the behaviour of a wide range of players: those involved in provision, financing or generation of other resources; the behaviour of stewards themselves;<sup>16</sup> of users or consumers, and non-health system actors whose actions affect health . . .

Six domains/sub-functions of stewardship are presented here for discussion. They are constructed from prevailing notions of what together constitute the

12 Davis et al., "Toward a stewardship theory", n. 11 above, p. 24.

13 WHO, *The World Health Report 2000: Health systems: improving performance* (Geneva: WHO 2000). For an in-depth exploration of the conceptual background to the WHO use of the concept of "stewardship", see R B Saltman and O Ferroussier-Davis, "The concept of stewardship in health policy" (2000) 78 *Bulletin of the World Health Organization* 732. See also G Magill and L Prybil, "Stewardship and integrity in health care: a role for organizational ethics" (2004) 50 *Journal of Business Ethics* 225, for an attempt to better integrate the WHO concept and general stewardship theory.

14 WHO, *World Health Report*, n. 13 above, p. viii.

15 *Ibid.* (original emphasis).

16 This element is rather puzzling. Who are the stewards who should influence the "stewards themselves"? Or, *quis custodiet ipsos custodes?*

function of stewardship. Some are primarily concerned with dealing with market failures that are common to health systems, and others are more concerned with addressing potential public sector failure. There may be questions about both the categories and their content, and these domains/sub-functions are expected to further evolve following wide debate.

Their definition, their contribution to effective stewardship, the effectiveness of different instruments and approaches within these domains/sub-functions, and the links to intermediate goals and outcomes can all be investigated.

- Generation of intelligence
- Formulating strategic policy direction
- Ensuring tools for implementation: powers, incentives and sanctions
- Building coalitions/Building partnerships
- Ensuring a fit between policy objectives and organizational structure and culture
- Ensuring accountability<sup>17</sup>

As we shall see below, the concepts of state stewardship in public health incorporate both this idea of stewardship as a high-level function and a much more mundane idea of stewardship as concerned with very concrete policy decisions. Apart from brief references to the WHO *World Health Report 2000*, there is little evidence that the specific elements of the WHO concept of stewardship has in itself played any major role in current discussions about stewardship in public health. None of the specifics of the WHO concept are mentioned or discussed in the academic literature, and there are no signs that it has influenced recent public health policy in any European jurisdiction.<sup>18</sup>

### State stewardship in public health

There is one obvious way in which the modern nation state acts as a steward in the health care field (including public health) and that is as a distributor of common resources. The revenue that the state extracts from taxation (and other forms of income) is held and distributed on behalf of the citizens. This is in itself unproblematic, except for radical libertarians.<sup>19</sup>

But this role of economic stewardship of health care resources by the state is not the concept of stewardship that is central to the discussion of state stewardship in public health. Here, we are talking about a broader concept that potentially engages a much wider range of the state's coercive powers, not just its power to tax. The Nuffield Council lays out its concept of stewardship in public health in this way:

The concept of stewardship means that liberal states have responsibilities to look after important needs of people both individually and collectively. Therefore, they are stewards both to individual people, taking account of different needs arising from factors such as age, gender, ethnic background or socio-economic status, and to the population as whole, including both citizens of the state, and

17 P Travis, D Egger, P Davies and A Mechbal, *Towards Better Stewardship: Concepts and critical issues* (WHO/EIP/DP/02.48) (Geneva: WHO 2002), p. 4.

18 That it has not influenced policy in Europe may reflect the fact that most European countries probably already consider themselves to have this high-level control of the function of the health-care system, without conceptualising it in stewardship terms.

19 The taxation is an infringement of liberty and thus anathema to libertarians, but the distribution of the resources obtained by taxation involves no infringement of liberty (in principle) and is therefore acceptable to liberals who usually accept fair taxation as morally justified.

those that do not have citizen status, but fall under its jurisdiction. In our view, the notion of stewardship gives expression to the obligation on states to seek to provide conditions that allow people to be healthy, especially in relation to reducing health inequalities . . .<sup>20</sup>

The difference between paternalism and our stewardship model is that the latter is less likely to support highly coercive universal measures. Instead, the stewardship model is more sensitive to the need to respect individuality, by seeking the least intrusive way of achieving policy goals, taking into account also the criteria of effectiveness and proportionality . . . The stewardship approach is also more sensitive than paternalism to the concept of mandate, and the need for policies to be adequately justified. It recognises the importance of open and transparent participatory processes as a necessary condition for public health policy making, but it is also clear that these are not sufficient by themselves. Stewardship is not exercised simply by following the public vote, especially where issues involve complex scientific evidence. Under the stewardship model, public health policy should be compatible with the views of the public, and the government should create conditions that allow the public to scrutinise and judge the appropriateness of proposed policies.<sup>21</sup>

Let us break down the Nuffield concept into its five constituent elements.

1. The state is a steward both in relation to individuals and to the population as a whole (and by extension to groups within the population).<sup>22</sup>
2. Stewardship gives expression to a more basic obligation on the state to provide conditions that allow people to be healthy.
3. This expression is particularly important in relation to reducing health inequalities (or alternatively there is a particular obligation in this regard).
4. The stewardship model differs from paternalism by:
  - a. being less likely to support highly coercive universal measures;
  - b. respecting individuality by seeking the least intrusive method to achieve goals (but taking into account effectiveness and proportionality);
  - c. being more democratic in taking mandate, justification, openness and transparency seriously.
5. Stewardship is not the same as following public opinion, especially where issues involve complex scientific evidence.

The first major philosophical issue that needs to be discussed is whether stewardship is really different from paternalism and in order to do so we need to be clear what paternalism is. There are many different kinds of paternalism but I take it that the core meaning of paternalism is that an agent A makes decisions on behalf of another agent B because A believes those decisions to be in B's best interest.<sup>23</sup> If B is unable to discern what is in his or her best interest, we have an instance of "genuine paternalism" as when a parent decides

20 Nuffield, *Public Health*, n. 2 above, p. 25 (footnotes removed).

21 *Ibid.* p. 26

22 It is unclear in what sense the state can be a steward in relation to individuals for which it is not already *in loco parentis*. Typical adult citizens have not given the state powers to run their households, neither are they absent from their own decision-making.

23 H Häyry. "Paternalism" in R Chadwick (ed.), *Encyclopedia of Applied Ethics* vol. 3 (San Diego: Academic Press 1998), p. 449.

for a child in a situation where the child genuinely does not know its own interests. This is morally unproblematic.<sup>24</sup>

If, however, B is able to discern what is in his or her best interest we have a morally problematic instance of paternalism, unless B wants A to make the decision.<sup>25</sup> Some argue that the only instances of paternalism that can be justified are instances of genuine paternalism, but this view is clearly not reflected in the policymaking of any modern welfare state.

Let us in the next couple of paragraphs, for the sake of argument<sup>26</sup> allow that paternalism is morally justifiable if 1) A has good reasons to believe that he or she is in a better position than B to discern B's interest, 2) the interests at stake are important interests, and 3) A acts with the sole motive of promoting B's interests.<sup>27</sup> What does this imply with regard to what actions A should do and how they should be done, if A is a justifiably paternalistic state agency? Well, it seems to imply that A should choose to act in the way that is most likely to achieve the goal of promoting B's interest (i.e. consider effectiveness) and that A should choose to act in the way that has the fewest negative side-effects (i.e. consider proportionality, seek the least intrusive method – in so far as intrusive methods are likely to have more negative side-effects than non-intrusive methods – and take issues of mandate and justification seriously in so far as this is likely to make A's actions more understandable and democratically palatable to citizens). But, if this is correct, a paternalistic state agency in a democracy has to take account of many of the same considerations as a stewardship agency. This would also seem to be the case if the paternalistic state agency simply applied the better governance and better regulation paradigm which is supposed to guide the actions of UK state agencies. And it is simply incorrect to state that stewardship inherently differs from paternalism in relation to the kind of interventions that can or will be chosen. When we compare the steward to the paternalist we should not compare the sophisticated, modern steward with the unreconstructed and traditional paternalist. The paternalist or paternalistic agency we should have in mind is the sophisticated one working within the structures and confines of a modern (semi-?)transparent and accountable democratic state. Such a paternalist would only choose overt paternalistic action when absolutely necessary and would try to minimise the number and effect of paternalistic actions.

The reason that paternalism has a bad name is that it infringes upon individual autonomy and liberty as famously encompassed in Mill's so-called "harm principle" as expressed in *On Liberty*:<sup>28</sup>

24 Parents may have obligations to help their children to develop decision-making abilities and, depending on the precise nature of these obligations, they may limit the range of cases in which even "genuine paternalism" is morally justifiable.

25 In relation to a state agency, the analysis of when paternalism is morally problematic becomes a little more complicated, because citizens may have agreed to give general powers to the state without realising the possible scope of their specific application. A citizen may thus at the same time want and not want the state to make certain decisions on his or her behalf.

26 It is important to keep in mind that the acceptance of paternalism in the next paragraphs is strictly *for the sake of argument*. I do believe that there are instances of justified paternalism, but giving a full account of what characterises those is beyond the scope of this paper.

27 This last criterion is important because there are many instances where decision makers override the decisions of others from motives other than promoting the interests of the others and such instances are not instances of paternalism. There are also many instances of mixed motives that should be classified along a spectrum of "impure paternalism".

28 J S Mill, *On Liberty*, E Rapaport (ed.) (Indiana: Hackett 1978), p. 9. I have chosen to provide a slightly longer quote than is usually presented to make it clear that Mill himself allows for remonstrance and other forms of attempts at persuasion of the person.

The object of this Essay is to assert one very simple principle, as entitled to govern absolutely the dealings of society with the individual in the way of compulsion and control, whether the means used be physical force in the form of legal penalties, or the moral coercion of public opinion. That principle is that the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise, or even right. These are good reasons for remonstrating with him, or reasoning with him, or persuading him, or entreating him, but not for compelling him, or visiting him with any evil, in case he do otherwise. To justify that, the conduct from which it is desired to deter him must be calculated to produce evil to some one else. The only part of the conduct of any one, for which he is amenable to society, is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign.

A dyed in the wool paternalist will, almost by definition, believe that Mill is wrong and that there are instances of purely self-regarding actions that can be overridden on the basis of the agent's own interests (cf. discussions about the ethics of suicide or euthanasia or discussions concerning recreational drug use).

A stewardship model can claim to adhere to the harm principle if the steward never interferes in purely self-regarding actions. But in principle, this difference between stewardship and paternalism may be far less important in practice in the public health arena than is generally realised. The practical irrelevance of the harm principle comes from two sources. The first is that almost any action that an individual performs that has health implications for him or her also has implications for public health and thereby for others.<sup>29</sup> Actions affecting individual health either presently or in the future have economic externalities.<sup>30</sup> Public actions have signalling effects as do many actions performed in the privacy of the home if anyone apart from the agent is present or can detect the effects. And there are numerous actions that, although primarily affecting the agent, also alter the risk that others will be affected by a particular disease or will take up or continue an unhealthy behaviour. It is not only infectious diseases that are communicable or transmissible: behaviours like smoking or conditions like overweight and obesity are also communicable in the sense that a person's risk of adopting the behaviour or getting the condition depends on the behaviours of others in his or her social network.<sup>31</sup>

The second source of irrelevance of the harm principle is that public health agencies most often intervene to affect the actions of groups. The goal of a specific intervention may be to reduce the incidence or prevalence of specific harmful behaviours and this is clearly only achieved if individuals change their behaviour, but the intervention is targeted at the group and is based on considerations at the group level. If the group is heterogeneous with regard to interests, level of reflection regarding the behaviour, level of personal

29 In so far as public health is a function of the individual health of members of the public, this is even an analytic truth, but arguably a fairly uninteresting one.

30 This is true for both publicly and privately funded health-care systems. What differs is only on whom the externalities fall.

31 See, for instance, N Christakis and J Fowler, "The spread of obesity in a large social network over 32 years" (2007) 357 *New England Journal of Medicine* 370.

commitment to the behaviour etc. – and most groups are – then the intervention may breach the harm principle in relation to some members of the group and not in relation to others. But if we allow that public health agencies can intervene at the group level, and it seems that we must allow this if we think that public health agencies have a role that is distinct from “individual health agencies” (i.e. health-care agencies), then we have to allow them to breach the harm principle in some circumstances, for instance, where most of the group cannot be said to have fully endorsed their own behaviour and where it is practically impossible to design an intervention that targets only that sub-group.

So, many public health interventions at the group level will technically breach the harm principle in relation to some members of the group who, upon reflection and with full understanding of the evidence, still endorse their own unhealthy behaviour.

From these considerations, it seems to follow that paternalism and stewardship are not nearly as distinct as claimed by the Nuffield Council.

Roger Brownsword’s concept of stewardship looks superficially like the Nuffield one, but is in my view fundamentally different because he connects stewardship to the context of the state as an (aspirant) moral community striving to flourish and develop as a moral community.<sup>32</sup> By creating that link, he can give much more specific content to the ways in which the state ought to approach its stewardship than is possible if the context is just the state and its citizens.

As an (aspirant) moral community, a community is not just a group of people who identify as a such, it is a community with a certain moral shape and moral goals:

no community may present itself as a moral community unless it holds its commitments sincerely and in good faith, it treats its standards as categorically binding and universalizable, some such standards at least are of an other regarding nature, and there is an integrity, consistency, and coherence about its commitments as a whole. Relative to this standard, there is no difficulty in accepting that utilitarians, rights theorists, and dignitarians are moralists and that communities guided by such standards are moral communities.<sup>33</sup>

The (aspirant) moral community thus comes with a set of moral commitments and the stewardship role of the state is justified if the state’s actions are guided by those commitments. This provides guidance in relation to what the state ought to do (i.e. promote the development of the aspirant moral community); and it provides limits concerning what the state cannot do.

In Brownsword’s preferred “community of rights” he argues that:

there are three circumstances in which stewardship might be legitimately invoked. First, if we suppose (as I do) that the members of a community of rights do not regard themselves as morally omniscient, the state has some margin to cater for the fallibility of the community. Accordingly, if it is argued that an action should be prohibited because it might put at risk the interests of *possible* rights-holders or because it might *indirectly* be damaging to rights-holders, the state may intervene (if only temporarily) on stewardship grounds. Secondly, the state has a responsibility to protect and promote the conditions that are conducive to the flourishing of agency. Public health seems to be such a case. Stewardship certainly requires the state to keep citizens informed about risks to their health and a community of rights might well judge that it is legitimate for the state to

32 And given Brownsword’s other commitments, the aspirant moral community ought to develop itself into a community of (Gewirthian) rights.

33 Brownsword, *Rights, Regulation and the Technological Revolution*, n. 3 above, p. at 115

exercise stewardship by requiring participation in programmes that are intended to improve the conditions of public health. Thirdly, to return to my basic point, the state has a stewardship responsibility to protect and promote the conditions that are constitutive of a meaningful moral community . . .<sup>34</sup>

Let us move on to look at other parts of the concepts of stewardship as put forward by the Nuffield Council and Roger Brownsword, respectively. According to the Nuffield Council, stewardship can especially be invoked in cases where “issues involve complex scientific judgement”. This may well be the case for stewardship outside public health as well and it coheres well with some elements of Brownsword’s concept of stewardship in the context of regulation of technology. Brownsword states in one of his explications of stewardship within a community of rights:<sup>35</sup>

that there are three circumstances in which stewardship might legitimately be invoked . . .

- (i) where state intervention is required in order to settle doubts (at least provisionally) about the application of the rights regime;
- (ii) where state intervention is required in order to maintain the conditions that are essential to a community’s survival; and
- (iii) where state intervention is required in order to maintain the conditions that are essential to the community’s self-perception as an aspirant moral community.

The two kinds of uncertainty or epistemic complexity alluded to by Brownsword’s first condition and by the Nuffield Council’s mention of “complex scientific judgments” are clearly different. One is a question of moral uncertainty/complexity and the other one of scientific uncertainty/complexity, but they are nevertheless worth considering together partly because they are sometimes difficult to disentangle, partly because there is a more general issue of whether uncertainty/complexity provides a specific justification for state stewardship.

If there is a policy question on which people in general could form a view if they had the time and opportunity to assess the question in all its complexity, but where a decision needs to be made urgently (e.g. where waiting to decide has significant opportunity costs), then there does seem to be a justification for the state to make the decision, taking into account all the considerations a democratic agency ought. That is clearly congruent with a stewardship model of decision-making, but also with many other models. But we might decide that there are advantages in separating and setting apart this kind of “epistemic” stewardship as a particular class of decision-making activity, if for no other reason than pointing out that the decision maker is here making decisions on behalf of principals who, due solely to epistemic complexity, are temporarily absent but will later become present.

Taking the lead from Brownsword, there is a need to consider whether such epistemic stewardship can be more than provisional or temporary. Here we need to distinguish between three different situations: 1) there is epistemic complexity, but there is sufficient evidence to make a secure final judgment; 2) there is epistemic complexity, and there is not yet sufficient evidence but it is likely that the issue can be resolved in the not too distant future; 3) there is epistemic complexity and it is unlikely that the issue can be resolved.

34 R Brownsword, “So what does the world need now? Reflections on regulating technologies” in R Brownsword and K Yeung, (eds), *Regulating Technologies: Legal futures, regulatory frames and technological fixes* (London: Hart 2008), p. 23, at p. 47 (original emphasis, footnote removed).

35 R Brownsword. “Rights, responsibility and stewardship” in H Widdows and C Mullen (eds), *The Governance of Genetic Information: Who decides?* (Cambridge: CUP 2009), p. 99, at p. 120.

A state acting on stewardship grounds in situations 1 and 2 would seem to have an obligation to inform the public about the available evidence so that the community could form its own opinion (which, if the judgment is secure, as in situation 1, will by necessity be the same as the state's) and to try to produce the further evidence that will resolve the complexity in situation 2. So, in these two situations, the state's stewardship role could only be provisional and temporary until sufficient evidence has been assembled and communicated to reach a state where all persons of good will and reflective ability can form a judgment.

In situation 3, the decision made by the stewardship state will still be provisional, but might end up being permanent if the complexity turns out to be irreducible.

Above, I made the claim that the two different types of uncertainty/complexity can be handled as one, i.e. both as cases of epistemic stewardship issues. But there are also important dissimilarities and exploring these will display the fundamental differences between the Nuffield Council and the Brownsword concepts of state stewardship. Both Nuffield and Brownsword locate the justification for stewardship in the idea of community. In a response to critics, Baldwin et al. claim that Nuffield's stewardship model is:

based centrally on the value of the community, which is the value of belonging to a society in which each person's welfare, and that of the whole community, matters to everyone.<sup>36</sup>

But this is clearly a much thinner concept of community than Brownsword's aspirant moral community, which again is much less specific than his aspirant moral community of rights. As we have seen, Brownsword's concept entails that any aspirant moral community is aspiring towards the ideal state of being a moral community of a particular kind (a community of rights, dignity, virtue, etc.) and members of the society and all of its agencies share this aspiration. This justifies moral stewardship when this is necessary "in order to maintain the conditions that are essential to the community's self-perception as an aspirant moral community",<sup>37</sup> for instance, when there is disagreement about the right moral approach because the community is still only an aspirant moral community.

But this further resource is not available to the Nuffield Council and it is therefore unclear how its stewardship model can deal with moral uncertainty or complexity. In public health decisions, we often have to balance the interests of some individuals against the interests of other individuals, the interests of present individuals against future individuals and, sometimes, the interest of community members against the interests of outsiders. But just knowing that "each person's welfare and that of the whole community, matters to everyone" will not get us far,<sup>38</sup> unless we have a way of deciding how much your interests ought to matter to me!

36 Baldwin et al., "Stewardship", n. 3 above, p. 116. We might in passing note that this seems to be a kind of community that is not achieved in any major nation state today; and that the value commitment implied may not even be shared by the majority in many nation states.

37 Brownsword, *Rights, Responsibility and Stewardship*, n. 3 above, p. 120.

38 I do realise that prescriptivists such as Richard Hare can derive all of morality from the meaning of the word "ought" and that Hare's student Peter Singer believes that very far-reaching conclusions can be reached from the mere fact that we have some interest in the welfare of others: R M Hare, *The Language of Morals* (Oxford: OUP 1952); P Singer, *Practical Ethics* 2nd edn (New York: CUP 1993). Similarly, Alan Gewirth and Gewirthians derive very far-reaching conclusions from the principle of generic consistency and its application to any situation where an agent asserts any kind of right: A Gewirth, *Reason and Morality* (Chicago: Chicago UP 1978); D Beyleveld, *The Dialectical Necessity of Morality: An analysis and defense of Alan Gewirth's argument to the principle of generic consistency* (Chicago: Chicago UP 1984). I am rather sceptical towards these claims that it is possible to derive very substantial moral conclusions from very formal claims.

To successfully invoke stewardship in a certain area it is not sufficient to be able to claim truthfully that something is in B's interest and that that interest can be furthered by appropriate stewardship (even in cases where B is clearly incompetent either epistemically or in relation to decision-making). This is because to be able to claim that B (or his or her steward) ought to act on an interest, more is needed. The action has to be in B's interest, all other things, and particularly all other interests of B considered! That B has a specific interest only gives B a *pro tanto* or *prima facie* reason to act on that interest, and it might be a very weak reason. It is only by taking all of B's interests into account that B or an outsider can decide what B has decisive reason to do.<sup>39</sup> To claim that each of us has an interest in the welfare of others only provides a sound basis for stewardship if this is a strong interest, or if it is in certain cases not outweighed by any other significant interests.

This analysis does not imply that a stewardship state on the Nuffield Council model cannot deal with moral uncertainty or complexity, but it does imply that it can in most instances not deal with these issues as a matter of stewardship. It may well do so, because all states balance interests or choose between competing rights claims, but it does not do this through the device of stewardship or with a justification in stewardship.

### Can international super-stewardship be justified?

In addition to state stewardship of public health, it has been suggested that we need super-stewardship at the international level, either performed by international organisations or through international agreements.<sup>40</sup>

At this level, a number of the problems already identified for state stewardship recur, but in even more accentuated forms.

It is, to be polite, not obvious that any community-based justification for decision-making can succeed at the international level. Even in the thinnest possible sense of community there is no global community to which we all belong. And in so far as most international organisations are intergovernmental, their members are not citizens or individual persons but states. This has been pointed out by Saltman and Ferroussier-Davies in their discussion of WHO's concept of state stewardship:

The various concepts of stewardship discussed above imply it to be a function of governments responsible for the welfare of populations and concerned about the trust and legitimacy with which its activities are viewed by the general public. This raises a question concerning the suggestion in The World Health Report 2000 that stewardship can extend beyond duly constituted national governments to the role of international agencies. International organizations can be appropriately termed stewards only in relation to their role as good agents for national governments, whereby both normative and efficiency-oriented objectives are combined in the expenditure of public monies allocated to the organizations by sovereign states.<sup>41</sup>

It might be argued that the European Union (EU) is a special case because changes in the 1992 Maastricht treaty have made it a community of European citizens<sup>42</sup> and that the

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39 And even then, what B has decisive reason to do prudentially (e.g. killing his arch-enemy) may be constrained by any side-constraints imposed by the rights held by others.

40 E.g. at the symposium on Super-stewardship in the Context of Public Health, University of Sheffield, 14 November 2009. And, in passing, in R Brownsword, "So what?", n. 34 above, p. 47.

41 Saltman and Ferroussier-Davies, "The concept of stewardship", n. 13 above, p. 735.

42 A similar, but more indirect argument can be made for the Council of Europe in relation to its human rights functions since citizens of nation states have access to a supra-national jurisdiction.

EU can therefore legitimately engage in super-stewardship.<sup>43</sup> I do not intend here to discuss the legal merits of this argument, i.e. whether the EU should legally be conceptualised as a community of citizens. Whatever the precise legal status of the EU is or can be argued to be, it seems to be an incontrovertible empirical fact that most people who are citizens of EU member states do not conceive of themselves primarily as members of some greater community of EU citizens.<sup>44</sup>

The most recent Eurobarometer (spring 2011) shows that, if asked to agree or disagree with the statement “You feel you are a citizen of the EU”, 62 per cent agree, with very large national differences ranging from 86 per cent agreement in Luxembourg to 41 per cent in the UK.<sup>45</sup> This might be taken as a strong indication of a feeling of EU citizenship, but this would be misleading. We don’t actually know how many EU citizens feel that they are citizens of their own nation state (a guess might be somewhere above 90 per cent in many states), and we don’t know what people’s primary identification is. If they had to choose, would they feel themselves to be, say, more Swedish citizens than EU citizens? That the meaning and importance of EU citizenship is still a project in development can be seen in the EU’s continuing efforts to promote EU citizenship and instil it in the young.<sup>46</sup> At the philosophical level, a community-based justification for a super-stewardship role for the EU is therefore not much stronger than for any other international organisation if we take a thin notion of community. Can we conceptualise the EU as an aspirant moral community, a community aspiring to “hand on to the next generation . . . an environment that is conducive to a moral way of life, to a way of life that hinges on agents trying to do the right thing, trying to respect the legitimate interests of fellow agents, and being held responsible for their actions.”<sup>47</sup> Perhaps. But without too much verbal contortion it is probably more realistic to conceive of the EU as an organisation aspiring to become an aspirant moral community at some point in the future. The EU clearly aspires to hand on to the next generation an environment that is conducive to a moral way of life, but there is still no clarity concerning exactly what kind of moral life and therefore no clarity concerning what kind of aspirant moral community the EU might be or might become in the future.

Could it then be argued that the “global public health” is itself a proper object of stewardship, just as “nature” might be conceived to be in relation to environmental ethics and policy? This could be made meaningful, but only if the object of stewardship is “the public health of future generations”. Present generations are not absent and not, in the main, ignorant of their own interests or their own health status. One way of making the claim meaningful is to say that global public health is a public good. The UNESCO *Universal Declaration on Bioethics and Human Rights* (adopted by acclamation on 19 October 2005), for instance, states in Article 14.2a that “health is essential to life itself and must be considered to be a social and human good”, but exactly what kind of good is health?

Many theories in political philosophy acknowledge health as a basic good, either on its own or because of the strong links between health and welfare and health and social participation. These arguments are not affected by the observation that there may be individuals who do not value health or for whom health is not important.

43 It is, however, worth noting, that if the argument holds, what the EU would be doing would not strictly be super-stewardship since it would just be the steward for its own citizens acting essentially with the same justification as any nation state exercising stewardship responsibility.

44 M Jolly, “A demos for the European Union” (2005) 25 *Politics* 12.

45 European Commission, *Eurobarometer 75: Public opinion in the European Union* (spring 2011).

46 See, for instance, European Commission, “Making citizenship work: fostering European culture and diversity through programmes for youth, culture, audiovisual and civic participation” COM (2004) 154 final.

47 Brownsword, *Rights, Regulation and the Technological Revolution*, n. 3 above, pp. 305–6.

There is also little doubt that having healthy citizens is a benefit to society and that health is a social or public good in that sense. The health of individuals contributes positively to general social conditions.

There is, however, another economic sense of “public good” in which it is more doubtful as to whether health or global health qualifies as a public good.<sup>48</sup> Economists distinguish between private goods that are characterised by being rival and excludable and public goods that are non-rivalrous and non-excludable. A non-rivalrous good is a good where my consumption does not affect your consumption of the same good and a non-excludable good is a good where it is impossible effectively to exclude some but not others from consumption (e.g. exclude non-payers but still allow payers to consume). Classic examples of economic public goods are clean air, effective national defence and street lighting. Economic theory predicts that there will be undersupply of public goods because their non-excludable nature means that it will be impossible to extract market value payment from all consumers of the goods. This entails that there is an economic argument for state intervention in the market and possible state provision of the good or taxation to make up for the market failure. If global health was an economic public good there would thus be a purely economic argument for providing health and engaging in super-stewardship (in reality, providing health promotion and care since health cannot be provided directly). This would reduce the need for appeal to moral or even prudential obligations to secure health care for those who cannot pay for it themselves.<sup>49</sup>

The “global health is a public good” argument does, however, face significant obstacles. It is clearly not the case that most forms of health care are non-rivalrous or non-excludable. Physical and manpower resources are finite, leading to rivalry between consumers, and it is very easy to exclude people from health care or the benefits of health care. Health care knowledge is non-rivalrous,<sup>50</sup> but it is not non-excludable and, therefore, still falls outside of the definition of an economic public good. The increasing tendency to patent university-based inventions in health care clearly indicates that exclusion is possible in the area of health-care knowledge, and that it is seen as economically desirable by some.

There are areas where it is more plausible to see global health as an economic public good, especially in relation to the prevention and treatment of infectious diseases which significantly reduces their spread. The fact that other people have immunisations benefits me and this general benefit of herd immunity is non-rivalrous and non-excludable. But similar arguments cannot be made for health care in general. My appendectomy does not in any appreciable way benefit you. In an economic sense, much of health (and most of health care) is a private good.

But acknowledging that health is a private good in an economic sense does not negate the fact that health is a public good in the much more straightforward sense outlined above, that a society with healthy citizens is a better society than one with much illness and a world with healthy people better than the one we have now. This can still be an excellent reason to promote health, but it is an open question as to whether we can establish a sufficiently robust sense of global health to justify super-stewardship of it.

Now, there are other possible justifications for seeking global public health regulations and the most obvious are the economic and other costs imposed by incompatible national

48 A J Culyer. *The Dictionary of Health Economics* (Cheltenham: Edward Elgar 2005).

49 L C Chen, T G Evans and R A Cash, “Health as a global public good” in *Global Public Goods* (Oxford: Oxford Scholarship Online Monographs 1999), p. 284.

50 In reality, even this is complicated because the exploitation of health-care knowledge may involve rivalry, for instance, between producers of the same pharmaceutical product.

regulations. It is, however, not obvious that the project of harmonising such regulations is best described as a project of stewardship. In discussion, Roger Brownsword has argued that a proper target for super-stewardship are those structures at the international level that are necessary to preserve a common arena for agency, i.e. those international structures that all (aspirant) moral communities rely on to survive and develop as communities.<sup>51</sup> Even if we accept this argument, such structures would, however, only constitute a limited subset of current global public health structures.

### Conclusion

In the discussion above, a number of critical issues have been identified in relation to stewardship and super-stewardship in the context of public health.

It has been argued that, whereas stewardship in public health is not identical to paternalism, the area of overlap between the two concepts is very large; and that it is still unclear whether stewardship adds much to our understanding of how a state ought to act in relation to public health. There is, thus, a risk that state actions that are clearly paternalistic and therefore need strong justification are re-badged as actions based on a presumably less controversial stewardship function of the state and therefore not subject to the same scrutiny as overtly paternalistic actions.

It has further been argued that the concept of stewardship put forward by the Nuffield Council on Bioethics lacks theoretical foundation and that, as a matter of theoretical justifiability, Roger Brownsword's concept of stewardship is preferable. Brownsword's concept also provides more specific action guidance to policymakers who conceive of themselves as making policy in an aspirant moral community. The Brownswordian steward has an obligation to steward according to the community's moral aspirations. This provides a clearer justification for some paternalistic actions, but this justification comes with added normative baggage.

Finally, it has been argued that it is difficult to find any cogent justification for international super-stewardship in the arena of public health. International public health policy still has to be formulated, but, given the status of the international bodies formulating this policy, it is preferable that they continue to see themselves as policymakers making policy in politically contentious areas, and not as stewards of the affairs of some partly fictional citizenship.

Will the public health steward then slowly change into the public health ruler? Insofar as stewardship is being invoked in circumstances where those who are subject to stewarding are not really absent, this has in one sense already happened. And it is a real risk whenever the stewards forget that some of their actions are also paternalistic.

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51 In his response to discussants at the symposium on Super-stewardship in the Context of Public Health, University of Sheffield, 14 November 2009.



# The European Union, its Court of Justice and “super-stewardship” in public health

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## Abstract

*Brownsword et al.’s concept of stewardship relies on the notions of “intervention ladders” and of “productive disconnection” and “intelligent purposive reconnection” between the written texts of the law and developments in science, society and the interface between the two. This article argues that “super-stewardship” (a modified version of stewardship applicable at the supranational level) provides an appropriate standpoint for analysis and assessment of the European Union’s (EU) law and policy-making institutions in the area of public health. The article gives a preliminary illustration of how super-stewardship might be used in this way. The overall argument is that intervention ladders, duly modified, provide a device for analysis or assessment of law and policy-making, and that productive disconnection and intelligent purposive reconnection, duly modified, provide a device for analysis or assessment of adjudication by the EU’s Court of Justice.*

## **Introduction: (super-)stewardship, public health and the EU**

“European Court backs ban on Red Bull over health concerns” (7 February 2004)

“EU alcohol ruling cheers traders” (23 November 2006)

“European Court slams Sweden’s alcohol import ban” (5 June 2007)

“Scotch trade body says minimum alcohol pricing breaches EU law” (9 March 2010)

“European Court rules minimum cigarette prices illegal” (20 March 2010)

“Food industry wins battle on ‘traffic light’ labels” (17 June 2010)

**P**ractitioners and academics within the health community have routinely been critical of involvement of the EU and its Court of Justice (the Court) in policy areas concerning healthcare-systems and public health, such as caffeine and vitamin-enhanced foodstuffs,

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\* Email: t.hervey@sheffield.ac.uk. I am grateful to the participants at the University Association for Contemporary European Studies-sponsored Symposium with Professor Roger Brownsword: Super-stewardship in the Context of Public Health, Saturday 14 November 2009, School of Law, University of Sheffield; for the support of the Economic and Social Research Council seminar series European Law and New Health Technologies (PI Dr Mark Flear) REF: RES-451-26-0764 and of the University of Sheffield CILASS SURE Summer Intern Scheme 2009; and for the comments of the anonymous reviewer.

alcohol and tobacco, as the quotations above, taken from the press,<sup>1</sup> illustrate. The critique advanced is often rather unspecified, to the general effect that the EU's institutions should not be making such decisions, because the EU is about free trade rather than public health.<sup>2</sup>

But the relationships between the interests of free trade and those of public health protection or promotion are such that a balancing exercise between these interests must be carried out through law and policy-making processes and, where disputes arise, through adjudication. Where states have chosen to become members of an international organisation based on free trade, such as the EU or the World Trade Organization (WTO), that balancing exercise must take place within the rules of such an organisation. In the case of the EU, the direct effect<sup>3</sup> and supremacy<sup>4</sup> of EU law, and the role of the Court in interpreting EU law, as set out in the EU treaties,<sup>5</sup> mean perforce that the balancing exercise will sometimes be carried out by the Court. Furthermore, it is not clear that the Court invariably prefers free trade to public health – both the Treaty on the Functioning of the European Union (TFEU) itself<sup>6</sup> and the Court's jurisprudence<sup>7</sup> recognise the need to protect values other than free trade within the context of the EU's internal market law.

Therefore, if we seek to assess whether the EU and its Court appropriately consider and weigh public health concerns in their decision-making processes, we need a more developed analytical standpoint from which to do so. The purpose of this article is to consider the

- 1 *The Independent*, 7 February 2004, [www.independent.co.uk/life-style/health-and-families/health-news/european-court-backs-ban-on-red-bull-over-health-concerns-569117.html](http://www.independent.co.uk/life-style/health-and-families/health-news/european-court-backs-ban-on-red-bull-over-health-concerns-569117.html); BBC News, 23 November 2006 <http://news.bbc.co.uk/1/hi/world/europe/6175646.stm>; *The Local: Sweden's News in English*, 5 June 2007 [www.thelocal.se/7508/20070605/](http://www.thelocal.se/7508/20070605/); *Beveridge Daily*, 9 March 2010 [www.beveragedaily.com/Regulation-Safety/Scotch-trade-body-says-minimum-alcohol-pricing-breaches-EU-law](http://www.beveragedaily.com/Regulation-Safety/Scotch-trade-body-says-minimum-alcohol-pricing-breaches-EU-law); R Watson, "European court rules minimum cigarette prices illegal" (2010) *BMJ* 340:c1498 [www.bmj.com/content/340/bmj.c1498](http://www.bmj.com/content/340/bmj.c1498); *EurActiv.com* [www.euractiv.com/en/food/food-industry-wins-battle-traffic-light-labels-news-495324](http://www.euractiv.com/en/food/food-industry-wins-battle-traffic-light-labels-news-495324) (all accessed January 2011).
- 2 See, e.g. the consultation among key stakeholders reported in B Baumberg and P Anderson, "Health, alcohol and EU law: understanding the impact of European single market law on alcohol policies" (2008) 18 *European Journal of Public Health* 392–8; G Hermans, A F Casparie and J H Paelinck (eds), *Health Care in Europe after 1992* (Leiden: Dartmouth 1992); M McKee, E Mossialos and P Belcher, "The influence of European Union law on national health policy" (1996) 6 *Journal of European Social Policy* 263–86; M McKee, E Mossialos and R Baeten, "The implications of European law for health care" in M McKee, E Mossialos and R Baeten (eds), *The Impact of EU Law on Health Care Systems* (Brussels: PIE-Pieter Lang 2002); A Gilmore and M McKee, "Tobacco policy in the European Union" in E A Feldman and R Bayer (eds), *Unfiltered: Conflicts over tobacco policy and public health* (Cambridge MA: Harvard UP 2004); V Hatzopoulos, "Health law and policy: the impact of the EU" in G de Búrca (ed.), *EU Law and the Welfare State: In search of solidarity* (Oxford: OUP 2005); D S Martinsen, "Towards an internal health market with the European Court" (2005) 28 *West European Politics* 1035–56; C Newdick, "Citizenship, free movement and health care: cementing individual rights by corroding social solidarity" (2006) 43 *Common Market Law Review* 1645–68; S Greer, *The Politics of European Union Health Policies* (Maidenhead: Open UP 2009).
- 3 Case 26/62 *Van Gend en Loos* [1963] ECR 1.
- 4 Case 6/64 *Costa v ENEL* [1964] ECR 585.
- 5 Article 267 TFEU.
- 6 Articles 36, 45(3), 52(1), 106 TFEU.
- 7 See e.g. Case 120/78 *Reve-Zentrale AG v Bundesmonopolverwaltung (Cassis de Dijon)* [1979] ECR 649; Case 178/84 *Commission v Germany (Beer Purity Laws)* [1987] ECR 1227; Case C-76/90 *Säger v Dennemeyer* [1991] ECR I-4221; Case C-55/94 *Gebhard* [1996] ECR I-4165; Case C-237/94 *O'Flynn v Adjudication Officer* [1996] ECR I-2617. For further discussion, see J Scott, "Mandatory or imperative requirements in the EU and the WTO" in C Barnard and J Scott (eds), *The Law of the Single European Market: Unpacking the premises* (Oxford: Hart 2002), pp. 269–93; C Barnard, *The Substantive Law of the EU: The four freedoms* (Oxford: OUP 2010), pp. 165–87, 241–2, 510–18; V Hatzopoulos, "Recent developments of the case law of the ECJ in the field of services" 37 (2000) *Common Market Law Review* 43–82; D Chalmers, "The single market: from prima donna to journeyman" in J Shaw and G More (eds), *New Legal Dynamics of European Union* (Oxford: OUP 1995).

extent to which Brownsword’s notion of stewardship, the subject of this special issue, provides such an analytical standpoint.

To this end, the article proceeds as follows. This introduction briefly outlines the concepts of stewardship and public health and the interface between them in the context of the EU. The article is organised into six potential objections to using the concept of stewardship to analyse EU institutional decision-making on public health. The first main section of the article considers the first of two overlapping groups of such objections. This first group of objections arises from claims to the effect either that the EU is in relevant respects no different from a state, or that the EU is too different from a state, and so stewardship does not provide an appropriate model to assess the EU’s activities. To what extent can one key analytical construct of stewardship in the context of public health, that is, Brownsword et al.’s intervention ladder,<sup>8</sup> be used to assess whether the EU’s public health policies (in general) are justified? What modifications to Brownsword et al.’s concept are required?

The focus then turns to the Court. The second main section of the article focuses upon a group of objections to using the concept of stewardship to analyse the jurisprudence of the Court on public health. It considers whether stewardship can be applicable to the Court, as a supranational court, within a particular “constitutionalised” legal order that predominantly values the liberties inherent in the notion of the EU’s internal market. To what extent can a second key analytical construct of stewardship in the context of public health, that is, Brownsword’s notions of productive disconnection and intelligent purposive reconnection, be used to assess whether the Court’s public health decisions are justified? What modifications to Brownsword’s concepts are required?

The two clusters of concerns overlap because the claims about the nature of the Court as a constitutionalised court go to the question of what kind of order or organisation the EU constitutes. The article concludes that no concern discussed justifies rejecting super-stewardship (a modified version of stewardship) as a valuable analytical standpoint by which to assess the EU’s decisions in public health fields. The value of super-stewardship, and in particular the notions of both ladders of intervention and of productive disconnection and intelligent purposive reconnection between the written texts of the law and developments in science, society and the interface between the two, is briefly illustrated throughout the article by reference to EU law concerning threats to public health arising from alcohol, tobacco, foodstuffs, pharmaceuticals, blood and human tissues.

Stewardship, according to Baldwin, Brownsword and Schmidt’s summary<sup>9</sup> of the notion as developed in the Nuffield Report on *Public Health: Ethical issues*,<sup>10</sup> can be characterised as follows:

Liberal states have responsibilities to look after important needs of people both individually and collectively. Therefore, states are stewards both to individual people, taking account of different needs arising from factors such as age, gender, ethnic background or socio-economic status, and to the population as a whole . . . [T]he notion of stewardship gives expression to the obligation on states to seek to provide conditions that allow people to be healthy, focusing attention, in particular, on reducing health inequalities.<sup>11</sup>

8 Nuffield Council on Bioethics, *Public Health: Ethical issues* (London: Nuffield Council on Bioethics 2007) (Nuffield Report), p. 42.

9 In T Baldwin, R Brownsword and H Schmidt, “Stewardship, paternalism and public health: further thoughts” (2009) 2(1) *Public Health Ethics* 113–19.

10 Nuffield Report, n. 8 above.

11 Baldwin et al., “Stewardship”, n. 9 above, pp. 115–16; Nuffield Report, n. 8 above, p. 25.

This conception echoes the World Health Organisation's (WHO) *World Health Report 2000*, which considers that stewardship consists in the "ultimate responsibility" of governments for health within a state.<sup>12</sup> Brownsword et al.'s conception of stewardship lies somewhere between "libertarian paternalism" and paternalism.<sup>13</sup> Their development of stewardship arises from their conviction that both paternalism and libertarian paternalism are inappropriate or problematic models for public health policies. Paternalism as a model for public health policies is insufficiently respectful of individual autonomy and choice. Libertarian paternalism allows too much individual choice, and thus absolves the state from important responsibilities,<sup>14</sup> especially to those who would otherwise be disproportionately disadvantaged in health terms by their age, gender, ethnic background or socio-economic status. Stewardship is thus based on equality and proportionality, where policy goals impinge on individual preferences or even individual rights. Stewardship is also based on transparency and participation, not simply representative models of democratic process. It is based on oversight and trusteeship; on governments working in partnership with individuals.<sup>15</sup>

For the purposes of this article, by "public health policies", I mean collective or public activities (regulation, governance, and "steering") aimed at the protection of the health of the population; and the promotion of good health and the prevention of ill-health among the population.<sup>16</sup> So defined, public health policy is a matter of shared competence between the EU and its member states, with the EU having some regulatory power, and also power to support, coordinate or supplement the actions of the member states.<sup>17</sup> The member states, and in practice the EU,<sup>18</sup> also share this responsibility with international organisations, in particular the WHO.<sup>19</sup> EU public health policy is formally based on Article 168 TFEU. In general, the EU's competences in public health, as defined in Article 168 TFEU, are to support and complement those of the member states. The EU has explicit legislative competence only in setting standards of organ and human tissue safety, veterinary and phytosanitary measures, and standards of safety for pharmaceuticals and medical devices.<sup>20</sup>

12 WHO, *World Health Report 2000* (Geneva: WHO 2000), pp. xiv, 119–40.

13 Nuffield Report, n. 8 above, pp. 17–25.

14 Ibid. p. 25.

15 WHO, *World Health Report*, n. 12 above, p. 119.

16 L O Gostin, *Public Health Law: Power, duties and restraints* (Berkeley and Los Angeles: University of California Press 2000); R Martyn and L Johnson (eds), *Law and the Public Dimension of Health* (London: Cavendish 2001).

17 Article 5 TEU; Articles 2 and 4(2)(k) TFEU 9 for "common safety concerns in public health matters", as defined in Article 168 TFEU; Article 6(a) TFEU for "protection and improvement of human health".

18 M McKee, T Hervey, A Gilmore, "Public health policies" in E Mossialos, G Permanand, R Baeten, T Hervey (eds), *Health Systems Governance in Europe: The role of EU law and policy* (Cambridge: CUP 2010), pp. 231–81.

19 Cooperation between the EU and the WHO was originally based on an exchange of letters between EU Commissioner David Byrne and WHO Director-General Gro Bundtland in 2000. High and medium-level meetings take place relatively regularly, see [http://ec.europa.eu/health/eu\\_world/international\\_organisations/who/index\\_en.htm](http://ec.europa.eu/health/eu_world/international_organisations/who/index_en.htm). Collaborative initiatives include, for instance, the Global Health Security Initiative, launched 2001 [www.ghsi.ca/english/index.asp](http://www.ghsi.ca/english/index.asp); the Framework Convention on Tobacco Control 2003, of which the EU is a signatory; see A Gilmore and J Collin, "The world's first major international tobacco control treaty" (2002) 325 *BMJ*, 19 October 2002, pp. 846–7; the Framework for Alcohol Policy in the WHO European Region 2006 [www.euro.who.int/\\_\\_data/assets/pdf\\_file/0007/79396/E88335.pdf](http://www.euro.who.int/__data/assets/pdf_file/0007/79396/E88335.pdf); and work on pandemic influenza preparedness <http://apps.who.int/gb/pip/>; see M Flear, "Supra-stewardship: a tool for citizen participation in European Union pandemic preparedness planning" in this issue. The EU also works with the Organisation for Economic Co-operation and Development and the Council of Europe on a range of health issues, see [http://ec.europa.eu/health/eu\\_world/international\\_organisations/index\\_en.htm](http://ec.europa.eu/health/eu_world/international_organisations/index_en.htm) (accessed January 2011).

20 Article 168 (4)(a), (b), (c) TFEU.

Is super-stewardship a useful analytical standpoint from which to assess the EU’s institutional decision-making in public health law and policy? The article first considers this question in general, before turning in a later section to a specific focus on the Court.

### Super-stewardship and EU public health law and policy: intervention ladders

Within their stewardship model, Brownsword et al.’s intervention ladder<sup>21</sup> provides a tool to consider and justify a range of different policy initiatives. The higher the “rung” on the ladder, the stronger the justification must be. The ladder is as follows (highest rung first):

- eliminate choice;
- restrict choice;
- guide choice through disincentives;
- guide choices through incentives;
- guide choices through changing the default policy;
- enable choice;
- provide information;
- do nothing or simply monitor the current situation.

To what extent might this analytical construct provide a means to assess EU public health law and policy? How might it need to be adjusted?

### **Objection 1: Stewardship responsibilities apply to the EU. There is no need to develop an idea of super-stewardship when assessing the EU’s public health policies.**

There are those – notably Giandomenico Majone – who have argued that the EU is already sufficiently “state-like” that we might say that it has stewardship responsibilities *tout court*. Indeed, Brownsword describes the “stewardship jurisdiction” as pertaining to “the regulatory state”,<sup>22</sup> and Majone, for instance, has described the EU as “a regulatory state”.<sup>23</sup> If the EU is a regulatory state, for the purposes of public health regulation, then the notion of stewardship, as developed for states, can be applied to the EU, without any need to develop it further.

Moreover, even if we consider that the EU is insufficiently state-like to count as a “state”, we might observe that the function of stewardship is essentially to mediate between different views about the balances between rights, freedoms and regulation in a particular society – in other words, to manage pluralist societies. If we take that functional approach to stewardship, then we can say that the EU embodies a pluralist society or group of societies and so again stewardship per se is perfectly acceptable as an analytical or normative tool to assess EU public health policy. Again, there is no need for a special version of stewardship – super-stewardship – for assessing EU activity.

21 Nuffield Report, n. 8 above, p. 42.

22 R Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: OUP 2008) (hereafter RRTR), p. 302.

23 G Majone, “The rise of the regulatory state in Europe” (1994) 17 *West European Politics* 77–101; G Majone, “A European regulatory state?” in J Richardson (ed.), *European Union: Power and policy-making* (London: Routledge 1996); G Majone, *Deregulation or Reregulation? Regulatory reform in Europe and the United States* (London: Pinter 1990). More recently, Majone’s work has been inspired by economic “club theory”, which emphasises pluralism, although this does not necessarily exclude the idea of the regulatory state as defined by Majone. See G Majone, *Dilemmas of European Integration: The ambiguities and pitfalls of integration by stealth* (Oxford: OUP 1995); G Majone, “Unity in Diversity: European integration and the enlargement process” 33 (2008) *European Law Review* 457–81. For another perspective on the EU as (potentially) a state, see G Mancini, “Europe: the case for statehood” (1998) 4 *European Law Journal* 29–42.

## Objection 2 is the polar opposite of the first objection: Stewardship is the responsibility of states, not of supranational organisations such as the EU

The concept of stewardship implies processes that legitimate public action.<sup>24</sup> For Brownsword et al., and for the WHO,<sup>25</sup> these legitimating processes are implicitly based upon a unitary community (the state). The failure to adopt the Constitutional Treaty, and the provisions of the post-Lisbon Treaty settlement, underline that the EU is a “process of creating an ever closer union among the peoples of Europe”, in which the member states give competence, in the treaties, to attain common objectives, but is not a state.<sup>26</sup> Is stewardship as a concept so state-based that we could not meaningfully talk about the EU being subject even to a modified version of stewardship – super-stewardship?

In response to this objection, we might first observe that, for the purposes of legitimisation of public action, it does not matter so much whether the relevant community is a state, or whether it is unitary (and we might argue about whether states can really be described as sovereign “unitary communities”);<sup>27</sup> what matters more is that it *functions* as a community. The essential basis of stewardship is both the value of community and the values of a community. So far, so good. But, if we translate this into super-stewardship at EU level, which community do we mean? Or do we mean communities? Even the post-Lisbon version of the EU’s treaties talks of the “peoples” of Europe.<sup>28</sup> A small number of writers think there is a “community” of Europeans of which the EU is an institutionalised representation, and which (might) legitimate the EU’s normative powers.<sup>29</sup> But many more are sceptical about such claims, pointing out that they are more aspirational discourse than reflecting present understandings, and that the EU has neither an existing *demos*,<sup>30</sup> nor even

24 Nuffield Report, n. 8 above, pp. 23, 26, 43–5, 46. The idea is also implicit in RRTR, n. 22 above.

25 WHO, *World Health Report*, n. 12 above.

26 Article 1 TEU; see e.g. the decision of the German *Bundesverfassungsgericht* 2 BvE 2/08 *Gauweiler v Treaty of Lisbon*, 30 June 2009; see also the decision of the Polish Constitutional Court *Polish Membership of the European Union* K18/04 May 2005; *Brunner v The European Union Treaty* [1994] 1 CMLR 57. See e.g. J Fischer, “From Confederacy to federation: thoughts on the finality of European integration” [http://centers.law.nyu.edu/jeanmonnet/papers/00/joschka\\_fischer\\_en.rtf](http://centers.law.nyu.edu/jeanmonnet/papers/00/joschka_fischer_en.rtf) (accessed January 2011); the discussion of the Constitutional Treaty and its rejection in P Craig, *The Lisbon Treaty: Law, politics and treaty reform* (Oxford: OUP 2010), pp. 6–25; the conversation between L Siedentop, “A crisis of legitimacy”, and A Moravcsik, “Europe without illusions: a category error” at [www.prospectmagazine.co.uk/2005/07/europewithoutillusions/](http://www.prospectmagazine.co.uk/2005/07/europewithoutillusions/) (accessed January 2011).

27 See e.g. N MacCormick, “Beyond the sovereign state” (1993) 56 *Modern Law Review* 1–18; N MacCormick, *Questioning Sovereignty: Law, state and nation in the European commonwealth* (Oxford: OUP 1999); N Walker, “Beyond boundary disputes and basic grids: mapping the global disorder of normative orders” (2008) 6 *International Journal of Constitutional Law* 373–96.

28 Preamble, recital 6 TEU; Article 1(2) TEU.

29 The best-known of these is J Habermas, “Why Europe needs a constitution” (2001) 11 *New Left Review* [www.newleftreview.org/A2343](http://www.newleftreview.org/A2343) (accessed January 2011). See also, J Habermas and J Derrida, “February 15, of what binds Europeans together” in D Levy et al., *Old Europe, New Europe, Core Europe: Transatlantic relations after the Iraq War* (London: Verso 2005), cited in D Chalmers, G Davies and G Monti, *European Union Law* (Cambridge, CUP 2010), pp. 6–7. For a defence of a more modest version of “constitutional patriotism” for the EU, which, however, recognises the EU as having multiple *demos*, see, J-W Müller, “A European constitutional patriotism? The case restated” (2008) 14 *European Law Journal* 542–57.

30 J Weiler, *The Constitution of Europe* (Cambridge: CUP 1999); W Van Gerven, *The European Union: A polity of states and peoples* (Oxford: Hart 2005); J Weiler, U Haltern and F Mayer, “European democracy and its critique” in J Hayward (ed.), *The Crisis of Representation in Europe* (London: Frank Cass 1995) and (1995) 18 *West European Politics* 4–39; P Craig, “The nature of the community: integration, democracy and legitimacy” in P Craig and G de Búrca (eds), *The Evolution of EU Law* (Oxford: OUP 1999); K-H Ladeur, “‘We the European people . . . – relâche?’” 14 (2008) *European Law Journal* 147–67.

a *telos* or “end game” that is a unitary community,<sup>31</sup> but is more about the process of managing communities within a pluralist regime of interacting legal (and political) systems.

The objections to the effect that the EU is not sufficiently state-like to generate the kind of community legitimacy implied by (super-)stewardship are more difficult to dismiss than those that claim that stewardship *tout court* is adequate. There is a lot to be said for the view that the EU lacks a unitary *demos*, or *telos* involving a community in the singular. However, one way to justify the development of super-stewardship as a standard against which to assess the EU might be to consider the EU as *process*, perhaps even constitutional, or constitutionalising, process.<sup>32</sup> The process of either constituting a community and/or mediating between communities (or perhaps just very simply, community as communication within a (constitutionalising) process) could be claimed to be a sufficient basis for super-stewardship obligations, within an analytical frame for assessing EU public health policy. We could then say that, in spite of the no *demos*/no community/no legitimacy arguments, there is sufficient community legitimacy – as *process* – within the EU context to support the application of a modified version of stewardship – super-stewardship – to the EU. The disconnection between “community” in the sense it is applied to a state, and “community” in this process-based sense, as applied to the EU, requires and justifies the modification of stewardship into super-stewardship.

Add to this observation the fact that, although responsibility for public health policy is shared between the EU and its member states, the EU’s legislative powers in this respect are narrow. This narrow range of legislative competence means that we cannot simply transfer the model of stewardship onto the EU institutions, because they do not have sufficient power to fulfil stewardship obligations in the way that states do. However, neither can we say

31 See e.g. C Joerges, Y Mény and J H H Weiler (eds), *What Kind of Constitution for What Kind of Polity? Responses to Joschka Fischer* (Cambridge MA: Harvard Law School 2000), also available at <http://centers.law.nyu.edu/jeanmonnet/papers/00/symp.html> (accessed January 2011), especially T Börzel and T Risse, “Who is afraid of a European Federation? How to constitutionalize a multi-level governance system”; and J Zielonka, “Enlargement and the finality of European integration” therein. See also J Monnet, *Memoires* (London: Doubleday 1978), pp. 522–3, cited in I Ward, *A Critical Introduction to European Law* (Oxford: OUP 2009), pp. 211–12.

32 Much of the relevant literature on this subject pertains to the ill-fated Treaty establishing a Constitution for Europe. See e.g. P Eleftheriadis, “Constitution or treaty?” (2004) *Federal Trust Online Paper* 12/04 1-12; J Shaw, “Europe’s constitutional future” (2005) *Public Law* 132–51; P Eleftheriadis, “The idea of a European constitution” (2007) 27(1) *Oxford Journal of Legal Studies* 1–21; J Snell, “‘European constitutional settlement’, and ever-closer union, and the Treaty of Lisbon: democracy or relevance?” (2008) 33 *European Law Review* 619–42. However, it also has a much longer pedigree, and involves more general reflection on EU constitutionalisation: see e.g. E Stein, “Lawyers, judges and the making of a transnational constitution” (1981) 75 *American Journal of International Law* 1; G Bermann, “The Single European Act: a new constitution for the European Community?” (1989) 27 *Columbia Journal of Transnational Law* 529–87; J Weiler, “The transformation of Europe” (1991) 100 *Yale Law Journal* 2403; D Curtin, “The constitutional structure of the union: a Europe of bits and pieces” (1993) 30 *Common Market Law Review* 17–69; P Eleftheriadis, “Aspects of European constitutionalism” (1996) 21 *European Law Review* 32–42; N Walker, “European constitutionalism and European integration” (1996) *Public Law* 266–90; J Shaw, “Postnational constitutionalism in the European Union” (1999) 6 *Journal of European Public Policy* 579–97; J-C Piris, “Does the European Union have a constitution? Does it need one?” (1999) 24 *European Law Review* 557–85; J Shaw, “Process and constitutional discourse in the European Union” (2000) 27 *Journal of Law and Society* 4–37; P Craig, “Constitutions, constitutionalism and the European Union” (2001) 7 *European Law Journal* 125–50; C Timmermans, “The constitutionalization of the European Union” (2002) 21 *Yearbook of European Law* 1–11; J Weiler and M Wind (eds), *European Constitutionalism Beyond the State* (Cambridge: CUP 2003); J Shaw, “Process, responsibility and inclusion in EU constitutionalism” (2003) 9 *European Law Journal* 45–68; V Breda, “A European constitution in a multinational Europe or a multinational constitution for Europe” (2006) 12 *European Law Journal* 33–44 (drawing on the work of James Tully); C F Sabel and O Gerstenberg, “Constitutionalising an overlapping consensus: the ECJ and the emergence of a coordinate constitutional order” (2001) 16 *European Law Journal* 511–50.

that the EU – when it exercises its public health competences – escapes the responsibilities encapsulated in the stewardship concept. A modified model – super-stewardship – encapsulates the nature of the duties on the EU institutions in the context of public health policy. The (admittedly catchy) term super-stewardship captures the relationships between the EU and its member states, echoing terms already used to describe that relationship and the EU’s responsibilities and competences within it, such as “supranational”.

So, for instance, we could use the ladder of intervention to assess the EU’s decisions restricting movements of cattle from the UK during the BSE/vCJD crisis during the late 1980s and the 1990s,<sup>33</sup> or the EU’s blood<sup>34</sup> or organ and tissue donation<sup>35</sup> law and policy. The fact that, at the height of the BSE/vCJD crisis (bovine spongiform encephalopathy/variant Creutzfeldt-Jakob disease), the EU had within its borders, on a scale at the time undetermined, a new and fatal human disease, the spread of which had not been contained and about which consumers had been misinformed,<sup>36</sup> justified interventions at the highest rung of the ladder – sales of British beef products likely to carry the disease were prohibited. The Blood Safety Directive<sup>37</sup> and Human Tissue and Organs Directives<sup>38</sup> provide for accreditation, authorisation and licensing of establishments that collect human blood, organs or tissues, and establish inspection and quality control requirements with

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33 E.g. Commission Decision 89/469/EEC OJ 1989 L 225/51; Decision 90/59/EEC OJ 1990 L 41/23; Commission Decision 94/474/EC OJ 1994 L 194/96; Commission Decision 96/239/EC OJ 1996 L 788/47 issuing a complete ban on the dispatch of live cattle and all cattle products from the UK.

34 Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC OJ 2003 L 33/30; Commission Communication on the application of Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC COM (2010)03 final; Directive 2009/135/EC of 3 November 2009 allowing temporary derogations to certain eligibility criteria for whole blood and blood components donors laid down in Annex III to Directive 2004/33/EC in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic OJ 2009 L 288/7; Commission Regulation 523/2008 of 11 June 2008 amending Annexes VIII, X and XI to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the import of blood products for the manufacture of technical products OJ 2008 L 153/23; European Commission Report on the promotion by member states of voluntary unpaid blood donations, COM (2006) 217 final; Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components OJ 2004 L 91/25.

35 Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation OJ 2010 L 207/14; European Parliament resolution of 22 April 2008 on organ donation and transplantation: Policy actions at EU level (2007/2210 (INI)) OJ 2009 C 259/1; Regulation 1394/2007/EC on advanced therapy medicinal products OJ 2007 L 324/121; Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells OJ 2004 L 102/48, as amended; Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells OJ 2006 L 38/40;

36 Infamously, the then incumbent UK Minister of Agriculture publicly tried to feed a beefburger to his four-year-old daughter on 16 May 1990.

37 Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC OJ 2003 L 33/30.

38 Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells OJ 2004 L 102/48; Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation OJ 2010 L 207/14.

respect to those establishments.<sup>39</sup> These provisions are designed to ensure traceability of human blood and tissue, to avoid a repetition of the public health scandals that surrounded donation of HIV-contaminated blood in the 1980s and 1990s.<sup>40</sup> Again the significant potential harm to individuals involved justifies an intervention at the highest rung of the ladder – no one can procure or apply human blood or tissue in the EU without being accredited to do so.

Equally, by contrast, we might consider that the EU’s food-labelling regime,<sup>41</sup> with respect to foods that are harmful to human health, for instance, in that they encourage obesity, is insufficiently high up the intervention ladder, in that it only provides information,<sup>42</sup> and indeed, that it does not require all necessary information for consumers to make informed choices.<sup>43</sup> Given the inequalities inherent in obesity as a public health problem in European

39 For discussion of the EU’s regulation of blood and human tissue, see S Henette-Vauchez, “Biomedicine and EU law: unlikely encounters?”, EUI Working Papers, RSCAS 2010/46, <http://cadmus.eui.eu/handle/1814/14174> (accessed January 2011); A-M Farrell, “The politics of risk and EU governance of human material” (2009) 16 *Maastricht Journal of European and Comparative Law* 41–64; A-M Farrell, “Is the gift still good? Examining the politics and regulation of blood safety in the European Union” (2006) 14 *Medical Law Review* 155–79; M Favale and A Plomer, “Fundamental disjunctions in the EU legal order on human tissue, cells and advanced regenerative therapies” (2009) 16 *Maastricht Journal of European and Comparative Law* 89–111; T Hervey and H Black, “The European Union and the governance of stem cell research” (2005) 12 *Maastricht Journal of European and Comparative Law* 3–40; J McHale, “Nanomedicine and the EU: some legal, ethical and regulatory challenges” (2009) 16 *Maastricht Journal of European and Comparative Law* 65–88; M Flear, “The EU’s biopolitical governance of advanced therapy medicinal products” (2009) 16 *Maastricht Journal of European and Comparative Law* 113–37.

40 T Hervey and J McHale, *Health Law and the European Union* (Cambridge: CUP 2004), pp. 343–8; P J Hagen, *Blood Transfusion in Europe: A White Paper* (Strasbourg: Council of Europe Press 1993); D Giesen, “Liability for transfer of HIV infected blood in comparative perspective” (1994) 10 *Professional Negligence* 2; Y Englert, (ed.), *Organ and Tissue Transplantation in the European Union* (Dordrecht: Martinus Nijhoff 1995) A-M Farrell, “The politics”, n. 39 above, p. 157.

41 Directive 2000/13/EC on the approximation of the laws of the member states relating to the labelling, presentation and advertising of foodstuffs OJ 2000 L 109/29, as amended; Directive 2009/39/EC on foodstuffs intended for particular nutritional uses OJ 2009 L 124/21; Regulation 834/2007/EC on organic production and labelling of organic products OJ 2007 L 189/1; Regulation 1924/2006/EC on nutrition and health claims made on foods OJ 2006 L 404/9. For discussion, see C MacMaoláin, “Waiter! There’s a beetle in my soup. Yes sir, that’s E120: disparities between actual individual behaviour and regulating food labelling for the average consumer in EU Law” (2008) 45 *Common Market Law Review* 1147–65; H Unberath and A Johnston, “The double-headed approach of the ECJ concerning consumer protection” (2007) 44 *Common Market Law Review* 1237–84; H-C con Heydebrand u.d. Lasa, “Free movement of foodstuffs, consumer protection and food standards in the European Community: has the Court of Justice got it wrong?” (1991) 16 *European Law Review* 391–415; S Weatherill, “Recent case law concerning the free movement of goods: mapping the frontiers of market deregulation” (1999) 36 *Common Market Law Review* 51; O Brouwer, “Free movement of foodstuffs and quality requirements: has the Commission got it wrong?” (1988) 25 *Common Market Law Review* 237–67.

42 Ibid.

43 In spite of regular calls for its introduction from the public health community, the EU has not yet been able to introduce mandatory food-labelling requirements that give full and clear information about the health-related qualities of foodstuff, such as the voluntary “traffic light” food-labelling system, adopted by the UK Food Standards Agency, see [www.eatwell.gov.uk/foodlabels/trafflights/#cat334844](http://www.eatwell.gov.uk/foodlabels/trafflights/#cat334844) (accessed January 2011). See “Traffic light food labelling: a position statement”, UK Faculty of Public Health [www.fph.org.uk/uploads/ps\\_food\\_labelling.pdf](http://www.fph.org.uk/uploads/ps_food_labelling.pdf) (accessed January 2011); House of Commons Health Committee, *Obesity*, Third Report of Session 2003–04 (London: The Stationery Office 2004); *EurActiv.com* [www.euractiv.com/en/food/food-industry-wins-battle-traffic-light-labels-news-495324](http://www.euractiv.com/en/food/food-industry-wins-battle-traffic-light-labels-news-495324). Regulation 1169/2011/EU on the provision of food information to consumers OJ 2011 L 304/18 does now include the requirement to provide information on the health impact of food – a “nutrition declaration” (Art 9 (1) (l); Art 30). However, it will not enter into force until 2014, and not until 2016 for the nutrition declarations. It may be that EU food-labelling law is moving in the right direction.

societies,<sup>44</sup> interventions higher up the ladder, for instance, that guide choices towards healthier eating patterns, would be justified under a super-stewardship model.

### **Objection 3: But how do we assess whether the EU should be involved at all in blood or human tissue safety regulation?**

Brownsword et al.'s intervention ladder gives no purchase with respect to the question of the "best level" for intervention, or better, within a multi-level and process-based system, such as the EU, the best combination of interventions, be they involving supra-national, national, or sub-national regulatory actors, or leaving matters to individual choice. In addition to the dimension of stewardship that concerns relationships between the individual and the state regulator, which is dealt with by the intervention ladder offered by Brownsword and his colleagues, super-stewardship must also concern itself with the best combination of interventions question.

Most, if not all, public health problems involve, for instance, communicable diseases that cross jurisdictional boundaries, or activity based on large-scale communities, such as immunisation, especially in the context of the abilities of human beings to move freely in an increasingly connected world. In a multi-level and process-based system, such as the EU, the question is not where we should place the entry point of a best-level intervention ladder. Rather, it is – to continue with the metaphor of ladders – about how many rungs on the ladder of institutional interactions a policy process should involve. Should public health decisions be left only to individuals? Should policy be made through interactions involving actors at local and national levels? Or should policy decisions be taken involving interactions with other levels, such as the international (the WHO) or the EU?

Brownsword et al.'s intervention ladder for assessing the relationship between individual and state regulator has individual autonomy and choice as its baseline, and the further from the base a proposed intervention, the higher the justification involved. What is the appropriate baseline for our multi-level ladder of intervention? One possible baseline, provided within EU law itself, is the doctrine of subsidiarity.<sup>45</sup> That would also begin at the level of the individual and involve requiring increasingly greater justification for any intervention with individual rights or freedoms that involves interactions with increasingly larger groups above that level. So, for instance, we might say that each local community should be empowered to define its public health policy, through interactions with individuals within that community. Policies formed through interactions between local and national-level institutions require greater justification.<sup>46</sup> However, given the community-based nature of public health, there is an argument to be made that the starting point on the multi-level intervention ladder should be at national level. Indeed, it could equally be argued that, given the fact that public health problems do not stop at state boundaries, as indeed the existence of international organisations such as the WHO attests, the starting

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44 Obesity is linked to social class, see UK Office for National Statistics [www.statistics.gov.uk/STATBASE/Product.asp?vlnk=11130&More=Y](http://www.statistics.gov.uk/STATBASE/Product.asp?vlnk=11130&More=Y) (accessed January 2011) and to poverty, see J Sobal and A J Stunkard, "Socioeconomic status and obesity: a review of the literature" (1989) 105 *Psychology Bulletin* 260–75; A Drewnowski and S E Specter, "Poverty and obesity: the role of energy density and energy costs" (2004) 79 *American Journal of Clinical Nutrition* 6–16; L McLaren, "Socioeconomic status and obesity" (2007) 29 *Epidemiological Review* 29–48. For further analysis of links between poverty, social exclusion and health, see Eurostat, *Combating Poverty and Social Exclusion* (Brussels: EUROSTAT 2010) [http://epp.eurostat.ec.europa.eu/cache/ITY\\_OFFPUB/KS-EP-09-001/EN/KS-EP-09-001-EN.PDF](http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-EP-09-001/EN/KS-EP-09-001-EN.PDF) (accessed January 2011).

45 Article 5(3) TEU.

46 For instance, towns or cities that are hot spots for communicable diseases, such as swine flu, should be able to define their own swine flu policy, and national policy that harmonises such policies must be justified.

point should be *international* level, and policy processes that fail to include this rung of the multi-level intervention ladder should justify this exclusion.

What matters for this article, however, is that *whichever* of these possible starting points were adopted, there would be a need to justify public health policy interventions involving EU (as opposed to national or international) actors. One possible approach to this justification would be to say that where the member states of the EU share sufficient contours of a particular public health problem – say, obesity – which are not shared globally, that *EU-level* (as opposed to international or national) involvement is justified. Alternatively, where other EU laws or policies (such as in agriculture; the environment; or the EU’s internal market) have an EU-specific effect on public health, EU-level policy would also be justified.<sup>47</sup> In other words, justification would be by reference to the need to protect the health of a community or group of communities beyond that of the nation state, but falling short of the global community.

Under super-stewardship, the multi-level ladder of intervention would be as follows (highest rung first). Inclusion of one rung implies a process of interactions between all the rungs below it. Again, the higher the rung, the greater the need for justification.

- decide rules or policies involving institutions or actors at EU level;
- decide rules or policies involving international level institutions (especially in this context, the WHO);
- decide rules or policies involving national level institutions and actors;
- decide rules or policies involving sub-national institutions and actors;
- individual decisions.

It is worth noting that the order of rungs on the best-level ladder appears to be counter-intuitive, in that EU level policies require a *greater* justification than international policies. Indeed, where EU policy departs from rules or policies determined by interactions between actors on the other four rungs of the ladder (e.g. WHO guidance), the greatest justification is required. This is because of the nature of public health protection, as a global activity, and the commonality of disease to humanity, rather than regionally based groups of human beings. If EU policy does not simply follow WHO policy, for example, this must be justified. The implication here is that the strongest justification must be advanced if EU-level institutions are to be involved in public health policy decisions. So, for instance, the development of the European Centre for Disease Prevention and Control (ECDC), which seeks to coordinate responses to communicable diseases<sup>48</sup> within the EU, would need to be justified by reference to super-stewardship. It is not at all clear what “added value” the ECDC brings to the work of national disease control institutions and the work of WHO Europe.<sup>49</sup> Equally, for instance, it is not clear that the EU’s involvement in the swine flu epidemic in 2009 was justified. The public health threat was global, there was nothing in particular about the problem that mandated an EU response. On the other hand, for instance, the long-standing common agricultural policy,<sup>50</sup> as well as the EU’s internal market

47 This is also supported by the post-Lisbon “mainstreaming” obligation with respect to human health, see Article 9 TFEU.

48 Such as SARS, avian flu, swine flu.

49 For discussion of the ECDC, see S L Greer, “The European Centre for Disease Prevention and Control: hub or hollow core?” and H Elliott, S L Greer, D K Jones, “Mapping disease control in the European Union”, both forthcoming 2012 *Journal of Health Politics, Policy and Law*.

50 See e.g. M Cardwell, *The European Model of Agriculture* (Oxford: OUP 2004).

in goods, justifies the elements of EU-level food law and policy that protect and promote public health.<sup>51</sup>

The discussion so far has shown that a modified version of stewardship provides a valuable analytical tool to assess the EU's public health law and policy. The shared competence for public health policy between the EU and its member states justifies the application of Brownsword's intervention ladder in terms of assessing the *content* of policy. Super-stewardship – the obligations of stewardship translated to a supranational context – requires the development of a second intervention ladder, which is concerned with which levels of intervention are appropriate for policy development and implementation.

### Super-stewardship and the Court in public health: productive disconnection and intelligent purposive reconnection

The second main part of the article considers the extent to which the observations made so far – that super-stewardship provides a credible analytical standpoint to assess the actions of the EU's institutions – apply to the Court of Justice of the EU.

#### Objection 4: Stewardship doesn't impose obligations on courts.

At first glance, in both the WHO *World Report 2000* and in Brownsword's work, especially in the Nuffield Report, stewardship seems to be about the state's responsibility as regulator – what seems to be intended is the responsibilities of legislatures and administrative authorities, and those bodies to whom they delegate legislative and administrative competence.<sup>52</sup> Moreover, public health (in common with some other fields such as the regulation of new technologies) seems to be a field where the legislature and executive both set and hold the regulatory position. It does not appear that courts are involved centrally in this process at all. Thus, stewardship does not at all seem to be about courts, still less the supranational/constitutional Court of Justice of the EU.

But we can dismiss this objection quite quickly, as, although the WHO's and Nuffield Report discussion of stewardship appears to be only about legislative or administrative

51 The EU's food safety law is based on the three stages of assessment, management and communication of risk. Formal audit procedures allow assessment of hazard analysis and critical control point mechanisms, which are self-regulatory controls operated at national level, with oversight by the EU's European Food Safety Authority. The system aims to provide transparency and traceability. See Regulation 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety OJ 2002 L 31/1, as amended; Conclusions of the Standing Committee on the Food Chain and Animal Health, Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation 178/2002 on General Food Law, approved 26 January 2010, [http://ec.europa.eu/food/food/foodlaw/guidance/docs/guidance\\_rev\\_8\\_en.pdf](http://ec.europa.eu/food/food/foodlaw/guidance/docs/guidance_rev_8_en.pdf) (accessed January 2011). See e.g. E Vos and F Wendler (eds), *Food Safety Regulation in Europe* (Antwerp: Intersentia 2006); C Ansell and D Vogel, "The contested governance of EU food safety regulation" in C Ansell and D Vogel (eds), *What's the Beef? The contested governance of European food safety* (Cambridge MA: MIT Press 2006); R O'Rourke, *European Food Law* (London: Sweet & Maxwell 2005); D Holland and H Pope, *EU Food Law and Policy* (The Hague: Kluwer Law International 2004); E Vos, "EU Food safety regulation in the aftermath of the BSE crisis" (2000) 23 *Journal of Consumer Policy* 227; E Vos, *Institutional Frameworks of Community Health and Safety Regulation* (Oxford: Hart 1999). The EU also has a (voluminous) body of legislation on the content, labelling and packaging of foodstuffs. This ranges from Directive 2000/36/EC relating to cocoa and chocolate products intended for human consumption OJ 2000 L 197/19, which replaces the "old style" Chocolate Directive 73/241/EEC OJ 1973 L 228/23, to new regulations on food flavourings (Regulation 1334/2008/EC, OJ 2008 L 354/34); additives (Regulation 1333/2008/EC OJ 2008 L 354/16); and enzymes (Regulation 1332/2008/EC OJ 2008 L 354/7), and includes Regulation 1169/2011/EU on the provision of food information to consumers OJ 2011 L 304/18.

52 For instance, Baldwin et al., "Stewardship", n. 9 above, assert that, under a stewardship model, "public health programmes should . . ." – in other words stewardship is a tool for assessing programmes, not adjudication.

activities, Brownsword himself deals (implicitly) with how stewardship obligations apply to courts at length in *Rights, Regulation and the Technological Revolution*.<sup>53</sup> Given the lag or gaps between regulation and the development of new technologies; new knowledge and understanding of the world; and new social or cultural practices, courts have to deal with “regulatory disconnection”. Courts acting as interpreters of the law have what are essentially stewardship obligations to consider whether to adopt a creative approach to interpretation, and “reconnect” law to developments; or to adopt a more conservative approach in order to prompt the legislature to fill the “regulatory void” that will become apparent by leaving the law and developments disconnected. Courts are required to act as stewards of the regulatory compact by distinguishing between “unproductive” and productive disconnection.<sup>54</sup> For Brownsword,<sup>55</sup> productive disconnection arises where there is a genuine question about whether, and how, developments in science and society fit within the spirit and intent of the regulatory scheme. In those circumstances, courts act as stewards when they decline to use creative or purposive interpretation to solve a problem that really needs to be addressed through law and policy-making processes.<sup>56</sup> “Reconnection” of law with developing science in society, by courts adopting purposive interpretations of legislative texts, is only “intelligent” or “smart” in Brownsword’s terms if the disconnection is merely “descriptive”<sup>57</sup> and “unproductive”.<sup>58</sup> Otherwise, courts should maintain the disconnections, as these will produce a realignment of the regulatory arrangements through legislative activity.<sup>59</sup> Whether courts adopt a purposive approach depends upon how they judge the “regulatory tilt”<sup>60</sup> – in other words the default position set by regulators.<sup>61</sup> Courts have stewardship responsibilities to consider their role (through avoiding creative interpretations that “paper over the cracks”) in re-opening debates that legitimate regulatory choices in pluralist societies.

Now, when we think about this stewardship role of courts, and its relationship with the stewardship role of the legislature, in terms of the Court and the EU legislature, the first obvious difference between the EU and a state is that the EU legislature is hopelessly slow at responding to changing scientific knowledge and information, or cultural practices, because it is full of veto points (significantly more so than national legislatures).<sup>62</sup> The EU legislative processes have been widely criticised as being insufficiently legitimate, including where the EU legislates in areas such as public health, where law interfaces with science and

53 RRTR, n. 22 above, ch. 6, “The challenge of regulatory connection”.

54 Ibid. pp. 166–7, 184.

55 Relying on Lon Fuller’s work, especially L Fuller, *The Morality of Law* (New Haven: Yale UP 1969), pp. 209–10; L Fuller, “Positivism and fidelity to law – a reply to Professor Hart” (1957–58) 71 *Harvard Law Review* 630, cited in RRTR, n. 22 above, pp. 161 and 167.

56 RRTR, n. 22 above, p. 167.

57 Where the descriptions in law or policy decisions no longer correspond to developments in science and/or society, *ibid.* p. 166.

58 Where developments in science and society are within the spirit and intent of law (or policy decisions), although not in the letter of the law, *ibid.* p. 167, see also p. 183.

59 *Ibid.* p. 184

60 *Ibid.* p. 172–3

61 *Ibid.* p. 21. See also R Thaler and C Sunstein, *Nudge* (London: Penguin 2008) which makes much of the default position of regulatory arrangements.

62 G Tsebelis and X Yataganas, “Veto players and decision-making in the EU after Nice. policy stability and bureaucratic/judicial discretion” (2002) 40 *Journal of Common Market Studies* 283–307; F Scharpf, “The joint decision trap: lessons from German federalism and European integration” (1988) 66 *Public Administration* 239–78.

society.<sup>63</sup> These features of the EU legislative process might mean that we need a different calibration of purposive reconnection for the Court. Brownsword's purposive reconnection is based upon an assumption that the legislature will intervene, within a reasonable timeframe, to fill the gap and reconnect the law and the new development. It also assumes that the legislative process is legitimate and appropriate. To make those assumptions in the context of EU legislation is problematic. For instance, we might point to the more than 10 years that it took the EU to agree the Directive on the Legal Protection of Biotechnological Inventions, and the significant discussion with respect to its legitimacy in doing so,<sup>64</sup> or the protracted, highly contested (and ongoing)<sup>65</sup> legislative process concerning EU-level regulation of tobacco<sup>66</sup> and its advertising.<sup>67</sup> Because of these

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- 63 See, for instance, B Kohler-Koch and B Rittberger (eds), *Debating the Democratic Legitimacy of the European Union* (Lanham MD: Rowman & Littlefield 2007); Weiler et al., "European democracy", n. 30 above; S Jasanoff, *Designs on Nature. Science and Democracy in Europe and the United States* (New Jersey: Princeton UP 2005).
- 64 Directive 98/44/EC on the legal protection of biotechnological inventions OJ 1998 L 213/13. For discussion see e.g. E Cloatre, "From international ethics to European Union policy: a case study on biopiracy in the EU's Biotechnology Directive" (2006) 28 *Law and Policy* 345–67; T Hervey and H Black, "The European Union and the governance of stem cell research" (2005) 12 *Maastricht Journal of European and Comparative Law* 11–48, at pp. 32–8; E R Gold and A Gallochat, "The European Biotech Directive: past as prologue" (2001) 7 *European Law Journal* 331–66; R Goldberg and J Lonbay (eds), *Pharmaceutical Medicine, Biotechnology and European Law* (Cambridge: CUP 2000).
- 65 Amended proposal for a Council Directive on the structure and rates of excise duty applied to manufactured tobacco COM(2010) 641 final; Proposal for a Council Directive on the structure and rates of excise duty applied to manufactured tobacco COM(2007) 587 final.
- 66 Council Directive 2010/12/EU amending Directives 92/79/EEC, 92/80/EEC and 95/59/EC on the structure and rates of excise duty applied on manufactured tobacco and Directive 2008/118/EC OJ 2010 L 50/1; Council Decision 2004/513/EC concerning the conclusion of the WHO Framework Convention on Tobacco Control OJ 2004 L 213/8; Commission Decision 2003/641/EC on the use of colour photographs or other illustrations as health warnings on tobacco packages OJ 2003 L 226/24; European Parliament and Council Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the member states concerning the manufacture, presentation and sale of tobacco products OJ 2001 L 194/26; Council Directive 1999/81/EC of 29 July 1999 amending Directive 92/79/EEC on the approximation of taxes on cigarettes, Directive 92/80/EEC on the approximation of taxes on manufactured tobacco other than cigarettes and Directive 95/59/EC on taxes other than turnover taxes which affect the consumption of manufactured tobacco OJ 1999 L 219/47; Council Directive 92/80/EEC of 19 October 1992 on the approximation of taxes on manufactured tobacco other than cigarettes OJ 1992 L 316/10; Council Directive 92/78/EEC of 19 October 1992 amending Directives 72/464/EEC and 79/32/EEC on taxes other than turnover taxes which are levied on the consumption of manufactured tobacco OJ 1992 L 316/5; Council Directive 92/41/EEC of 15 May 1992 amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the member states concerning the labelling of tobacco products OJ 1992 L 158/30.
- 67 Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products OJ 2003 L 152/16; Directive 98/43/EC of the European Parliament and of the Council of 6 July 1998 on the approximation of the laws, regulations and administrative provisions of the member states relating to the advertising and sponsorship of tobacco products OJ 1998 L 213/9; Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in member states concerning the provision of audiovisual media services OJ 2010 L 95/1, Articles 9(d), 10(2) and 11(4); Directive 2007/65/EC of the European Parliament and of the Council of 11 December 2007 amending Council Directive 89/552/EEC on the coordination of certain provisions laid down by law, regulation or administrative action in member states concerning the pursuit of television broadcasting activities OJ L 2007 332/27, Articles 3e (d), 3f (2) and 3g (3); Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee – Report on the implementation of the tobacco advertising directive (2003/33/EC) COM(2008) 330 final. For discussion, see M McKee, T Hervey and A Gilmore, "Public health policies" in E Mossialos, G Permanand, R Baeten and T Hervey (eds), *Health Systems Governance in Europe: The role of European law and policy* (Cambridge: CUP 2010), pp. 262–5; D Wyatt,

features of the EU legislative process, super-stewardship – a version of stewardship adjusted for the Court – might involve a greater degree of “unproductive disconnection”, and thus an enhanced role for judicial creativity. Whether we want to entrust the Court with this responsibility is a matter of disagreement.<sup>68</sup> But super-stewardship and an obligation to consider a recalibrated choice between intelligent purposive reconnection and productive disconnection could provide a yardstick by which to assess whether the Court is properly discharging such responsibility.

**Objection 5: Most of the EU’s public health policy involves only policy, or at best, soft law. The scope for Court involvement is minimal.**

The EU’s public health policy, as discussed so far in this article, defined by reference to Article 168 TFEU, is administered by the European Commission’s Directorate General (DG) for Health and Consumers (SANCO). DG SANCO seeks to work with various EU agencies<sup>69</sup> with responsibilities for specific public health fields, such as food safety,<sup>70</sup> environmental protection<sup>71</sup> and communicable diseases.<sup>72</sup> DG SANCO has had some success, especially in awareness-raising of high priority health issues, through operating discrete, niche, public health programmes, such as those on cancer<sup>73</sup> and

[n. 67 continued] “Community competence to regulate the internal market” in M Dougan and S Currie, *50 years of the European Treaties: Looking back and thinking forward* (Oxford: Hart 2009); T Hervey, “Up in smoke: Community (anti) tobacco law and policy” (2001) 26 *European Law Review* 101–25; T Hervey, “Community and national competence in health after tobacco advertising” (2001) 38 *Common Market Law Review* 1421–46.

68 Probably the best-known area for critique of the Court as a forum for making these kinds of judgments concerns its human rights jurisprudence. See, seminally, J Coppell and A O’Neill, “The European Court of Justice: taking rights seriously?” (1992) 29 *Common Market Law Review* 669–92; and J H H Weiler and N Lockhart, “Taking rights seriously” seriously: the European Court and its fundamental rights jurisprudence” (1995) 32 *Common Market Law Review* 51–94 and 579–620. See also e.g. D R Phelan, “Right to life of the unborn v promotion of trade in services: the European Court of Justice and the normative shaping of the European Union” (1992) 55 *Modern Law Review* 670–89; B de Witte, “The past and future role of the European Court of Justice in the protection of human rights” in P Alston (ed.), *The EU and Human Rights* (Oxford: OUP 1999).

69 For discussion of the roles of agencies in the EU, see e.g. D Geradin, R Muñoz and N Petit (eds), *Regulation through Agencies in the EU: A new paradigm of European governance* (Cheltenham: Edward Elgar 2005); Vos, *Institutional Frameworks*, n. 51 above; O De Schutter, N Lebesis and J Paterson (eds), *Governance in the European Union* (Luxembourg: European Communities 2001).

70 European Food Safety Authority [www.efsa.europa.eu/](http://www.efsa.europa.eu/) (accessed January 2011). See Vos and Wendler, *Food Safety Regulation*, n. 51 above; Ansell and Vogel, “contested governance”, n. 51 above.

71 European Environment Agency [www.eea.europa.eu/](http://www.eea.europa.eu/) (accessed January 2011). See D A Westbrook, “Environmental policy in the European Community: observations on the European Environment Agency” (1991) 15 *Harvard Environmental Law Review* 257; D Chalmers, “Inhabitants in the field of European Community environmental law” (1998–99) 5 *Columbia Journal of European Law* 39–79.

72 ECDC [www.ecdc.europa.eu/en/Pages/home.aspx](http://www.ecdc.europa.eu/en/Pages/home.aspx) (accessed January 2011). See Greer, “The ECDC”, n. 49 above, and Elliott et al., “Mapping disease”, n. 49 above.

73 Resolution of the Council and representatives of the governments of the member states, meeting within Council of 7 July 1986, on “Europe against cancer”, OJ 1986 C 184/19; Decision 88/351/EEC on “Europe against cancer” OJ 1988 L 160/52; Decision 90/238/EEC on “Europe against cancer 2” OJ 1989 L 346/1; Decision 646/96/EC on “Europe against cancer 3” OJ 1996 L 95/9; Council Recommendation of 2 December 2003 on cancer screening OJ 2003 L 327/34, now funded by European Parliament and Council Decision 1350/2007/EC establishing a second programme of Community action in the field of health (2008–13) OJ 2007 L 301/3. For discussion, see L Trubek, M Nance and T Hervey, “The construction of a healthier Europe: lessons from the fight against cancer” (2008) 26 *Wisconsin International Law Journal* 804–43.

HIV/AIDS.<sup>74</sup> Although the programmes have extremely modest budgets, they have provided guidelines and positive incentives for change at the national health policy level.<sup>75</sup> Nevertheless, because much of this policy is based on programmes and soft law, the scope for involvement of the Court in EU health policy in this narrow sense is minimal. To what extent can stewardship apply to the Court if its adjudicatory role in EU public health policy is so minimal?

To the objection that much of EU public health policy does not involve hard law, and so Court involvement is minimal, we might observe that, in addition to the EU's public health policy in this narrow sense, many other policies directly relevant to public health also fall within the scope of EU activity. For example, EU law and policy on illicit drugs has been developed within its policy on "freedom, security and justice".<sup>76</sup> Responsibility for the EU's borders, a vital defence against smuggling of narcotics and tobacco, resides with DG Justice. EU food safety policy, and policy on the EU's food supply, important for public health questions such as obesity,<sup>77</sup> has been developed through the common agricultural policy, and responsibility for food safety now resides with the European Food Safety Authority.<sup>78</sup> Public health research, of which the European Union is now a major funder, is the responsibility of DG Research, while consistent Europe-wide information on health and its determinants is collected by Eurostat.<sup>79</sup> Health and safety at work is covered by DG Employment.<sup>80</sup> The EU's long-standing environmental policy, with a significant body of

74 Decision 91/317/EEC "Europe against AIDS 1" OJ 1991 L 175/26; Decision 647/96 "Europe against AIDS 2" OJ 1996 L 95/16; European Parliament and Council Decision 1786/2002/EC adopting a programme of Community action in the field of public health 2003–2008 OJ 2002 L 271/1; European Commission, *Communication on Combating HIV/AIDS in the European Union and neighbouring countries*, 2009–2013 COM(2009) 569 final, funded by European Parliament and Council Decision 1350/2007/EC establishing a second programme of Community action in the field of health (2008–13) OJ 2007 L 301/3.

75 Trubek et al., "The construction of a healthier Europe", n. 73 above; L Trubek, T Oliver, C-M Liang, M Mokrohisky and T Campbell, "How regulatory frameworks fight cancer: two examples from the United States and the European Union" (25 August 2010) 14 *Journal of Health Care Law and Policy*; University of Wisconsin Legal Studies Research Paper No 1128, available at SSRN: <http://ssrn.com/abstract=1665187> (accessed January 2011).

76 Council of the European Union, *EU Drugs Strategy 2005–2012*, 22 November 2004, <http://register.consilium.europa.eu/pdf/en/04/st15/st15074.en04.pdf> (accessed January 2011); EU Drugs Action Plan for 2009–2012 OJ 2008 C 326/7; European Parliament and Council Decision 1150/2007/EC establishing for the period 2007–2013 the specific programme "Drug prevention and information" as part of the General Programme "Fundamental rights and justice" OJ 2007 L 257/23; European Parliament and Council Regulation 1920/2006/EC on the European Monitoring Centre for Drugs and Drug Addiction OJ 2006 L 376/1; Council Framework Decision 2004/757/JHA laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking OJ 2004 L 335/8; Council Joint Action 96/698/JHA on cooperation between customs authorities and business organizations in combating drug trafficking OJ 1996 L 322/3. It appears that the EU's anti-drugs policy is now also being developed in the context of EU citizenship and freedom to provide services in the internal market, see Case C-137/09 *Josemans v Burgemeester van Maastricht* judgment of 16 December 2010, nyr in ECR.

77 Faculty of Public Health, *A CAP on Health: The impact of the EU Common Agricultural Policy on public health* (London: Faculty of Public Health 2007).

78 See n. 70 above.

79 <http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/> (accessed January 2011); M McKee and J Ryan, "Monitoring health in Europe: opportunities, challenges and progress" (2003) 13(3 Suppl.) *European Journal of Public Health* 1–4.

80 With significant involvement of the European Agency for Health and Safety at Work <http://osha.europa.eu/en/front-page> (accessed January 2011) and the European Foundation for the Improvement of Living and Working Conditions [www.eurofound.europa.eu/](http://www.eurofound.europa.eu/) (accessed January 2011).

environmental law involving matters such as air and water quality,<sup>81</sup> waste disposal,<sup>82</sup> and noise pollution,<sup>83</sup> all with direct consequences for public health, falls under the auspices of DG Environment. Several of these policy areas, which relate to the EU’s contribution to public health protection and promotion, include binding legal norms, and therefore there is scope for the Court to be involved in their interpretation and application through its jurisdiction, especially that under Article 267 TFEU. Where the Court interprets that law, we can consider the extent to which it complies with the obligations of stewardship.

Secondly, though, and more important, in terms of the contribution of the Court to public health protection or promotion within the EU, is the interface between internal market law and public health. Internal market law aims to create and sustain the conditions of free movement of the factors of production, and free and fair competition, within the geographical territory of the EU. Because of relationships between public health and free availability or free circulation of certain types of products or services which may jeopardise public health, internal market law exerts a major influence on public health.<sup>84</sup> This influence is both in terms of general safety of products and services, and in terms of specific products which have a particularly detrimental effect upon public health; and services, such as advertising services, related to those products. In particular, the application of internal market law to tobacco and alcohol<sup>85</sup> has had profound implications for national laws, regulations and administrative practices and policies dealing with those products, and the advertising of these products, as part of national public health policies.<sup>86</sup>

Internal market law thus represents the most important site of engagement of the Court with public health. Internal market law is not simply deregulatory. It allows for the protection of public interests other than the interest in free trade and open competition. But national rules, administrative practices or policies that have the effect of impeding cross-border trade in goods or services have to be justified within the terms of internal

81 Includes European Parliament and Council Directive 2008/50/EC on ambient air quality and cleaner air for Europe OJ 2008 L 152/1; Council Directive 96/62/EC on ambient air quality assessment and management OJ 1996 L 296/55; and Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy OJ 2000 L 327/1.

82 Includes European Parliament and Council Directive 2008/98/EC on waste and repealing certain Directives OJ 2008 L 312/3.

83 Includes Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise OJ 2002 L 189/12.

84 Recently, for instance, the Court has considered whether national rules, prohibiting the import of blood products from donations which were not entirely unpaid, breach internal market law, see Case C-421/09 *Humanplasma* 9 December 2010, nyr in ECR.

85 See e.g. Cases C-1/90 & 176/90 *Aragonesa* [1991] ECR I-4151; Case C-189/95 *Franzen* [1997] ECR I-5909; Case C-405/98 *Gourmet International Products* [2001] ECR I-1795; Case C-262/02 *Commission v France (Loi Evin)* [2004] ECR I-6569; Case C-429/02 *Bacardi France v TF1* [2004] ECR I-6613; Case C-434/04 *Abokainen and Leppik* [2006] ECR I-9171; Case 170/04 *Rosengren* [2007] ECR I-4071; Case C-186/05 *Commission v Sweden (Alcohol Monopoly)* [2007] ECR I-129. At least arguably, older case law such as Case 120/78 *Cassis de Dijon*, n. 7 above, Case 75/81 *Blesgen* [1982] ECR 1211 and Case 178/84 *Commission v Germany (Beer Purity)* [1987] ECR 1227 also falls into this category.

86 For instance, internal market law forced Finland to dismantle elements of its state alcohol monopoly and, shortly afterwards, it reduced domestic prices as a consequence of its inability to block imports of cheap drinks from nearby Estonia. As predicted, there has been a steep rise in deaths from alcohol-related disorders, see A Koski, R Sirén, E Vuori and K Poikolainen, “Alcohol tax cuts and increase in alcohol-positive sudden deaths: a time-series intervention analysis” (2007) 102(3) *Addiction* 362–8. Proposals in 2009 by the Scottish government and the chief medical officer for England to impose a minimum price on alcohol prompted the proposed use of EU litigation to challenge such measures, see M McKee, P Belcher and T Hervey, “Reducing harm from alcohol” (2009) *BMJ* 338, b1191.

market law.<sup>87</sup> The Court is charged with oversight of that process and the balancing of values it implies. Through applying legal principles, such as that of non-discrimination and proportionality, in determining whether national public health policies are justified, the Court determines the extent to which public health interests can be articulated, and protected, within the constraints of internal market law. This broad sense of EU public health policy is thus where a stewardship obligation could most obviously apply to the Court in the field of public health.

Moreover, in the context of internal market law, there is a stronger reason than the “regulatory lag” phenomenon discussed above to adopt a different calibration of or approach to intelligent purposive reconnection/creative interpretation and to productive disconnection/literal interpretation to that provided by the stewardship model – a super-stewardship model. The reason concerns the constitutional position of the core provisions of directly effective<sup>88</sup> internal market law. Being part of the TFEU, these measures of EU law cannot be amended except by treaty revision and, in fact, the core provisions have not been amended<sup>89</sup> in the entire lifetime of what is now the EU.<sup>90</sup> Treaty revision involves an even more difficult process than adoption of EU legislation, with every member state enjoying a veto. In practice, therefore, creative interpretation is a primary means by which these measures of EU law can be altered through time and in response to new challenges or developments, including those in the public health field.

Internal market law enjoys a position of “constitutional asymmetry” in the EU’s legal order. As several authors, notably Fritz Scharpf,<sup>91</sup> have argued, the law of the internal market embeds a constitutional favouring of free trade interests as opposed to other interests, including those of “social Europe”, such as employment conditions and social welfare provision. The constitutional asymmetry can also be said to extend to interests such as public health protection and promotion. While I have been (and remain) sceptical about the “strong” version of the constitutional asymmetry argument (in brief, because it reflects an insufficiently nuanced understanding of the way that the jurisprudence of the Court actually works in practice), I think that a “weak” version of the argument stands. It is not that EU law, as interpreted and applied by the Court and national courts, is always deregulatory and always favours free trade interests over other interests. The possibility to

87 Article 36 TFEU; Articles 52 and 62 TFEU; Case 120/78 *Cassis de Dijon*, n. 7 above; Case C-55/94 *Gebhardt* [1995] ECR I-4165.

88 That is, a measure that can be relied upon in litigation before a national court.

89 Save by renumbering.

90 Witness the difficulties of the French to ensure that the “Anglo-Saxon model” was headed off by the Treaty of Lisbon – although there are new provisions about “services of general interest”, and although the term “competition” alone was removed from the provision about the aims of the EU, to be replaced with an aim of “a highly competitive social market economy”, Article 3(3) TEU.

91 F Scharpf, “A new social contract? Negative and positive integration in the political economy of European welfare states” (1996) EUI Working Paper RSC 96/44; F Scharpf, “The European social model: coping with the challenges of diversity” (2002) 40 *Journal of Common Market Studies* 645–70; F Scharpf, “The joint-decision trap revisited” (2006) 44 *Journal of Common Market Studies* 845–64; F Scharpf, “Legitimacy in the multilevel European polity” (2001) FPIFG Working Paper 09/1 [www.mpifg.de/publications/workingpapers](http://www.mpifg.de/publications/workingpapers). See also e.g. C Joerges, “European economic law, the nation-state and the Maastricht Treaty” in R Dehousse (ed.), *Europe after Maastricht: An ever closer union* (München: Beck 1994); more recently, C Joerges and F Rödl, “On the ‘social deficit’ of the European integration project and its perpetuation through the ECJ judgments in *Viking* and *Laval*” (2008) RECON Online Working Paper 2008/06 [www.reconproject.eu/projectweb/portalproject/RECONWorkingPapers.html](http://www.reconproject.eu/projectweb/portalproject/RECONWorkingPapers.html); C Offe, “The European model of ‘social’ capitalism: can it survive European integration?” (2003) 11 *Journal of Political Philosophy* 437–69; L Moreno and B Palier “The Europeanization of welfare: paradigm shifts and social policy reforms”, in P Taylor-Gooby, (ed.), *Ideas and Welfare State Reform in Western Europe* (New York: Palgrave Macmillan 2005); G Davies, “The process and side-effects of harmonisation of European welfare states” (2006), Jean Monnet Working Paper, No 02/06, 1–64.

*justify* restrictive regulatory activities remains available. It is the fact that the discussion of the matter becomes framed by the discourse of internal market law, and indeed, in the context of the EU’s membership of the WTO, also by the discourse of WTO law. This framing effect may discourage or impede courts from articulating arguments on any basis other than that of liberalism, and result in the resolution of disputes within a pluralist society articulated only in terms of free trade and markets. As I expressed it in the context of the *Diane Blood* litigation, concerning export of frozen sperm from the UK to a Belgian fertility clinic in circumstances where the use of the sperm would have been unlawful in the UK:

the applicability of E[U] law may operate to constrain, or to skew in certain directions, debates (including those carried out through litigation) in the Member States concerned with [public health] . . . the application of E[U] law may encourage or at least enable national courts to resolve cases by applying economic concepts, for instance relating to trade in goods and services. The European Union legal order, with its underlying principles of market openness, and conceptualisation of individuals as market actors, might aid this type of approach. Indeed, the *Blood* case may be an example of such an interplay between national and European regulatory orders. The Court of Appeal’s judgment makes scant reference to the justification issue, perhaps sending a signal that it viewed Diane Blood’s rights in E[U] law as indisputable, which was clearly not the case . . . it was at least arguable that a public interest justification could have been found to support the Authority’s refusal to allow Diane Blood to export the sperm.<sup>92</sup>

The way that EU law (and indeed WTO law) frames non-free trade interests, such as public health protection and promotion, is as *exceptions* to the (liberal) norm of freedom of movement.<sup>93</sup> Stewardship obligations in the public health context require a quite different framing. The possibility of “reconnection” of the gap between emergent understandings of what is needed for public health protection with the relevant internal market law is not feasible through legislative amendment – the place of the internal market is “constitutionally embedded” within EU law. This embeddedness suggests that the Court, if exercising a super-stewardship approach, should hesitate to adopt literal interpretations of the relevant regulatory system/strategy (i.e. internal market law), where these will not and cannot protect public health, on the basis that “this is for the legislature to fix”. The disconnection between internal market law and public health protection is “unproductive”, because the EU legislature cannot “fix” internal market law in that sense. Thus, if the Court is to act as a super-steward, we would expect from it greater creative interpretation of internal market law, so as to “reconnect” internal market law with emergent understandings of how best to protect and promote public health within the EU.

**Objection 6: Super-stewardship cannot serve as a model to assess the contribution of the Court in the field of internal market law, because stewardship and the internal market do not share a common frame of reference.**

The final objection to applying super-stewardship as a model or analytical framework to assess the work of the Court of Justice of the EU in determining the balance between free trade/fair competition and public health, discussed in this article, relates to the point above.

92 T Hervey, “Buy baby: the European Union and regulation of human reproduction” (1998) 18 *Oxford Journal of Legal Studies* 207–33, pp. 230–1.

93 See also, adopting a particular version of individualism, A Somek, *Individualism: An Essay on the authority of the European Union* (Oxford: OUP 2008), especially pp. 7; 10–11, 82–137, 184–99; A Somek, “The owl of Minerva: constitutional discourse before its conclusion” (2008) 71 *Modern Law Review* (2008) 473–89, p. 485 and fn. 38.

It concerns the very different frames of reference of stewardship and the internal market, encapsulated in the following quotations:

Once we venture beyond the gated and secure conditions of a community of rights, stewardship might prove to be a hostage to fortune . . .<sup>94</sup>

The [European] Union shall offer its citizens an area of freedom, security and justice without internal frontiers, in which the free movement of persons is ensured . . . The [European] Union shall establish an internal market<sup>95</sup> . . . The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured . . .<sup>96</sup>

The model of stewardship offered by Brownsword et al. operates essentially within a framework of constraint of state or public action, within a closed (“gated and secure”) “community of rights” (a state). The main addressees of stewardship are public authorities<sup>97</sup> and individuals who may be more or less healthy, and their “personal values”. By contrast, the way that the Court, when operating within the frame of reference of internal market law, conceptualises individuals (with their particular health needs and personal values) is as consumers (and producers) operating within an open (“without internal frontiers”) internal market. Individuals are not conceptualised here as human beings with health needs and choices relating to health. This conceptualisation or framing is inherent in the nature of internal market law, or at least internal market law as developed hitherto by the Court. Thus, the Court’s jurisdiction in internal market law and the idea of stewardship each involve a totally different frame of reference – one is about values within an implicitly closed community; the other is about the implicitly valued openness of the EU’s internal market. If we try to apply stewardship to the Court, the objection is that we will essentially be requiring the Court to ignore the constitutional framework within which it is obliged to operate, and apply a different framework (which respects the values encapsulated in the idea of stewardship, including not only autonomy but also substantive equality, which means different treatment for those who are more vulnerable). It is not legitimate to criticise an apple for not being a pear!

In response to this objection, we might observe that stewardship is used precisely to justify and respond to an “overly individualistic focus that has emerged as canonical . . . over recent decades”.<sup>98</sup> The very nature of public health goods is such that they can often outweigh liberal ideas about protecting individual liberties and freedoms,<sup>99</sup> including those pertaining to the creation and maintenance of the EU’s internal market. So, just as

94 R Brownsword, “So what does the world need now? Reflections on regulating technologies” in R Brownsword and K Yeung (eds), *Regulating Technologies: Legal Futures, regulatory frames and technological fixes* (Oxford and Portland OR: Hart 2008), p. 47.

95 Article 1 TEU.

96 Article 26(2) TFEU.

97 Of course, in the public health domain, we might wonder whether the state/public domain is really so distinct as it perhaps once was from the private domain. For instance, several (Beveridge model) national health authorities within the EU have experimented with contracting out services to private actors. The Bismarkian model health authorities have always used (at least quasi) private actors, such as insurance organisations. For discussion of the different arrangements for public health care in the EU’s member states, see e.g. W Palm, J Nickless, H Lewalle and A Coheur, *Implications of Recent Jurisprudence on the Coordination of Health Care Protection Systems* (Brussels: AIM 2000); V Hatzopoulos, “Health law and policy: the impact of the EU”, in G De Búrca (ed.), *EU Law and the Welfare State: In search of solidarity* (Oxford: OUP 2005), pp. 111–68; M Steffen, *Health Governance in Europe: Issues, challenges and theories* (London and New York: Routledge 2005). M Flear, *Does the Free Movement of Persons Cause Change in Healthcare Systems?*, unpublished PhD thesis, University of Nottingham, Nottingham, UK, 2006.

98 Baldwin et al., “Stewardship”, n. 9 above, p. 114.

99 Ibid.

stewardship is *precisely* about justifying or assessing departures from freedoms within a particular state, so we could use the same sort of reasoning, in the modified form of super-stewardship outlined above, to justify departures from freedoms (free movement, freedom to trade) within the internal market, and the individual rights in EU internal market law, that the Court must interpret and national courts must apply. Understood thus, a super-stewardship obligation would not only empower, but also require, the Court to reframe disputes concerning the balance between free trade and public health, so as to consider, by reference to the ladder of intervention, whether restrictions on free trade (at the “do nothing” rung of the ladder) are justified, and, by reference to the best-level ladder of intervention, who gets to decide.

By way of illustration, this final section of the article considers how super-stewardship, as outlined above, could be used as a standpoint for analysis and critique of the Court in the context of its jurisprudence on public health protection within EU internal market law. Obviously, the examples discussed here are selective. They are based on a review of the Court’s caselaw in public health fields, from the 1950s to 2009.<sup>100</sup>

In its early jurisprudence, the Court recognised that public health was essentially a matter for national administrations, allowing a wide margin of discretion to member states in this respect. As the Court put it, in a case involving national rules restricting the sale of medicinal products to pharmacies:

it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection [for human health] they intend to assure and in particular how strict the checks to be carried out are to be.<sup>101</sup>

The Court’s interpretation here of internal market law may be characterised as intelligent purposive reconnection. At this point in time, there are no EU-level rules on selling arrangements for pharmaceuticals, nor is the creation of such rules by the EU legislature envisaged. The Court thus operates within a super-stewardship model by interpreting internal market law to give significant regulatory space to national administrations. The national policy at issue here is relatively high up the ladder of intervention, involving a *de facto* restriction of individual choice, by restricting the places in which certain products, deemed by the national administration to be potentially harmful to public health, can lawfully be sold. But the restriction of choice is justified by reference to understanding at the time of the harm or potential harm to public health were pharmaceuticals to be sold to consumers outside the setting of a pharmacy, where professionally qualified staff can give tailored advice to offset the information deficit that the consumer of pharmaceuticals has, and to prevent a future charge on national healthcare systems if pharmaceuticals are consumed and harm to the consumer’s health ensues. The question of whether that extent of intervention with individual liberty (to trade) is justified – and, crucially, who gets to decide – is informed also by the best-level ladder of intervention. In the absence of either EU-level or internationally agreed rules on selling arrangements for pharmaceuticals, and given the fact that pharmaceuticals markets were essentially national, the decision to permit national-level rules or policies is justified.

However, mindful that allowing too wide a discretion to member states in this respect would have completely undermined the Court’s drive to create the internal market in

100 I am grateful to Michelle Dunning for her research assistance under the University of Sheffield CILASS SURE Summer Intern Scheme 2009.

101 Case C-62/90 *Commission v Germany* [1992] ECR I-2575, para 10. This case dates from the early 1990s. It echoes earlier cases dating back to the 1970s: Case 104/75 *De Peijper* [1976] ECR I-613; Case 174/82 *Sandoz* [1983] ECR 2445; Case 227/82 *van Bennekom* [1983] ECR 3883; Case 97/83 *Melkunie* [1984] ECR 2367; Case 247/84 *Motte* [1985] ECR 3887; Case 304/84 *Muller* [1986] ECR 1511.

goods,<sup>102</sup> the Court has also, through the principle of proportionality, developed some control over national public health protection policies. National regulation is permitted in EU law, subject to the proviso that such regulation is proportionate to the aims of the internal market.<sup>103</sup> There are essentially two versions of the proportionality test (a stronger and a weaker test),<sup>104</sup> and the Court has applied different versions at different points in time to its scrutiny of the balance between free trade as implied by the logic of the internal market and protection of public health.

From the beginning of the 1970s, into the mid-1980s, the Court applied the weaker version of the proportionality test to its scrutiny of national measures designed to protect public health. For instance, in cases involving national rules designed to protect against known and agreed risks to human health – e.g. from pesticides in food,<sup>105</sup> or from certain levels of active coliform bacteria and active micro-organisms in milk products<sup>106</sup> – the Court stresses that there is a known risk to human health, that harmonised EU law on the products concerned is incomplete and that therefore different member states may adopt different approaches without breaching EU law. For instance, the Court explained:

In so far as the relevant [EU] rules do not cover certain pesticides, the Member States may regulate the presence of residues of those pesticides on foodstuffs in a way which varies from one country to another according to the climatic conditions, the normal diet of the population and their state of health.<sup>107</sup>

The weaker version of proportionality also applied in cases where the science was less clear. For instance, in *Rene-Zentralefinanz GmbH v Landwirtschaftskammer*,<sup>108</sup> the Court held that the different treatment of imported and domestic products does not breach EU law, so long as effective measures prevent the distribution of contaminated domestic products and there is *reason to believe* that there is a risk of harmful organisms spreading without inspection of imported products.<sup>109</sup> There was no need to *prove* the risk – it was enough to

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102 If member states could adopt any national policies they wished, simply by invoking the grounds, however spurious, of human health protection, then the single market would be easily thwarted by protectionist national rules.

103 Case 272/80 *Biologische Producten* [1981] ECR 3227; Case 266 & 267/87 *R v Royal Pharmaceutical Society of Great Britain, ex parte Association of Pharmaceutical Importers* [1989] ECR 1295; Case C-60/89 *Monteil* [1991] ECR I-1547; Case 293/94 *Brandsma* [1996] ECR 3159.

104 W Sauter, “Services of general economic interest and universal service in EU law” (2008) 33 *European Law Review* 167–93. In the weakest version, a measure that is prima facie suitable to protect public health, and is not manifestly disproportionate, is permissible. In the strictest version, only the least restrictive means of protecting public health are permissible, and the relevant body must show that no other imaginable measure could achieve that objective with a lesser detrimental effect to free trade.

105 Case 94/83 *Heijn BV* [1984] ECR 3263 and Case 54/85 *Mirepoix* [1986] ECR 1067.

106 Case 97/83 *Melkunie*, n. 101 above.

107 Case 54/85 *Mirepoix*, n. 105 above, para. 15.

108 Case 4/75 [1975] ECR 843, involving an inspection system to protect plant health.

109 Para. 8.

show that it was reasonable for the national administration to believe it existed. This softer version of proportionality continued in cases throughout the 1980s.<sup>110</sup>

Again we can say that the Court adopts intelligent purposive reconnection here, leaving regulatory space for national administrations to protect and promote public health within the context of the “letter” of internal market law. The restriction or elimination of choice entailed in the regulatory structures at issue in these cases (which involved matters such as bans on additives in food), which is relatively high on the intervention ladder, is justified by the reasonable belief that serious risks to human health are present, although in precautionary examples such as these the case is less strongly persuasive than that outlined in the example above. Again the best-level ladder of intervention, given that there is a lack of EU-level regulation of the matters concerned, indicates that national levels are the appropriate level within which the procedures whereby the different interests at stake are balanced should take place.

However, by the early 1990s, the Court began to modify its jurisprudence in this field, by adding a procedural dimension to its application of proportionality. So in a series of cases involving the addition of sorbic acid,<sup>111</sup> the nutrient L-Carnitine,<sup>112</sup> and the nutrient Co-enzyme Q10,<sup>113</sup> the Court’s position moved towards a stricter version of proportionality, by scrutinising the transparency, speed and accessibility of the national marketing authorisation procedures at issue. The context for this development is the fact that the EU had by this time incrementally developed its own regulatory capacity to adopt law and policy on at least some sources of risk to human health, in particular within the food chain.<sup>114</sup> Originally, following decisions taken by member states, the EU began to

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110 See e.g. Case 174/82 *Sandoz*, n. 101 above; Case 53/80 *Ejsssen* [1981] ECR 409; Case 247/84 *Motte*, n. 101 above; and Case 304/84 *Muller*, n. 101 above. In Case 174/82 *Sandoz*, n. 101 above, the Court reasoned: “In view on the one hand of scientific uncertainties and on the other of the fact that the harmfulness of vitamins depends on the quantity absorbed with the whole nutrition of a person *it is not possible to say with certainty whether any food to which vitamins have been added is harmful or not.*” and “*Scientific research does not appear to be sufficiently advanced to be able to determine with certainty the critical quantities and the precise effects*” (paras 10–11, emphasis added). Similar reasoning is found in Case 53/80 *Ejsssen* [1981] ECR 409: “It is indeed accepted that the increasingly widespread use of that substance, not only in milk but also in numerous preserved products, has revealed *the need, both at national level in certain countries and at international level, to study the problem of the risk* which the consumption of products containing the substance presents, or may present, to human health” and “*although those studies have not as yet enabled absolutely certain conclusions to be drawn* regarding the maximum quantity of nisin which a person may consume daily without serious risk to his health” (para. 13, emphasis added).

111 Case C-42/90 *Bellon* [1990] ECR I-4863.

112 Case C-24/00 *Commission v France (Red Bull)* [2004] ECR I-1277.

113 Case C-95/01 *Greenham and Abel* [2004] ECR I-1333.

114 These activities related to the common agricultural policy, a policy area that was originally seen as rather separate from internal market law. In 1964, the Commission set up “a panel of veterinary experts”, to recommend whether infected bovines or swine could lawfully be prohibited entry into a member state, Directive 64/432/EEC, OJ 1964 L 121/1977, Article 10. The Standing Committee on Foodstuffs was set up in 1969, Decision 69/414/EEC OJ 1969 L 291/9. These bodies now form part of the Standing Committee on the Food Chain and Animal Health (Regulation 178/2002/EC, as amended, n. 51 above), within the European Food Safety Authority. Originally deciding on matters that seem only technical (e.g. whether a particular additive counts as a “colour” for the purposes of EU legislation (Directive 94/36/EC OJ 1994 L 237/13); whether additives are being used in accordance with EU legislation (Directive 95/2/EC OJ 1995 L61/1), over time these comitology procedures built up a body of EU-level decisions about the risk to human health of various food additives and hazards in food (including toxins and biological hazards such as bacterial pathogens/zoonotic agents). So, for instance, in 2002, the Commission adopted a decision that the additive Konjac (E425) was no longer authorised within products marketed in the EU. See Holland and Pope, *EU Food Law*, n. 51 above, pp. 55–6.

develop its own idea of scientific knowledge<sup>115</sup> informing tolerable (and intolerable) levels of risk concerning human health within the food chain. The Court's jurisprudence, developing an increasingly suspect position towards *nationally* determined versions of hazard, supports this EU-level legislative and policy development.

In these circumstances, the question is whether, considering the best-level ladder of intervention, the EU level is the appropriate level within which decisions about risk should be made. The products concerned are not the subject of global restrictions or bans on their trade.<sup>116</sup> But is there sufficient commonality between the member states of the EU in terms of the contours of the public health problem being tackled here, which is not shared globally, so as to justify special EU-level rules protecting the health of a community or group of communities beyond that of the nation state (the EU), but falling short of the global community? Is there an EU-level law or policy that significantly interfaces with public health protection? If there is (the common agricultural policy and the EU's food law probably constitute such policies), then the Court's approach in supporting the emergent EU-level law and policy is justified. We might, for instance, suggest that a European social and cultural approach to food additives exists,<sup>117</sup> and justifies the EU level of intervention. However, if such a case cannot be made out, then a super-stewardship analysis would suggest that this is a matter best left to national levels.

Moreover, the way that the Court reasons in its jurisprudence concerning the interface between the internal market and public health is insufficiently sensitive to the ladder of

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115 Such knowledge being not only scientifically, but also socially and politically constructed, see Jasanoff, *Designs on Nature*, n. 63 above.

116 Such as, for example, nuclear or chemical weapons, or narcotics. The Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction 1993 [www.opcw.org/chemical-weapons-convention/](http://www.opcw.org/chemical-weapons-convention/) aims to eliminate an entire category of weapons of mass destruction by prohibiting the development, production, acquisition, stockpiling, retention, transfer or use of chemical weapons by states. Private trade in chemical or nuclear weapons is de facto prohibited by the Missile Technology Control Regime (with 34 members) [www.mtrc.info/english/index.html](http://www.mtrc.info/english/index.html); the Wassenaar Arrangement (with 40 members) [www.wassenaar.org/controllists/index.html](http://www.wassenaar.org/controllists/index.html); the Nuclear Suppliers Group (with 46 members) [www.nuclearsuppliersgroup.org/Leng/03-member.htm](http://www.nuclearsuppliersgroup.org/Leng/03-member.htm); and the Australia Group (with 41 members) [www.australiagroup.net/en/index.html](http://www.australiagroup.net/en/index.html). The UN has been working towards an Arms Trade Treaty, and agreement in principle was reached in October 2009. See [www.fc.gov.uk/en/global-issues/weapons/arms-trade-treaty/](http://www.fc.gov.uk/en/global-issues/weapons/arms-trade-treaty/). The UN's Single Convention on Narcotic Drugs 1961 [www.unodc.org/unodc/en/treaties/single-convention.html?pref=menu](http://www.unodc.org/unodc/en/treaties/single-convention.html?pref=menu) limits the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes. The UN's Convention on Psychotropic Substances 1971 [www.unodc.org/unodc/en/treaties/psychotropics.html?pref=menu](http://www.unodc.org/unodc/en/treaties/psychotropics.html?pref=menu) establishes an international control system for psychotropic substances.

117 This might, for instance, be illustrated by the different approaches to genetically modified food and food ingredients in Europe as opposed to in the USA. Putting it simply, the USA considers that genetically modified products are essentially similar to non-genetically modified products, whereas the EU, though conceding that GM products are "like products", argues that their different production processes justify regulation and an exemption from the application of WTO law. Discussion of these differences has taken place in the context of whether the EU rules are compliant with WTO obligations, and within the WTO dispute settlement arrangements, in particular *EC-Measures Affecting the Approval and Marketing of Biotech Products Complaints by the USA, Canada and Argentina* (WT/DS291/R; WT/DS292/R; WT/DS293/R 29 September 2006). See the reviews in R Howse and P Mavroidis, "Europe's evolving regulatory strategy for GMOs: the issue of consistency with WTO law: of kine and brine" (2000) 24 *Fordham International Law Journal* 317–70; J Scott, "European regulation of GMOs and the WTO" (2003) 9 *Columbia Journal of European Law* 213–39; J G Carrau, "Lack of sherpas for a GMO escape route in the EU" (2009) 10 *German Law Journal* 1169–99. Another example is the attitudes to hormones in meat, see J Scott, "On kith and kine (and crustaceans): trade and environment in the EU and WTO" in J H H Weiler, *The EU, the WTO and NAFTA* (Oxford: OUP 2000), pp. 125–67; *EC Measures Concerning Meat and Meat Products (Hormones), Complaints by the USA and Canada* (WT/DS26/R; WT/DS48/R 18 August 1997).

intervention. In a large number of cases concerning food and alcohol labelling,<sup>118</sup> the Court has consistently held, applying the stronger version of the proportionality test, that providing consumer information (the second rung of the intervention ladder, after only the “do nothing” of unregulated free trade) is a proportionate response to public health concerns, and, crucially, that anything else is disproportionate. But, as Brownsword et al. point out, interventions that are information-based (such as nutrition labelling, anti-smoking adverts or drink-driving campaigns) may have the effect of increasing social inequalities.<sup>119</sup> Labelling of food or alcohol relies on the consumer’s ability to read and understand the labels, and translate the information presented into choices about which products to consume. More advantaged groups in society are more likely to be able to do this and thus avail themselves of health protection or promotion advice. Other factors, such as availability, convenience, presentation, familiarity, price and palatability, may play a significant role in consumer choices,<sup>120</sup> and because of this states may justifiably (in a stewardship sense) seek to regulate any or all of these through measures higher up the intervention ladder, such as prohibiting certain additives or restricting choice through restricting places where products may lawfully be sold.<sup>121</sup>

However, both in cases where the detriments to public health arising from the product or service relating to the product are contested<sup>122</sup> and in those, such as with respect to tobacco, where they are known and agreed upon,<sup>123</sup> the Court’s reasoning remains trapped within the (liberal) frame of constitutional asymmetry, where the individual is conceptualised as a consumer within a market, and regulatory activities that restrict free trade must be justified as exceptions to the rule of freedom. Given that the EU legislature, or, better, the governments of the member states in treaty-revision processes, in practice are unable to reconnect the text of the law with scientific and/or social and cultural developments in understanding of public health risks, the Court should be slow to adopt the productive disconnection approach, but rather should fix the disconnections by

118 See, for instance, Case 120/78 *Cassis de Dijon*, n. 7 above; Case 261/81 *Raw* [1982] ECR 3961; Case 94/82 *De Kievsorsch Groothandel-Import-Export* [1983] ECR 947; Case 178/84 *Commission v Germany (Beer Purity)*, n. 7 above; Case 274/87 *Commission v Germany (Meat Products)* [1989] ECR 229; Case C-67/88 *Commission v Italy (Edible Fats)* [1990] ECR I- 4285; Case 407/85 *Drei Glocken* [1988] ECR 4233; Case C-17/93 *Van der Veldt* [1994] ECR I-3537; Case C-123/00 *Bellamy* [2001] ECR I-2795; Case C-14/00 *Commission v Italy (Chocolate)* [2003] ECR I-513; Joined cases C-421/00, C-426/00 and C-16/01 *Sterbenz and Haug* [2003] ECR I-1065; Case C-24/00 *Commission v France (Red Bull)*, n. 112 above; Case C-270/02 *Commission v Italy (Sports Foods)* [2004] ECR I- 1559; Joined Cases C-158/04 and C-159/04 *Alfa Vita* [2006] ECR I- 8135; Case C-319/05 *Commission v Germany (Garlic Capsules)* [2007] ECR I- 9811; Case C-446/08 *Solgar Vitamin’s France* [2010] ECR I-3973. For critique, see Weatherill, “Recent case law”, n. 41 above; von Heydebrand u d Lasa, “Free movement”, n. 41 above; Brouwer, “Free movement”, n. 41 above; MacMaoláin, “Waiter”, n. 41 above; Unberath and Johnston, “The double-headed approach”, n. 41 above.

119 Nuffield Report, n. 8 above, p. 40, citing D Acheson, *Independent Inquiry into Inequalities in Health: Report* (London: The Stationery Office 1998); A Gepkens and LJ Gunning-Schepers, “Interventions to reduce socioeconomic health differences: a review of the international literature” (1996) 6 *European Journal of Public Health* 218–26.

120 Nuffield Report, n. 8 above, p. 41.

121 See, for instance, the Swedish rules on the sale of alcohol, Case C-434/04 *Abokainen and Leppik*, n. 85 above.

122 See, for instance, Case C-24/00 *Red Bull*, n. 112 above.

123 See e.g. Joined Cases 177 & 178/82 *van de Haar* [1984] ECR I-1797; Case C-376/98 *Tobacco Advertising I* [2000] ECR I-8419; Case C-491/01 *British American Tobacco* [2002] ECR I-11453; Case C-380/03 *Germany v European Parliament and Council of the European Union Tobacco Advertising II* [2006] ECR I-11573; Case C-74/99 *R v Secretary of State for Health and Others, ex parte Imperial Tobacco Ltd and Others* [2000] ECR I-08599; Case C-197/08 *Commission v France (Tobacco Retail Prices)* [2010] ECR I-1599; Case C-198/08 *Commission v Austria (Tobacco Retail Prices)* [2010] ECR I-1645; Case C-221/08 *Commission v Ireland (Tobacco Retail Prices)* [2010] ECR I-1669; Case C-571/08 *Commission v Italy (Tobacco Prices)* 24 June 2010 nyr in ECR.

intelligent purposive reconnection/creative interpretation of internal market law. That would be to adopt a super-stewardship approach.

### Conclusion

The article has shown the extent to which Brownsword et al.'s notion of stewardship provides an appropriate analytical model for critique of the EU's law and policy in the public health field. Having reviewed six key objections to the use of stewardship as such a model, the article concludes that stewardship can play such a role, provided that the concept of stewardship is modified to super-stewardship, to take account of the differences between the EU and the state. Super-stewardship relies on the idea of ladders of intervention, to assess whether regulatory interventions and restrictions on individual autonomy and choice are justified, and whether the relevant policy-making institutions have been involved in a particular regulatory decision concerning public health. A preliminary assessment suggests that much EU-level law and policy making on public health can be justified by reference to this analytical model, although there are some areas where the justification for EU involvement has not (yet) been made out.

Super-stewardship also relies on the ideas of intelligent purposive reconnection and productive disconnection to assess whether courts (and in particular the Court) have properly exercised their stewardship obligations with respect to judicial decision-making that concerns the balance between public health interests and other interests. Given the relationship between public health protection and promotion and the EU's internal market law, the most important judicial decisions concerning such balancing involve restrictions on free trade within the EU's internal market that are aimed to protect or promote public health. Such restrictions involve, for instance, limitations on by whom, or when, or where, or how, certain products, or advertising services for such products, may be traded. Relevant products that may involve hazard to public health include, in particular, blood and human tissue, pharmaceuticals, food, alcohol and tobacco. The place of the law of the internal market within the EU's constitutional arrangements requires a much greater emphasis on purposive reconnection than implied by Brownsword's idea of stewardship as applied to courts in national contexts. In a preliminary analysis, the article has shown that, in interpreting internal market law, the Court of Justice of the EU does not always successfully play its role as a super-steward of public health in the EU.

# Public health *sans frontières*: human rights NGOs and “stewardship on a global scale”

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## 1 Introduction

Does the Nuffield report *Public Health: Ethical issues*<sup>1</sup> neglect non-governmental organisations (NGOs)? I think the answer has to be “yes” and in this article I set about explaining why I take this view and what might be done to fill the gap. The Nuffield report, to be fair, is not entirely silent on NGOs: it refers to them in its discussion of “third parties”, noting that all such parties have an “obligation to reflect on their role in public health”.<sup>2</sup> In total, however, there are just two paragraphs on NGOs (commercial organisations, another of Nuffield’s third parties, are discussed at much greater length). These paragraphs describe NGOs as “important stakeholders”. More particularly, they note that “whether [NGOs] are ‘grass roots’ or established national or multinational organisations”, they can have a “valuable role to play in policy development”. There is also a caution, however: “it should be borne in mind that NGOs may have a vested interest, a commercial imperative and a ‘product’ in a way that is not dissimilar to a business”.<sup>3</sup>

Two paragraphs on NGOs may seem more than enough. This, after all, is a report about the state – at core, its argument is that the state needs to adopt what it calls a “stewardship model” in the arena of public health.<sup>4</sup> Thus it may be said that there was no reason for extended engagement with NGOs or, for that matter, with any other non-state actor. I take a different view, however. There are, of course, issues and instances when it is important to keep state and non-state separate; at the same time, however, I believe that being rigid about the distinction is likely to obscure one of the defining features of public health today: namely, the role of non-state actors, including the ways in which such actors work with, within and against the state, and at times as – or instead of – it. I believe, in other words,

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\* School of Law, University of Nottingham. My thanks to Mark Flear, the editor of this special issue, and to both Noel Whitty and the anonymous reviewer for comments on an earlier version.

1 Nuffield Council on Bioethics, *Public Health: Ethical issues* (London: Nuffield Council on Bioethics 2007), available at [www.nuffieldbioethics.org/public-health](http://www.nuffieldbioethics.org/public-health) (accessed 1 September 2011) (hereafter Nuffield report).

2 Ibid. para. 2.46. In similar vein, it notes that “the stewardship responsibility of the state does not absolve other parties . . . from their responsibilities” (para. 1.12).

3 Ibid. n. 1 above, paras 3.42–3.43.

4 The terms of reference do not, however, make direct mention of the state. Moreover, the corporate sector – a non-state actor – is discussed at some length in the report, and there are also recommendations concerning the WHO and “the international community”.

that we ought to be thinking in terms of public health *sans frontières* – of public health “without borders”.

By way of illustration, consider the HIV/AIDS epidemic. This has been – is – a devastating epidemic, and no account of it should omit either the terrible death toll (more than 25 million people have now died of HIV-related causes),<sup>5</sup> or the ways in which government policies have added to the numbers of dead and dying, of orphans and child-headed households, and of those vulnerable to infection. To stop there, however, would make the account incomplete; most notably, it would mean leaving out the part played by non-state actors – from pharmaceutical companies and NGOs to organisations such as the Bill and Melinda Gates Foundation, the Clinton Foundation and the Global Fund to Fight AIDS, Tuberculosis and Malaria.<sup>6</sup> In this article I shall be looking at just one of these non-state actors – NGOs, and in particular global human rights NGOs. I have chosen these organisations for two reasons. First, ethical considerations are supposed to be their very essence: to put it crudely, human rights NGOs are meant to be about making an effort to “do good” in the world. They are, as Ong puts it, “practitioners of humanity”.<sup>7</sup> Secondly, looking at the HIV/AIDS epidemic – an example I come back to again and again throughout the article – it is clear that such efforts have had a deep, even transformative, impact on how the illness is perceived and, relatedly, on what can and should be done to halt its spread and bring it to an end.

Translated into the language of the Nuffield report, we might say that via their work on HIV/AIDS, human rights NGOs have been engaged in “stewardship on a global scale”.<sup>8</sup> Should that prove controversial – because for example it is only the state that should be seen in stewardship terms, or because stewardship is too problematic an idea – then the same basic point can be made by saying that human rights NGOs seem to be doing exactly what the Nuffield report recommends: that is to say, they are “third parties” that seek out a role in public health, taking on responsibilities rather than shrugging them off as obligations of the state, and the state alone.<sup>9</sup>

Yet, when the Nuffield report refers to global stewardship, the context is not NGOs or, indeed, HIV/AIDS or any of the other public health problems with which human rights NGOs have strong associations. In the report, global stewardship is an entry point for discussing ethical and legal obligations associated with “pandemic preparedness”; in other words, the obligations that stem from the need to tackle emerging and re-emerging infectious diseases such as SARS or virulent influenza.<sup>10</sup> The report focuses in particular on a quartet of actors: states; the World Health Organization (WHO); the international community; and pharmaceutical companies. I have no quibble with any of these foci but, as I have said, I believe global stewardship points in another direction too: it points towards NGOs, and in particular towards human rights NGOs. So, with that in mind, I use this article to establish, first, why it is that human rights NGOs have be part of any account of public health stewardship on a global scale and, secondly, what this means in terms of the ethical issues facing such organisations. Put differently, I use this article to take some first steps towards an account of public health *sans frontières*.

5 UNAIDS, *Global Report: UNAIDS report on the global AIDS epidemic 2010* (Geneva: UNAIDS 2010), available at [www.unaids.org/globalreport/global\\_report.htm](http://www.unaids.org/globalreport/global_report.htm) (accessed 1 September 2011).

6 See respectively [www.gatesfoundation.org](http://www.gatesfoundation.org), [www.clintonfoundation.org](http://www.clintonfoundation.org) and [www.theglobalfund.org](http://www.theglobalfund.org) (accessed 1 September 2011).

7 A Ong, *Neoliberalism as Exception: Mutations in citizenship and sovereignty* (Durham NC: Duke UP 2006), p. 198.

8 Nuffield report, n. 1 above, para. 4.68.

9 *Ibid.* para. 1.12.

10 *Ibid.* paras 4.47–4.55, 4.66–4.68.

## 2 Public health *sans frontières*

Let's begin by looking more closely at the part played by NGOs in the HIV/AIDS epidemic. Recall, for instance, that during the epidemic's earliest years it was a campaign by ACT-UP, a US-based NGO, that changed conventions on drug-testing and licensing, and that this in turn helped to accelerate the development of antiretrovirals (ARVs).<sup>11</sup> Later, at the Doha round of trade talks, it was the negotiating power of NGOs (working with a network of emerging and less-developed economies) that helped to secure a new configuration of trade and human rights via agreement on what is known as the Doha Declaration. That declaration affirmed that the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)<sup>12</sup> contains flexibilities – what Rochelle Dreyfuss calls “wobble room”<sup>13</sup> – that allow member states to get around patents on medicines when this is necessary in order to protect public health.<sup>14</sup> It also set the scene for two further years of negotiation after which agreement was reached on a mechanism that gives more flexibility to states that have insufficient or no manufacturing capacity in the pharmaceutical sector, allowing them to bring in medicines from a foreign generic producer.<sup>15</sup>

Perhaps most notably of all, NGOs were key players when it came to building the case for universal access to treatment. In order to achieve this goal, NGOs fixed their attention on both “can and should”:<sup>16</sup> thus, they called for access to be accepted and secured as a human right, as a global public good, but they did not stop there; they also demonstrated that universal access was achievable – that poor people did adhere to complex drug regimes,<sup>17</sup> that treatment saved money as well as lives, and that the differential pricing and generics competition that could help to make ARVs more affordable was not going to imperil research and development (R&D) on global public health. The message reached its intended recipients: in 2006 the international community pledged universal access to HIV prevention, treatment, care and support — “as close as possible . . . by 2010 for all those who need it”<sup>18</sup> – thereby bolstering the commitment, made in the Millennium Development Goals, to reverse the epidemic by 2015.

The best-known NGO in the HIV/AIDS field is probably Treatment Action Campaign (TAC), an organisation founded in South Africa by a “handful of people”<sup>19</sup> on international human rights day in 1998. TAC's first campaign, launched on the same day, called on the

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11 See S Epstein, *Impure Science* (Berkeley: University of California Press 1996).

12 Marrakesh Agreement Establishing the World Trade Organization, opened for signature 15 April 1994, 1867 UNTS 3, annex 1C (Agreement on Trade-Related Aspects of Intellectual Property Rights) (entered into force 1 January 1995) (TRIPS).

13 R C Dreyfuss, “TRIPS and essential medicines: must one size fit all? Making the WTO responsive to the global health crisis” in T Pogge, M Rimmer and K Rubenstein (eds), *Incentives for Global Public Health: Patent law and access to essential medicines* (Cambridge: CUP 2010), p. 55.

14 Declaration on the TRIPS Agreement and Public Health (adopted 14 November 2001) WTO Doc. WT/MIN(01)/DEC/2 (Doha Declaration).

15 Implementation of para. 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003, WTO Doc. WT/L/540; Amendment of the TRIPS Agreement: Decision of 6 December 2005, WTO Doc. WT/L/641.

16 E B Kapstein and J W Busby, “Making markets for merit goods: the political economy of antiretrovirals” (2010) 1 *Global Policy* 75, p. 87.

17 See e.g. P Farmer, *Infection and Inequalities: The modern plagues* (Berkeley: University of California Press 1999).

18 UNGA Res. 60/262 (the “Political Declaration of Commitment on HIV/AIDS”), available at [http://data.unaids.org/pub/Report/2006/20060615\\_HLM\\_PoliticalDeclaration\\_ARES60262\\_en.pdf](http://data.unaids.org/pub/Report/2006/20060615_HLM_PoliticalDeclaration_ARES60262_en.pdf) (accessed 1 September 2011).

19 M Heywood, “South Africa's treatment action campaign: combining law and social mobilization to realize the right to health” (2009) 1 *Journal of Human Rights Practice* 14, p. 15.

South African government to implement a comprehensive national programme to prevent mother-to-child transmission (PMTCT) of HIV. Achieving that goal was, however, neither easy nor immediate. TAC had to battle the government both in and out of court, and it had to combine this with a range of other initiatives, including working *with* the government in order to challenge the drug-pricing practices of major pharmaceutical companies. Along the way, TAC encountered not just arguments in favour of patent protection on ARVs and other AIDS medicines, but also both AIDS denialism (and the dissident science that supported it) and a remarkably widespread belief that the right to health was non-justiciable. Put differently, TAC found itself in a “chain of disputes”<sup>20</sup> and, as Zackie Ahmat, a founding member and former chairperson of TAC, explains what was toughest of all was that some of these disputes gave the organisation no option other than taking on the ANC:

The difficult decision . . . was not to take off my suit and go to the streets and fight for treatment . . . That was easy. The emotionally torturous thing for me to do was to recognize we had to take on the ANC. *Our ANC*.<sup>21</sup>

By taking on the ANC on a matter of *health* policy, TAC compounded its problems. Intervening in this arena brought the organisation face-to-face with the legacy of apartheid – an era when “health” was used “to justify, first, racial segregation measures and, later, exploitation of the labor force . . . [when] tuberculosis and syphilis provided a foundation on which to construct theories of black inferiority and African sexual promiscuity”.<sup>22</sup> It also brought TAC face-to-face with the appeal of traditional medicine, and with the view – popular amongst public health experts – that poor, ill-educated people were not going to adhere to treatment regimes.

Knowing this makes TAC’s achievements all the more remarkable: TAC paved the way not only for a nationwide programme for the prevention of MTCT but also a national ARV treatment plan for all those with HIV/AIDS. More than this, its treatment literacy campaign demonstrated just how wrong it was to assume that poor patients would not follow complex drug regimes. It also delivered a new generation of South African “biocitizens” – well-informed and ready to engage and make demands on matters of health policy. As of 2010, South Africa had one million people living with HIV on treatment, the largest number worldwide.<sup>23</sup> The country’s government had also increased the HIV budget by 33 per cent, and launched a campaign to test 15 million people by 2011 – a move that has been described by the Executive Director of UNAIDS as “the biggest national mobilization around any single issue since the end of apartheid and the largest HIV counselling, testing and treatment scale-up in the history of the HIV epidemic”.<sup>24</sup>

To sum up then: locally, nationally and at the international level, NGOs have shaped responses to the HIV/AIDS epidemic. They have influenced law and policy, and in so doing they have challenged the taken-for-granted – including both the alleged non-justiciability of the right to health and the assumed deadlock between the trade view of the world and its human rights counterpart. More than this, NGOs have redirected research and become involved in directing it too, and they have also delivered prevention, care, treatment and support on the ground. To achieve these ends, NGOs formed networks amongst themselves, and they also partnered with states, international organisations and fellow non-

20 D Fassin, *When Bodies Remember: Experiences and politics of AIDS in South Africa* (Berkeley: University of California Press 2007), p. 70.

21 S Power, “Letter from South Africa: the AIDS rebel”, *New Yorker*, 19 May 2003, p. 65.

22 Fassin, *When Bodies Remember*, n. 20 above, p. xviii. It also led to encounters with dissident science, and with traditional medicine too.

23 UNAIDS, *2009 Report on the Global AIDS Epidemic* (Geneva: UNAIDS 2010), p. 29.

24 M Sidibé, *Delivering Results in Transformative Times* (Geneva: UNAIDS 2010), p. 8.

state actors (including new health-oriented super-philanthropists such as the Gates Foundation). In so doing, they helped to forge what is sometimes called “AIDS exceptionalism”; an unprecedented conjunction of state and non-state actors working towards the resolution of a public health problem, willing to consider and push ahead with new ways of thinking (such as the human rights approach to public health pioneered by Jonathan Mann, the first director of UNAIDS) and unwilling to let accepted ideas about “effective” health delivery stand in their way. They also of course provided a template that others, working on different public health problems, are now very keen to follow.

What I take from this is that a report on “public health: ethical issues” that does not engage fully with NGOs has to be seen as an incomplete report. The neglect of NGOs is more problematic still when we recall that the Nuffield report does not limit itself to engagement with the state and, moreover, that it brings the idea of “stewardship on a global scale” into play. In order to address that neglect, the remainder of this article draws out a range of points that could be part of a *revised* Nuffield report – a report that does engage with NGOs. What follows will be nowhere near a full engagement; for example, I spend no time examining the Nuffield Council’s understanding of stewardship or the pros and cons of applying that understanding to human rights NGOs. Instead, the emphasis is on shaping possible lines of enquiry: the aim is to give basic form and, more importantly, impetus to the argument that any viable account of “public health: ethical issues” has to incorporate NGOs – both the roles they are playing and the effects on states, on fellow non-state actors and, of course, on NGOs themselves.

The latter question is the one I focus on here. In what follows I look, first, at the relationship between human rights-based approaches to public health and their humanitarian counterparts; then, at the commitment of global human rights NGOs to economic, social and cultural (ESC) rights; and third and, finally, at the challenging nature of what we may call “human rights triage”.

### 3 Public health: ethical issues – the case of NGOs

I begin with a possible objection: namely, that as regards NGOs and the matter of “public health: ethical issues” the work has already been done – mostly by NGOs themselves via the production of codes of good practice. The best-known of such codes is the one prepared jointly by the International Federation of Red Cross and Red Crescent Societies and the International Committee of the Red Cross (ICRC): often called the Red Cross code, its full title is “The Code of Conduct for the International Red Cross and Red Crescent Movement and Non-Governmental Organisations (NGOs) in Disaster Relief”,<sup>25</sup> and since its creation in 1994 it has been signed by hundreds of NGOs. Another increasingly well-known example is the Sphere Project’s “Humanitarian Charter and Minimum Standards in Disaster Response”, which was devised in 2000 and has since had two revisions.<sup>26</sup>

These codes are now practically “industry standards”. By no stretch of the imagination, however, can they be seen as an ethical framework for NGO policymaking and practice in the field of public health. They were not, of course, designed with that broad purpose in mind; their focus is much narrower – disaster relief or response. They were also crafted by

25 [www.icrc.org/en/publications-and-reports/code-of-conduct/](http://www.icrc.org/en/publications-and-reports/code-of-conduct/) (accessed 1 September 2011).

26 [www.sphereproject.org](http://www.sphereproject.org) (accessed 1 September 2011). A third example is the Humanitarian Accountability Partnership’s (HAP) “Standard in Humanitarian Accountability and Quality Management”, [www.hapinternational.org](http://www.hapinternational.org) (accessed 1 September 2011); see, in particular, HAP, *The Guide to the HAP Standard* (Oxford: Oxfam Publishing 2008). See more generally the International NGOs Accountability Charter, available at [www.ingoaccountabilitycharter.org](http://www.ingoaccountabilitycharter.org) (accessed 1 September 2011), and the ongoing project of the International Council on Human Rights Policy, [www.ichrp.org/invitation\\_to\\_dialogue\\_en.pdf](http://www.ichrp.org/invitation_to_dialogue_en.pdf) (accessed 1 September 2011).

and for humanitarian organisations, not their human rights counterparts. Still, given that disasters have been a key site of NGO public health work, these codes merit scrutiny here. Indeed, if it can be established that these codes address the ethical considerations that confront human rights NGOs in disaster sites, then at least part of the project to build an account of NGOs and “public health: ethical issues” is already complete.

Let’s start with the Red Cross code; specifically, principle 2 which states that “[a]id is given regardless of race, creed or nationality of the recipients and without adverse distinction of any kind. Aid priorities are calculated on the basis of need alone.” My own reaction to this principle is akin to that of Jennifer Rubenstein, who asks: “What precisely is it prescribing?”<sup>27</sup> As Rubenstein points out, the sentences that make up principle 2 – the first foregrounding non-discrimination, the second calling for “need alone” to be determinative – are no self-evident partnership. In particular, there is nothing about non-discrimination that compels a needs-based approach; maximising harm reduction, for instance, might be just as compatible with the principle of non-discrimination. More generally, where need exceeds aid, focusing on “need alone” will not offer decisive guidance on either the sorting of needs or the day-to-day selection (and thus non-selection) of individuals.

Prioritising “most urgent need” might be an option here, but it too calls for further scrutiny. Sorting and selection – human rights triage<sup>28</sup> – are not going to be eliminated by the use of an urgency criterion; indeed, they may become more complex given that the criterion calls for a border between urgent and less urgent need that will have to be established and then policed. Moreover, the prior question, concerning why need (rather than, say, maximising harm reduction) has been chosen, still has to be answered too.<sup>29</sup> Finally, whether need or urgent need is the criterion, NGOs will still face follow-on questions about the impact of their interventions. For example, are their interventions meeting need partly by luring locals to “NGOland”,<sup>30</sup> draining the primary healthcare system of trained staff? And are they also wreaking havoc on the prospects of local (fee-based) services?

The Sphere code is not problem-free either. To illustrate this point, let’s take a brief look at its emphasis on minimum standards. There is, of course, clear affinity between that emphasis and a human rights-based approach; minimum standards provide a threshold below which protection should not fall, and the idea of “minimum core obligations” has been promoted by the Committee on Economic, Social and Cultural Rights (CESCR), the treaty body responsible for the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>31</sup> At the same time, however, and especially amidst an emergency, a

27 J C Rubenstein, “The distributive commitments of international NGOs” in M Barnett and T G Weiss (eds), *Humanitarianism in Question: Politics, power, ethics* (Ithaca: Cornell UP 2008), pp. 218–19.

28 Here I am drawing on the discussion of triage in P Redfield, “Sacrifice, triage, and global humanitarianism” in Barnett and Weiss, *Humanitarianism in Question*, n. 27 above, p. 196.

29 Of course, as noted by Rubenstein, “The distributive commitments”, n. 27 above, p. 222: “It is possible that, if NGOs intentionally tried to maximally reduce harm in every decision that they made, they would miscalculate, cut corners, find the process overly psychologically taxing, or spend too much time and money collecting information. Paradoxically, therefore, it might be that NGOs will do more to reduce harm if they comply with the principle of prioritizing the worst off than they would if they straightforwardly tried to act on the principle of maximally reducing harm.”

30 P Farmer, “Challenging orthodoxies: the road ahead for health and human rights” (2008) 10 *Health and Human Rights* 5, p. 10, available at [www.hhrjournal.org/index.php/hhr/article/view/33/100](http://www.hhrjournal.org/index.php/hhr/article/view/33/100) (accessed 1 September 2011). In elaborating on principle 2, the Red Cross code states that: “Wherever possible, we will base the provision of relief aid upon a thorough assessment of the needs of disaster victims and *the local capacities already in place to meet those needs.*” (emphasis added) See also principles 6, 7, 8 and 9 of the code.

31 An excellent account is provided by K G Young, “The minimum core of economic and social rights: a concept in search of content” (2008) 33 *Yale Journal of International Law* 113.

minimum can readily become the ceiling not the floor as NGOs adjust downwards in light of local factors. Moreover, claims that minimum standards have to be met may encourage “quality assurance”, whereby NGOs limit the range of their interventions so as to boost levels of care and protection amongst the more select group that is being assisted. The point I am making here is not that NGOs that confine or contextualise are indisputably “bad” NGOs, but rather that a minimum standards approach is not always-and-everywhere synonymous with a fully fledged rights-based one: minima draw us towards survival, a vital goal, but in so doing they can draw us away from human dignity – including the need for NGOs to follow a dignity-infused approach when defining and meeting the requirements for survival.<sup>32</sup>

The Red Cross and Sphere codes present other difficulties too. Two, in particular, merit comment here: first, these codes were designed by and for humanitarian NGOs, not their human rights counterparts; and second, they target “disaster” rather than the full spectrum of public health. I think these, however, should be seen as *productive* difficulties; by this I mean they are difficulties that provoke helpful lines of enquiry. For example, they encourage us to enquire into the kind of NGO challenges that are produced when public health problems are framed as “disasters” or “emergencies”. NGOs themselves are no strangers to the logic of emergency; they have wielded it in response to both sudden crises and embedded or long-term ones, such as the HIV/AIDS epidemic and maternal mortality. The logic of emergency is also wielded by states and, increasingly, by the international community too. For the latter, emerging infectious diseases – from SARS and virulent new forms of influenza, to bioterrorism and both multi- and extensively drug-resistant forms of tuberculosis – have been a particular preoccupation. Indeed, over the last decade or so, these diseases have had a profound impact, immersing us in the need for “preparedness”, the pull of “action now” and the importance of governing the “exceptional”. In so doing they have shaped (and been shaped by) a new lexicon, one featuring not only variations on “preparedness” but also “risk”, “resilience” and various takes on “security”, including “biosecurity”, “human security” and what the World Health Organization (WHO) calls “global public health security”.<sup>33</sup>

This makes for difficult terrain for human rights NGOs engaged in public health work. Looking first at the new lexicon, it is only human security that has overt human rights resonance;<sup>34</sup> by contrast, the other terms, and more generally the construction of particular public-health problems as emergencies, can make it difficult for human rights claims to get a fair hearing.<sup>35</sup> Second, attacking the logic of emergency is no plain and simple option for human rights NGOs. For all that it is misleading, this logic is not an out-and-out lie: the globalised world does have emerging epidemics and it does make sense for these to be of international concern. NGOs also have their own reasons for endorsing the logic of emergency. For example, they have been offered a “seat-at-the-table” by the revised

32 On dignity, survival and the minimum core, see generally M Salomon, “Why should it matter that others have more? Poverty, inequality and the potential of international human rights law”, available at [www.lse.ac.uk/collections/law/wps/WPS2010-15-Salomon.pdf](http://www.lse.ac.uk/collections/law/wps/WPS2010-15-Salomon.pdf) (accessed 1 September 2011).

33 WHO, *The World Health Report 2007: A safer future – global public health security in the 21st century* (Geneva: WHO 2007). For discussion of the lexicon’s terms, see T Murphy and N Whitty, “Is human rights prepared? Risk, rights and public health emergencies” (2009) 19 *Medical Law Review* 219, available at <http://medlaw.oxfordjournals.org/content/17/2/219.short> (accessed 1 September 2011).

34 See *Human Security Now* (New York: Commission on Human Security 2003).

35 See W Parmet, *Public Health and Social Control: Implications for human rights* (Geneva: International Council on Human Rights Policy 2009), available at [www.ichrp.org/files/papers/173/public\\_health\\_and\\_social\\_control\\_wendy\\_parmet.pdf](http://www.ichrp.org/files/papers/173/public_health_and_social_control_wendy_parmet.pdf) (accessed 1 September 2011).

International Health Regulations (IHR), which allow the WHO to use information about disease outbreaks provided by unofficial (that is, non-state) sources.<sup>36</sup>

In practice, specialist public health surveillance networks and institutions (such as GOARN,<sup>37</sup> which was established by WHO itself) are far more likely than NGOs to be in a position to provide relevant information on outbreaks. Nonetheless the underlying shift away from states as the sole voice on public health matters does help to establish the legitimacy of non-state perspectives, including, of course, those of human rights NGOs. More generally, rising global interest in public health emergencies, of which the revised IHR are one sign, offers NGOs a means by which they may be able to lift particular public health problems from a state of neglect to the resource-rich international stage; a means perhaps to emulate the widely envied success of the HIV/AIDS campaign for universal access to treatment.

The problem, of course, is that the logic of public health emergency is also misleading. For starters, its focus on emerging epidemics – on the future – may be exacerbating neglect of people who are dying today of public health problems, such as maternal mortality, that are entirely solvable. Second, the logic of emergency pitches public health together with security, protection with policing, disaster with crime – a matrix that is likely to favour criminal law-focused approaches and solutions to public health problems. And, thirdly, in the logic of public health emergency, drugs are dominant. Today's public health emergencies are "drug emergencies"; the underlying determinants of the public's health – including sanitation, water and the quality of the primary health infrastructure – lag a long way behind. Immediate access to drugs can, of course, be life-saving: a sudden outbreak of cholera clearly is a public health emergency that is a drug emergency. Nevertheless, as I explain below, the equation "public health = drugs" – what others have called "the pharmaceuticalisation of public health"<sup>38</sup> – has its downsides too.

#### HUMAN RIGHTS, HUMANITARIANISM AND "HUMAN RIGHTS-LITE"

At this juncture, let's go back to the other difficulty arising from the Sphere and Red Cross codes: namely, that these codes were developed by and for humanitarian NGOs, rather than their human rights counterparts. The reason I see this difficulty as productive, or helpful, is that it directs attention towards the relationship between humanitarianism and human rights. In so doing it encourages us to ask: in what ways, and with what effects, are humanitarianism and human rights connecting and disconnecting in the field of public health, in particular amidst rising interest in ESC rights on the part of human rights NGOs?<sup>39</sup>

The NGO world is clearly one of the places we can look to answer that question. And if, within that world, we look at the Sphere code, a code produced by and for *humanitarian* NGOs, we find quite considerable use of the language of human rights. More tellingly, the Nobel Prize-winning and avowedly humanitarian NGO Médecins Sans Frontières (MSF) has become involved in both the provision of HIV/AIDS treatment and a campaign on

36 World Health Assembly, International Health Regulations, WHO Doc. WHA58/2005/REC/1 (23 May 2005), [www.who.int/csr/ihr/IHRWHA58\\_3-en.pdf](http://www.who.int/csr/ihr/IHRWHA58_3-en.pdf) (accessed 1 September 2011), Articles 9, 10 and 11. "When justified by the magnitude of the public health risk", WHO is empowered to share information with other states when the affected state is not cooperating with its verification and control efforts.

37 GOARN stands for Global Outbreak Alert and Response Network, [www.who.int/csr/outbreaknetwork/en/](http://www.who.int/csr/outbreaknetwork/en/) (accessed 1 September 2011).

38 See A Petryna and A Kleinman, "The pharmaceutical nexus" in A Petryna, A Lakoff and A Kleinman (eds), *Global Pharmaceuticals: Ethics, markets, practices* (Durham NC: Duke UP 2006).

39 The question of connections and disconnections between international human rights law and international humanitarian law in the context of *armed conflict*, in particular the "convergence" thesis, may well be pertinent here too: see N K Modirzadeh, "The dark sides of convergence" (2010) 86 *US Naval War College International Law Studies (Blue Book) Series* 349.

access to essential medicines, which includes the funding and management of R&D on new drugs. In so doing, MSF does not appear to have made any public shift towards human rights; in fact, as Peter Redfield points out, at MSF there seems to be “continued avoidance of human rights rhetoric”.<sup>40</sup> Yet, as Redfield goes on to explain, it is hard to see how either the provision of HIV/AIDS treatment or advocacy and research on essential medicines can claim to be conventionally humanitarian; they are, frankly, far more akin to a *rights*-based approach.<sup>41</sup> More than this, given that HIV/AIDS treatment – to be successful – requires more than access to medicines, these initiatives may draw MSF deep into human rights terrain, taking it well beyond the claim of universal access to treatment. The reason for this is simple: treatment may save lives, it may even be “one of the most potent prevention tools we have”,<sup>42</sup> but people do not live on treatment alone. Moreover, if there is a shortage of transport to and from the health centre, or a lack of clean water, even the offer of free treatment will be compromised.

MSF’s drug initiatives could pan out differently, however. In particular, they could pull the organisation towards what we may call “human rights lite”.<sup>43</sup> The initiatives could, for example, tighten the grip of pharmaceuticalisation, entrenching the drug emergency as the core way in which state and non-state actors alike think about public health. More to the point, MSF is by no means the only actor on this particular frontier. Today, looking at the HIV/AIDS epidemic – widely regarded as an NGO success story and, more broadly, a human rights one – it is clear that the centrality of treatment and testing can encourage a shrunken sense of what it is to take a rights-based approach. Universal access to treatment is, to be sure, a vitally important goal. But as emphasised earlier, programmes of treatment and voluntary testing cannot be the sum of a rights-based approach. If people are to avail themselves of services, and if they are to be able to use them on a long-term basis, programmes that attack stigma, discrimination, violence and all of the other barriers that prevent people from coming forward, or from continuing with treatment, need to be committed to as well. To put that more succinctly, rights-based approaches to public health “comprise more than packages of goods and services”.<sup>44</sup>

Treatment and testing are crucial, but standing alone they are human rights-lite.<sup>45</sup> In addition, although mobilisation around universal access to HIV/AIDS treatment is one of the forces that helped to forge interest in global health policy, it has also intensified the grip of *disease-specific* programming. The problem with this, as Meier and Fox have pointed out, is that when priority is given to vertical interventions directed at particular diseases,

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40 P Redfield, “Doctors without borders and the moral economy of pharmaceuticals” in A Bullard (ed.), *Human Rights in Crisis* (Aldershot: Ashgate 2008), pp. 139–40.

41 MSF’s human rights-inflected humanitarianism is not the only new configuration in the human rights/humanitarian relationship in the field of public health; there is also what might be described as humanitarian-inflected human rights. On the latter, see e.g. M Ticktin, “Medical humanitarianism in and beyond France: breaking down or patrolling borders” in A Bashford (ed.), *Medicine at the Border: Disease, globalization and security, 1850 to the present* (Basingstoke: Palgrave Macmillan 2006), p. 116.

42 Sidibé, *Delivering Results*, n. 24 above, p. 2.

43 See relatedly A M Klasing, P S Moses and M Satterthwaite, “Measuring the way forward in Haiti: grounding disaster relief in the legal framework of human rights” (2011) 13 *Health and Human Rights* 1, available at [www.journal.org/index.php/hhr/article/view/408/610](http://www.journal.org/index.php/hhr/article/view/408/610) (accessed 1 September 2011).

44 A E Yamin, “Will we take suffering seriously? Reflections on what applying a human rights framework to health means and why we should care” (2008) 10 *Health and Human Rights* 45, p. 48, available at [www.hhrjournal.org/index.php/hhr/article/view/27/89](http://www.hhrjournal.org/index.php/hhr/article/view/27/89) (accessed 1 September 2011).

45 See, relatedly, the idea of “biological citizenship” as developed by e.g. J Biehler, *Will to Live: AIDS therapies and the politics of survival* (Princeton: Princeton UP 2007); A Petryna, *Life Exposed: Biological citizens after Chernobyl* (Princeton: Princeton UP 2002).

primary health-care systems focused on the underlying determinants of public health tend to be neglected.<sup>46</sup>

Moreover, NGOs play a very real part in this form of prioritisation, both because they champion particular diseases and because donors, looking for the best way to spend their money, may prefer to fund NGO provision rather than pursue the riskier strategy of giving to individual states in support of a considerably looser goal such as sector-wide health investment.<sup>47</sup>

### THE LIMITS OF HUMAN RIGHTS NGOS

MSF, as noted earlier, is a past winner of the Nobel Peace Prize. It is not, however, the only Peace Prize recipient amongst NGOs: in 1997 the prize went to Jody Williams and the cluster of NGOs that had come together to form the International Campaign to Ban Landmines.<sup>48</sup> One of those sharing that prize was Human Rights Watch (HRW), widely seen as the archetypal global human rights NGO. In recent years, both HRW and, its fellow global giant, Amnesty International have broadened out from their classic focus on civil and political rights, extending their remit so that they now include ESC rights. Amnesty explains the change of focus in the following way:

Amnesty International has broadened its mission in recognition that there are many more prisoners of poverty than prisoners of conscience, and that millions endure the torture of hunger and slow death from preventable disease.<sup>49</sup>

And for HRW, according to the history pages on its website, it was the HIV/AIDS epidemic that led the organisation to develop a programme devoted to human rights and health.<sup>50</sup>

Yet there have been demands for these NGOs to do still more; most notably from Paul Hunt, the first UN special rapporteur on the right to health, who argued that “civil society within the health and human rights movement could and should be doing much more”, and that established NGOs should be working on health and human rights issues “just as vigorously as they already campaign on disappearances, torture and prisoners of conscience”.<sup>51</sup> Kenneth Roth of HRW sees things differently, however.<sup>52</sup> Roth has argued that:

46 B Mason Meier and A M Fox, “International obligations through collective rights: moving from foreign health assistance to global health governance” (2010) 12 *Health and Human Rights* 61, available at [www.hhrjournal.org/index.php/hhr/article/view/203/298](http://www.hhrjournal.org/index.php/hhr/article/view/203/298) (accessed 1 September 2011).

47 *Ibid.* p. 62.

48 [www.icbl.org](http://www.icbl.org) (accessed 1 September 2011). Their work helped forge the Convention on the Prohibition of the Use, Stockpiling, Production and Transfer of Anti-Personnel Mines and on their Destruction (Mine Ban Treaty), entered into force 1 March 1999, 36 ILM (1997) 1507. For a critical account, see K Anderson, “The Ottawa Convention banning landmines: The role of international non-governmental organizations and the idea of international civil society” (2000) 11 *European Journal of International Law* 91.

49 Amnesty International, *Human Rights for Human Dignity: A primer on economic, social and cultural rights* (London: Amnesty International 2005), p.4.

50 See “Our history”, available at [www.hrw.org](http://www.hrw.org) (accessed 1 September 2011).

51 “Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt”, UN Doc. A/HRC/4/28 (17 January 2007), para. 37.

52 K Roth, “Defending economic, social, and cultural rights: practical issues faced by an international human rights organization” in D A Bell and J-M Coicaud (eds), *Ethics in Action: The ethical challenges of international human rights nongovernmental organizations* (New York: CUP 2007), p. 169. See relatedly S Hopgood, “Dignity and ennuï” (2010) 2 *Journal of Human Rights Practice* 151.

when outsiders ask international human rights organizations such as Human Rights Watch to expand our work on ESC rights, we should insist on a more sophisticated, and realistic, conversation than has been typical so far.<sup>53</sup>

He says that, in his experience, advice to international human rights NGOs to “do more” to protect ESC rights has tended to be “little more than sloganeering”.<sup>54</sup> In particular, he says, “it . . . ignores the question of which issues can and cannot effectively be taken up by international human rights organizations that rely on shaming to generate public pressure”.<sup>55</sup>

HRW, Roth’s own organisation, is well known for its use of a shaming methodology. Roth’s core claim is that, if this methodology is to be effective, there has to be clarity on three fundamentals: the violation, the violator and the remedy. He maintains that “[i]f any of these three elements is missing, the capacity to shame is greatly diminished”.<sup>56</sup> The difficulty with ESC rights, of course, is that this clarity can be hard to achieve: responsibility tends to be multiple not singular, and the question of what would be an appropriate remedy is often disputed. The upshot, according to Roth, is that HRW’s shaming methodology simply does not work for violations of ESC rights bar in that subset of cases where it is possible to pinpoint arbitrary or discriminatory conduct that is causing, or substantially contributing to, the violation:

[I]f all an international human rights organization can do is argue that more money be spent to uphold an ESC right – that a fixed economic pie be divided differently – our voice is relatively weak . . . On the other hand, if we can show that the government (or other relevant actor) is contributing to an ESC shortfall through arbitrary or discriminatory conduct, we are in a relatively powerful position to shame: we can show a violation (the rights shortfall), the violator (the government or other actor, through its arbitrary or discriminatory conduct), and the remedy (reversing that conduct).<sup>57</sup>

There is more detail in Roth’s account but let’s see how these basics might measure up in an ethics test. We should begin by acknowledging that there is more than one way of doing good in the world, and indeed that this is a good thing; “cookie-cutter” NGOs would not be attractive or useful. It is also important to acknowledge that we are not dealing with a “blank slate”:<sup>58</sup> HRW has a history, which means that members and contributors alike have particular expectations and this in turn means that veering too far from those expectations might be akin to hitting a self-destruct button. Because of its history, HRW also has a specific expertise; expertise that might not be so useful in the field of public health or health rights more generally.

On the other hand, though, HRW is no ordinary NGO. It is, indisputably, a gatekeeper NGO – issues that are taken up by it are a great deal more likely to gain a global audience, and that in turn brings funding and other forms of momentum too. Moreover, for all that there is no blank slate, the priority that HRW gives to shaming is surprising at a time when human rights method is a growth area, as evidenced, for example, by expanding interest in

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53 Roth, “Defending economic, social, and cultural rights”, n. 52 above, p. 180.

54 Ibid. p. 170.

55 Ibid.

56 Ibid. p. 173.

57 Ibid. p. 174.

58 J H Carens, “The problem of doing good in a world that isn’t: reflections on the ethical challenges facing INGOs” in Bell and Coicaud, *Ethics in Action*, n. 52 above, p. 260.

impact assessment, indicators and human rights budgeting,<sup>59</sup> and by the use of quantitative methods as a prosecution tool at the International Criminal Tribunal for the former Yugoslavia.<sup>60</sup>

To be clear: I am not suggesting that HRW should abandon its shaming methodologies, that newer human rights methods are better or, indeed, that Roth is wrong when he says that responsibility for violation of ESC rights is often multiple. The claim instead is that gatekeeper NGOs, precisely because they are gatekeepers, should be seen as having particular responsibilities. Where a gatekeeper NGO frames shortcomings in ESC rights as, by and large, outside its remit – where it frames such shortcomings as mostly “matters of pure distributive justice”<sup>61</sup> – it sends a message about what is, and what is not, a human rights matter. In so doing, it may cause harm to the standing of ESC rights both as a prompt for claims-making and as a component part of the law.<sup>62</sup> And that in turn increases the risk that these rights will be thrown back onto a frame dominated by the language of needs, and of the deserving and undeserving. It also threatens the progress that has been made towards treating ESC rights as rights “proper” rather than, say, directive principles, and it offers less than fulsome support to the position of the CDESCR which sees “all members of society” as possessing certain “responsibilities regarding the realization of the right to health”.<sup>63</sup> Other harms could follow too, not least more limited openings for solidarity between gatekeeper NGOs and their local and national counterparts and also, crucially, less room for manoeuvre for the latter.<sup>64</sup>

It seems to me that mindset, not methodology, may be the main obstacle. HRW has in fact been able to engage with a range of public health problems in recent years, from disasters and displaced populations to sexual and reproductive health.<sup>65</sup> There are also several new openings for the organisation’s preferred shaming methodology, both in the field of ESC rights in general and in public health in particular. To start with, ESC rights are now guaranteed in a significant number of constitutions and, as we saw earlier, at least one NGO, South Africa’s TAC, has used a constitutional guarantee of the right to have access to health-care services<sup>66</sup> as part of its successful campaigning on public health matters. Another opening is provided by the new optional protocol to the ICESCR<sup>67</sup> which, when it enters into force, will allow CDESCR to receive and consider individual complaints

59 See generally T Murphy, *Health and Human Rights* (Oxford: Hart forthcoming).

60 P Ball, W Betts, F Scheuren, J Dudukovich and J Asher, *Killings and Refugee Flow in Kosovo March–June 1999: A report to the International Criminal Tribunal for the former Yugoslavia* (Washington: American Association for the Advancement of Science 2002). See, relatedly, J Hagan, H Schoenfeld and A Palloni, “The science of human rights, war crimes, and humanitarian emergencies” (2006) *32 Annual Review of Sociology* 329, p. 329, calling for the development of a “critically informed sociological synthesis that joins our understanding of the . . . health and violence dimensions of . . . ‘complex’ humanitarian emergencies”.

61 Roth, “Defending economic, social, and cultural rights”, n. 52 above, p. 179.

62 See, relatedly, K G Young, “Freedom, want, and economic and social rights” (2009) *24 Maryland Journal of International Law* 191.

63 CDESCR, “General Comment No. 14: The right to the highest attainable standard of health (art. 12)”, UN Doc. E/C.12/2000/4 (11 August 2000), para. 42. See also the Universal Declaration of Human Rights, UN Doc. A/810 (10 December 1948), preamble and Article 28.

64 See L S Rubenstein, “How international human rights organizations can advance economic, social and cultural rights: a response to Kenneth Roth” (2004) *26 Human Rights Quarterly* 845; Yamin, “Will we take suffering seriously?”, n. 44 above.

65 See e.g. HRW, “‘Nobody remembers us’: failure to protect women’s and girls’ right to health and security in post-earthquake Haiti” (2011), available at [www.hrw.org/sites/default/files/reports/haiti0811.webwcover.pdf](http://www.hrw.org/sites/default/files/reports/haiti0811.webwcover.pdf) (accessed 1 September 2011).

66 South African Constitution 1996, s.27.

67 Optional Protocol to the ICESCR, UN Doc. A/RES/63/11 (adopted 10 December 2008; not yet in force).

concerning alleged violations of Covenant rights. And, as Roth himself seems to recognise,<sup>68</sup> the human rights responsibility of international co-operation and assistance could be used to produce a third opening.<sup>69</sup> As pointed out by the first UN special rapporteur on the right to health, the “contours, content and legal nature”<sup>70</sup> of this responsibility need to be spelled out more clearly. The special rapporteur’s own report on the matter uses Sweden as a case study, praising the country as a model high-income state – “[f]rom a right-to-health perspective . . . its international policies on development, health and human rights are among the best in the world”<sup>71</sup> – but noting that even this “model” state does not accept that it has a *legal* obligation of international assistance and co-operation. Furthermore, even though both the special rapporteur and CESCR<sup>72</sup> have emphasised that there is such an obligation, the stance taken by Sweden is by no means unique – rather, it is widespread amongst high-income states, which surely points to the importance of further human rights NGO advocacy on this issue.

The timing might be right too, in that rising interest in emerging infectious diseases – what WHO calls “global public health security” – may provide an opportunity to press claims for international assistance and co-operation. The revised IHR, for example, are premised on global interconnectedness. And the Nuffield report seems to draw on the same theme when it recommends applications of its preferred stewardship model “at the global level” or “on a global scale”.<sup>73</sup> Thus the report calls for compliance with the disease-notification requirements in the revised IHR, emphasising that “countries have an ethical obligation to reduce the risk of ill health that people might impose on each other across borders”.<sup>74</sup> It also calls on wealthy states to help improve “the capacities of developing countries to conduct effective surveillance of infectious diseases”; and it encourages “WHO, the international community and pharmaceutical companies” to build on existing pledges to improve manufacturing capacity for flu vaccines in developing countries.<sup>75</sup>

Of course, all of these recommendations for global-level stewardship fit with what I described earlier as the logic of public health emergency; thus, they focus on emerging infectious diseases (as opposed to present-day killers or basic survival needs) and they give centre-stage to surveillance and drugs. Still, given that the emphasis on “security” helped to forge the human-rights-friendly concept of “human security”, it is surely possible that the idea of “stewardship ‘on a global scale’”, or indeed “global public health security”, given

68 Roth, “Defending economic, social, and cultural rights”, n. 52 above, 177: “If the issue is not how a foreign government divides a limited economic pie but how much money a Northern government or an international financial institution spends on international assistance for the realization of ESC rights, Northern-based international human rights organizations speak less as an outside voice and more as a domestic constituency.”

69 The obligation draws in particular on the UN Charter, Articles 1(3), 55 and 56; the Universal Declaration of Human Rights, Articles 22 and 28; and the ICESCR Articles 2(1), 11(1), 11(2), 15(4), 22 and 23. As regards health, the obligation is explained in CESCR, “General Comment 14”, n. 63 above.

70 “Report of the special rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Paul Hunt”, UN Doc. A/HRC/7/11/Add.2 (5 March 2008), para. 135.

71 *Ibid.* para. 134.

72 CESCR, “General Comment 14”, n. 63 above, para. 45: “For the avoidance of any doubt the Committee wishes to emphasize that it is particularly incumbent on States parties and other actors in a position to assist, to provide ‘international assistance and cooperation, especially economic and technical’ which enable developing countries to fulfil their core and other obligations.”

73 Nuffield report, n. 1 above, paras 4.50 and 4.68 respectively. See also the Maastricht Principles on extraterritorial obligations of states in the area of economic, social and cultural rights (28 September 2011) available at [www.icj.org](http://www.icj.org) (accessed 1 December 2011). At para. 4.49, the Nuffield report notes that “the stewardship model . . . is usually applied at the national level in relation to obligations that states have towards those affected by their laws and policies. However, it is also reasonable to apply it at a much higher level”.

74 *Ibid.* para. 4.50.

75 Nuffield report, n. 1 above, paras 4.50, 4.68.

their preoccupation with global interconnectedness, could in turn provide a way in for advocacy on the human rights responsibility of international assistance and co-operation.

#### SAVE THE WORLD?

Others may take a harder line on HRW-type arguments about what is, and is not, an appropriate project for global human rights NGOs. For example, the philosopher Thomas Pogge has made the exceptionally strong claim that “even a project that does more good than harm should be abandoned when a lot more net good can be achieved with the same resources elsewhere”.<sup>76</sup> The first point to make about this claim is that engaging with it is not easy. As I said earlier, human rights NGOs are widely seen as making an effort to do good in the world and that fact alone makes Pogge’s critique difficult, even indecent. Pogge himself says that the standard he sets is sure to prove “inadequate in various ways”.<sup>77</sup> But the problem seems to run far deeper: how precisely does one critique “good practice”, and is it wrong even to try?

Perhaps it is for one or both of these reasons that NGOs, by and large, refrain from criticising one another. Moreover, calling for auto-critique – for NGOs to engage in self-scrutiny – is not problem-free either. Self-scrutiny may now be standard practice for NGOs – demanded by donors, expected by supporters and embraced by NGOs themselves as a way to assess whether and how desired outcomes are being achieved<sup>78</sup> – but scrutiny on *ethics* seems to be of a different order. There are at least four reasons for this. First, inside individual NGOs the view from the field tends to differ from that in head office, especially on the question of human rights triage. Logical or principled choices about selection and non-selection generally feel less logical and less principled when one is face-to-face with the people who are going to be affected in profound ways by these choices. As Redfield has pointed out, from a local perspective, “the end of engagement is less clearly justifiable, and appears akin to abandonment or sacrifice of that population”.<sup>79</sup> What I take from this is that, if not handled with extreme care, auto-critique on the ethics of human rights triage could rupture the organisational culture of individual NGOs.

Second, not all publicity is good publicity and encouraging human rights NGOs to go public on how they handle difficult ethical issues could have damaging repercussions.<sup>80</sup> We tend to think of human rights NGOs as actors who target others; in so doing we sometimes forget that NGOs can be targets too. We forget that they have no immunity against manipulation or, indeed, direct attacks on their personnel or the goods they provide. NGOs also face both hostility and scepticism; indeed, as the profile of human rights NGOs has risen in recent years, so too has the criticism they face. In some ways this is fair enough: NGO transparency and accountability are important matters.<sup>81</sup> There are critics who seek far more than this, however; critics who do not want human rights NGOs to survive

76 T Pogge, “Respect and disagreement: a response to Joseph Caren’s” in Bell and Coicaud, *Ethics in Action*, n. 52 above, p. 273.

77 Ibid. p. 278.

78 See e.g. I Gorvin, “Producing the evidence that human rights advocacy works: first steps towards systematized evaluation at Human Rights Watch” (2009) 1 *Journal of Human Rights Practice* 477.

79 Redfield, “Sacrifice, triage, and global humanitarianism”, n. 28 above, p. 198. See also R C Fox and E Goemaere, “They call it ‘patient selection’ in Khayelitsha: the experience of Médecins sans Frontières-South Africa in enrolling patients to receive antiretroviral treatment for HIV/AIDS” (2006) 15 *Cambridge Quarterly Healthcare Ethics* 302; C Sinding and L Schwartz, “‘Playing God because you have to’: health professionals’ narratives of rationing care in humanitarian and development work” (2010) 3 *Public Health Ethics* 147.

80 Rubenstein, “The distributive commitments”, n. 27 above, p. 215.

81 See e.g. S Charnovitz, “Accountability of non-governmental organizations in global governance” in L Jordan and P Van Tuijl (eds), *NGO Accountability: Politics, principles and innovations* (London: Earthscan 2006), p. 21.

scrutiny. Being transparent about human rights triage is not, then, straightforward – there are high stakes for NGOs, for their staff members who stay behind when other internationals have moved on, for locals who have worked with the NGO, and of course for others too who are left behind.<sup>82</sup>

Third, NGOs are not, or not only, lone operators. Choosing a particular course of action, continuing with it and pulling out are actions where NGOs are influenced in part by donor sentiments. Moreover, NGOs today tend to seek out connections with one another; they may also be connected to international organisations, states and fellow non-state actors. TAC, for example, has worked with ACT-UP and COSATU (a South African trade union) amongst others. Similarly, MSF, an NGO that has been tenacious in protecting its own autonomy (including its right to bear witness to human rights violations, and to pull out of projects), opted to work with TAC and a range of other organisations as part of an access to medicines campaign. The point here is not that being in a network, or being in partnership, dissolves the need to consider ethics; simply, that it is likely to make their consideration and pursuit a good deal more difficult.

Fourth and finally, ethical considerations are not resource-neutral: resources spent on ethics are resources that are not being spent elsewhere – NGOs are not resource-rich enough for it to be any other way. Take, for example, participation: amongst human rights NGOs, participation by beneficiaries is widely seen as both an ethical imperative and a means of improving the likely effectiveness of a project. Yet resources spent on training NGO staff in modes of participation are resources that could have been spent in other ways.<sup>83</sup> And, although at first glance this may seem a foolish example (after all, why be against participation?), the rise of a new accountability culture amongst NGOs could produce an excess of posts in this arena (as well as “the ‘bureaucratic personalities’” that these positions sometimes encourage).<sup>84</sup>

Still, even with these problems Pogge’s argument should not be dismissed out of hand. For starters, although we may want to insist that there is more than one way of doing good, there still has to be a way to identify NGOs that do harm. Put differently, even if agreement on what is good is unlikely, we can – and must – look for agreement on what is unarguably wrong. The phenomenon of “servile NGOs”<sup>85</sup> (that is, organisations that are government-sponsored and focused on serving a state interest, not a public one) makes this an important task. Interestingly, even the limited consideration of NGOs in the Nuffield report picks up on this point, noting that:

[a]lthough NGOs are often perceived as acting “for the good of the public” and therefore as more trustworthy than officialdom, it should be borne in mind that NGOs may have a vested interest, a commercial imperative and a “product” in a way that it not dissimilar to a business. Some may be sponsored by a commercial company with an interest or agenda in this area. An organisation that campaigns on behalf of a sector of the public with a particular kind of worry may even rely for its support on that worry being amplified and even distorted.<sup>86</sup>

82 See relatedly P Alston, “The challenges of responding to extra-judicial executions: interview with Philip Alston” (2010) 2 *Journal of Human Rights Practice* 355, discussing the responsibilities of UN special procedures mandate-holders and of the UN Human Rights Council to those who assist their work on the ground.

83 Rubenstein, “The distributive commitments”, n. 27 above, p. 225.

84 C Heimer, “Side effects: accountability in international HIV/AIDS programs”, abstract available at [www.princeton.edu/CCSO/seminars/carol-heimer/](http://www.princeton.edu/CCSO/seminars/carol-heimer/) (accessed 1 September 2011).

85 O de Frouville, “Domesticating civil society at the United Nations” in P-M Dupuy and L Vierucci (eds), *NGOs in International Law: Efficiency in flexibility* (Cheltenham: Edward Elgar 2008), p. 73.

86 Nuffield report, n. 1 above, para. 3.43.

Money, of course, is one area where NGOs have been willing to be critical of one another. Fundraising practices have been their principal target,<sup>87</sup> but what if we were to stretch the trend so as to look at other NGO practices concerning money? One question that comes immediately to mind is: given that human rights activism is often seen as a vocation, that volunteerism is prized, who should be paid for their work? For instance, is paying community health workers for the work they do on behalf of their neighbours, a vital element in the achievement of health and human rights goals or is it, as some would argue, an unsustainable practice?<sup>88</sup> And, as mentioned earlier, what are the ethical responsibilities of NGOs when their work creates “a local brain drain by luring nurses, doctors, and other professionals from the public hospitals . . . to ‘NGOland,’ where salaries are better and the tools of [the] trade more plentiful?”<sup>89</sup> Also, shifting ground a little, what about NGO interns – the recent graduates who have been declared winners in the fierce competition for short-term, unpaid appointments? I know from the classes I teach that, for human rights students, few jobs have more appeal, but what exactly are the ethical responsibilities of NGOs towards this unpaid workforce?<sup>90</sup>

Of course, what matters to Pogge is something different. His concern is project selection<sup>91</sup> by international NGOs, and in particular what he sees as the imperative to do more good rather than less. Assuming an NGO accepts this imperative, following through is not always going to be practicable: in choosing between projects, an NGO has to take account of more than what will do most good – its mission, for example, is also relevant to the calculation. The NGO may also be faced with insufficient information to allow it to complete a proper ranking as between the different choices.

Still, even with these caveats, Pogge’s imperative presents global NGOs with at least one compelling challenge: namely, to explain why they choose to “save the world” when they might be more effective – when they might do more good – if they were to apply limits to the geographic scope of their work.<sup>92</sup> HRW, for example, is engaged in research and advocacy in around 90 countries.<sup>93</sup> Would it object to a contraction of the geographic scope of its efforts? If so, on what basis? As Joseph Carens has noted, “[i]t would be instructive to learn whether [NGOs such as HRW] think there is a deep, principled reason for the choices they make or whether it is a response to fund-raising or other imperatives”.<sup>94</sup>

#### 4 Conclusion

I close with an anecdote drawn from teaching human rights courses over a good number of years. The students in my classes are almost always interested in the relationship between academia and activism; at the same time, however, because many of them imagine their human-rights future working “in the field” (or perhaps at a headquarters in New York,

87 The use of images of suffering as a fundraising tool has been a particular flashpoint. Principle 10 of the Red Cross code tackles the problem in the following way: “In our information, publicity and advertising activities, we shall recognize disaster victims as dignified humans, not hopeless objects.”

88 Farmer, “Challenging orthodoxies”, n. 30 above, p. 8.

89 Ibid. p.10.

90 As regards Amnesty, see S Hopgood, *Keepers of the Flame: Understanding Amnesty International* (Ithaca: Cornell UP 2006), p. 19: “its inner working culture has often been unsympathetic and unforgiving, sacrificial even”.

91 Carens, “The problem of doing good”, n. 58 above, p. 270 makes this point, noting that choices about mission or basic strategy are, by contrast, “characterized by a much higher degree of uncertainty than Pogge allows for . . . although no one can doubt the wisdom of a general prescription that says do more good rather than less, other things being equal, it is often impossible to tell what will do more good” (p. 267).

92 Ibid. pp. 270–1.

93 Gorvin, “Producing the evidence”, n. 78 above, p. 479.

94 Carens, “The problem of doing good”, n. 58 above, p. 271.

London, Geneva or elsewhere), they will often ask why anyone wanting to do human rights would choose to be an academic not an activist. Viewed from a teaching perspective it is an excellent question. But, if I am honest, it is vexing too: it seems to suggest that this choice – the choice of what to be in human rights – is the crucial one. It is, of course, an important choice, one that will have consequences both for the individual making it and for the future of human rights. Yet choice does not end at this point: life as an academic involves choice, and choice is also part and parcel of human rights activism. Indeed, in the activists’ world, choice can be both relentless and oppressive; it can also be a matter of life and death – for activists themselves and for others too. Put simply, choice is abundant in the activists’ world.

That in a way is what motivated this article. True, the article itself engages with just one context – public health – wherein NGOs face choices: choices that are important for them, for other public health actors and, of course, for the rest of us too. The article proposes that wider recognition and debate concerning such choices would be a good thing – though it will be precarious too. More specifically, the article proposes a *revised* Nuffield report; a report that is more fully engaged with the phenomenon I have labelled “public health *sans frontières*”.

Were there to be such a report, I would like it to include the following. First, the relationship between human rights and humanitarianism in the public health arena, and perhaps more broadly too (say, in relation to the government of war and armed conflict). Second, the commitment of global human rights NGOs to public health issues, and the extent to which we ought to be concerned both about the scope of such commitments and about the form that they take. Third, the particular challenges of *human rights* triage: what are those challenges, and in what ways are they genuinely distinctive to human rights (because of its commitments, say, or perhaps because of its practices)? Does human rights need a set of ethics<sup>95</sup> to handle such challenges or just a more thorough and more open engagement both with extant principles, such as participation and non-discrimination, and with extant health and human rights practices, such as those of South Africa’s TAC? And, finally, I have also emphasised that global health security has to be part of the backdrop to any such discussion, not least because this new preoccupation is already producing both challenges and opportunities for human rights NGOs who work in the field of public health.

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95 P Gready, “Introduction: responsibility to the story” (2010) 2 *Journal of Human Rights Practice* 177, p. 189, proposes an “enabling ethics” – albeit in a different, non-public health context.



# “Supra-stewardship”: a tool for citizen participation in European Union pandemic preparedness planning

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## Abstract

*This article proposes developing the public bioethics aspect of stewardship and applying it to the European Union (EU) as “supra-stewardship”, a tool for opening a discursive space for citizen participation in EU pandemic preparedness planning. With this in mind, the article highlights some of the contours for engagement on the boundaries of responsibility and production of governance distortions and failures brought out by attention to framing, distribution, vulnerability and learning. This should help citizens to tackle the complementary expert and public rationalities that undermine their involvement, contribute supplementary knowledge towards governance, and help promote institutional learning by the EU and resilience.*

**Key words:** pandemic influenza; preparedness; security; participation; supra-stewardship

## Introduction

The EU has an increasingly prominent role in public health issues,<sup>1</sup> as highlighted by its pandemic preparedness planning, such as for the recent influenza strain H1N1 or “swine flu”.<sup>2</sup> This planning aims to ensure the EU is of “added value” in the face of “emergency”<sup>3</sup> by respecting member state (MS) responsibility for the “management of health services and medical care and the allocation of the resources assigned to them”.<sup>4</sup> It does so by ensuring the interoperability of proliferating MS plans and, as an instance of reflexive governance or the “government of governments”,<sup>5</sup> the readiness of “essential

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1 For an overview, see T K Hervey and J V McHale, *Health Law and the European Union* (Cambridge: CUP 2004).

2 For instance, [www.bbc.co.uk/health/physical\\_health/conditions/swineflumulti1.shtml](http://www.bbc.co.uk/health/physical_health/conditions/swineflumulti1.shtml) (last accessed 5 September 2011).

3 As required by the principle of subsidiarity in Article 5(1) and (3) amended Treaty on European Union (TEU).

4 Article 168(7) Treaty on the Functioning of the European Union (TFEU) (emphasis added).

5 Coining Dean’s “government of government”: M Dean, *Governmentality* 2nd edn (London: Sage 2010), p. 226.

infrastructures". These comprise: planning and coordination; monitoring and assessment; prevention and containment; health system response; and communication. EU preparedness distributes responsibilities<sup>6</sup> around the EU's multi-level system of governance to a range of actors, including: the European Commission (the Commission); the European Centre for Disease Control (ECDC); MS authorities; private actors such as manufacturers of vaccines; the news media; and the EU's citizenry.<sup>7</sup> While the "imperative of preparedness is not new",<sup>8</sup> EU preparedness (hereafter simply preparedness) is still quite a recent and underexplored phenomenon.<sup>9</sup>

Working within science and technology studies' (STS) view that "the technical is political", Jasanoff terms risk assessment and management techniques like preparedness "technologies of hubris" since they make problems like pandemics visible in an effort to manage them and keep the economy working.<sup>10</sup> Making a point that resonates with the governmentality perspective used in this article and introduced in section 2 below, Jasanoff stresses how these technologies operate to depoliticise and naturalise governance, and as such help to quiet contestation and dissent, and ultimately legitimate that governance. Yet, they also engender "perils of prediction", especially in contexts of high uncertainty, such as masking the normative in the technical, and the production of governance distortions and failures.

Jasanoff asserts that identifying, managing and potentially correcting such "perils" requires a "civic epistemology" that gathers supplementary knowledge from throughout society.<sup>11</sup> This is to be achieved through a "technology of humility": citizen participation around the focal points of framing, vulnerability, distribution and learning to query the purpose of risk governance, whom it hurts, whom it benefits, and how we might know.<sup>12</sup> Given this, how might citizen participation around the focal points be facilitated to resist depoliticisation and naturalisation of governance, to raise awareness and promote discussion around the boundaries of responsibility as well as the production of governance distortions and failures, and generate knowledge for decision-making? How might law – specifically human rights<sup>13</sup> – assist in facilitating this task and with what tools?

While recognising that citizen participation requires a range of formal and informal mechanisms, processes and fora, I focus on constructing a biopolitical<sup>14</sup> discursive space in which citizens can use the focal points to demand and contest decision-making. I develop and seek to facilitate human rights' recent interest in citizen participation – also a hot topic in the

6 S J Collier and A Lakoff, "Distributed preparedness: space, security and citizenship in the United States" (2008) 26(1) *Environment and Planning, D: Society and Space* 7.

7 Article 9 TEU and Article 20 TFEU.

8 F Lentzos and N Rose, "Governing insecurity: contingency planning, protection, resilience" (2009) 38(2) *Economy and Society* 230, pp. 235–6.

9 Cf. S Mounier-Jack and R Coker, "Pandemic influenza: are Europe's institutions prepared?" (2006) 16(2) *European Journal of Public Health* 119; S L Greer, "The European Centre for Disease Prevention and Control: hub or hollow core?" and H Elliott, S L Greer and D K Jones, "Mapping disease control in the European Union", (2011) *Journal of Health Politics, Policy and Law* (forthcoming).

10 S Jasanoff, "Technologies of humility: citizen participation in governing science" (2003) 41 *Minerva* 223, p. 238.

11 Ibid; S Jasanoff, *Designs on Nature* (Woodstock: Princeton UP 2005), p. 250.

12 Jasanoff, "Technologies of humility", n. 10 above.

13 After the "human rights revolution" law tends to be thought of "as a system of rights which frames and contains government power": N Walker, "Review of M Loughlin, *Sword and Scales: An examination of the relationship between law and politics*" (2001) *Public Law* 644, p. 646 (emphasis added).

14 Jasanoff, *Designs on Nature*, n. 11 above, p. 36. See also: M Dillon and L Lobo-Guerrero, "Biopolitics of security in the 21st century" (2008) 34(2) *Review of International Studies* 265.

EU<sup>15</sup> – as being about empowerment.<sup>16</sup> Attention to empowerment resonates with the nuance in STS that “the technical is *potentially* political”,<sup>17</sup> in that it helps attune framing, vulnerability, distribution and learning towards the identification of disempowerment and potentially unjust power relations – that is, *when* citizen participation makes sense and preparedness *should* be political.<sup>18</sup>

This is part of a broader attempt by human rights to develop something other than a zero-sum relationship with discourses of risk, safety and security,<sup>19</sup> and maintain a connection with the targets of governance especially in fast-moving contexts typified by high uncertainty. Human rights must also demonstrate efficacy in the face of competition for regulatory relevance – and different figurations of citizen participation – from the other points of the “bioethical triangle” shaping governance: a largely restrictive and disempowering dignitarian perspective<sup>20</sup> and a pragmatic utilitarian perspective. Even as failure might create a “toxic” backlash against human rights as it seeks to shape risk governance, encouraging public interest has been highlighted as the main benefit of such an approach.<sup>21</sup> At the same time, citizen participation around the focal points is intended to recognise the *possibility* of ambiguity or unforeseen consequences, supplement dominant technologies of hubris, and as such might make governance and human rights more resilient in the event of failure.

Bearing in mind Moore’s observation that “public bioethics has so far remained largely separate from the analysis of public participation in scientific governance”,<sup>22</sup> in the next section I nominate and seek to instrumentalise the public bioethics aspect of stewardship, a model for population-level bioethics that is linked to and inflected by human rights. As I explain, this link to human rights makes stewardship adept at being honed into supra-stewardship by and for citizens: a tool to open a discursive space around, and their participation in, preparedness.

In section 3, I suggest how supra-stewardship could be used to make an initial attempt at bringing out the normative in the technical by exploring the construction of preparedness through discourses of risk, security, public understanding of science (PUS), and which are undergirded by neoliberalism. I recommend only some of the contours for engagement on the boundaries of responsibility and governance distortions and failures brought out by attention to framing, distribution and vulnerability. Further, I highlight the denial of citizens’ potential to connect with and make a substantive contribution towards

15 Making it a site of great hope for the democratisation of the global governance of life: S Jasanoff, “Biotechnology and empire: the global power of seeds and science” (2006) 21 *OSIRIS* 273.

16 M Flear and A Vakulenko, “A human rights perspective on citizen participation in the EU’s governance of new technologies” (2010) (10)4 *Human Rights Law Review* 661.

17 A Moore, “Beyond participation: opening up political theory in STS” (2010) 40(5) *Social Studies of Science* 793, p. 797 (emphasis added). This is a review of: M B Brown, *Science in Democracy: Expertise, institutions and representation* (Cambridge MA: MIT Press 2009).

18 Brown, *Science in Democracy*, *ibid*. Also see: A E Yamin, “Suffering and powerlessness: the significance of promoting participation in rights-based approaches to health” (2009) 11 *Health and Human Rights* 5.

19 Such as “rights as risk” and “risk within rights” in: T Murphy and N Whitty, “Is human rights prepared? Risk, rights and public health emergencies” (2009) 17 *Medical Law Review* 219.

20 For example, see: R Brownsword, “Human dignity, ethical pluralism, and the regulation of modern biotechnologies” in T Murphy (ed.), *New Technologies and Human Rights* (Oxford: OUP 2009).

21 T Murphy, “Technology, tools and toxic expectations: post-publication notes on *New Technologies and Human Rights*” (2009) 2 *Law, Innovation and Technology* 181.

22 A Moore, “Public bioethics and public engagement: the politics of ‘proper talk’” (2010) 19(2) *Public Understanding of Science* 197, at p. 197. Also: A Moore, “Public bioethics and deliberative democracy” (2010) 58 *Political Studies* 715.

governance through their construction within a disempowering “deficit model” as being in need of education through their participation.<sup>23</sup> This “peril of prediction” complements the hubristic expert rationality in preparedness. In the final section, I explain that supra-stewardship might help citizens to resist the deficit model, especially by allowing them to contribute knowledge towards decision-making, and promote institutional learning by the EU as well as resilience.

### Supra-stewardship

In sketching supra-stewardship I overview and highlight some key and useful features of stewardship models in the context of public health. I do not examine their respective advantages and disadvantages.<sup>24</sup> I use a critical theory and especially Foucault-influenced way of thinking about supra-stewardship, citizen participation and governance. Put simply, I am interested in these as discourses because they literally produce power – and provide a way to shape it.<sup>25</sup> In the context of disease, epidemiology and risk have historically laid the basis for governance. Their focus on population as the “end and instrument of government”, make it “possible to think, reflect, and calculate . . . outside the juridical framework of sovereignty”,<sup>26</sup> and give rise to governmentality.

In this setting freedom is “one of the facets . . . of the deployment of apparatuses of security”.<sup>27</sup> Security is about responding “to a reality in such a way that . . . [it] cancels out the reality to which it responds . . . regulates it”.<sup>28</sup> In late modernity there is resort to neoliberal rationality<sup>29</sup> through the use of market techniques and practices of “governing at a distance” in order to induce self-management and optimisation of health and welfare.<sup>30</sup> Extending this are moves towards reflexive governance. Dean explains that these work 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”.<sup>31</sup> Moreover, the accountability and legitimacy of governmentality becomes ever more important as formally accountable sites of power tighten their relations with science and technology,<sup>32</sup> and citizens engage with this reflexively as a “knowledge society”.<sup>33</sup>

23 Flear and Vakulenko, “A human rights perspective”, n. 16 above.

24 Cf. the other articles in this special issue. This article uses the approach and borrows elements developed elsewhere: Flear and Vakulenko, “A human rights perspective”, n. 16 above.

25 M Foucault, *The History of Sexuality, vol. I: The will to knowledge* (London: Penguin 1998), p. 101.

26 M Foucault, *Security, Territory, Population: Lectures at the Collège de France, 1977–1978* (Basingstoke: Palgrave Macmillan 2007), pp. 104–5.

27 Ibid. p. 49.

28 Ibid. p. 47.

29 Rose et al. describe “rationality” 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, p. 84.

30 M Foucault, *The Birth of Biopolitics: Lectures at the Collège de France, 1978–1979* (Basingstoke: Palgrave Macmillan 2008). Cf. T Lemke, “The birth of biopolitics”: Michel Foucault’s lecture at the Collège de France on neoliberal governmentality” (2001) 30(2) *Economy and Society* 190; W Brown, *Edgework* (Woodstock: Princeton UP 2005), pp. 39–44.

31 Dean, *Governmentality*, n. 5 above, p. 226 (emphasis added).

32 W Brown, *Regulating Aversion: Tolerance in the age of identity and empire* (Princeton NJ: Princeton UP 2006), p. 15; Jasanoff, *Designs on Nature*, n. 11 above, pp. 5–6.

33 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 UP 1999); N Stehr, *Knowledge Societies* (London: Sage 1994).

In light of this, supra-stewardship can be sketched out. In the World Health Organisation’s (WHO) version, stewardship is linked and even conflated with governance.<sup>34</sup> The *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”.<sup>35</sup> It is “the very essence of good government”, with state governments having the “[u]ltimate”<sup>36</sup> responsibility.

More recently, the Nuffield Council on Bioethics in its report *Public Health: Ethical issues*<sup>37</sup> (Nuffield) sought to develop a human rights-based approach to incorporate a precautionary way of thinking into population-level bioethics for public health contexts. Three of Nuffield’s authors, Baldwin, Brownsword and Schmidt, note how stewardship means that “liberal states have responsibilities to look after important needs of people both individually and collectively. Therefore, states are stewards both to individual people . . . and to the population as a whole”.<sup>38</sup> Developing stewardship beyond the state into “super-stewardship” is noted by Brownsword as “a significant item of unfinished business”.<sup>39</sup>

Part of that task is developing the public bioethics aspect of stewardship as a tool for citizen participation. As Ashcroft explains, public bioethics is “a set of practices for legitimating the ‘social license to practise’”<sup>40</sup> of medicine and the broader governance of life. Recognising the de-legitimising crises and failures of late modernity’s technologies of hubris – such as bovine spongiform encephalopathy (BSE) and genetically modified organisms (GMOs) – and in an attempt to tackle normative concerns, there has been a widespread turn towards bioethics – including within the EU – that arguably displaces the centrality of those scientific and technical models.<sup>41</sup> As such, instrumentalising and widening the rhetorical opening provided by public bioethics is a useful resource for a human rights-oriented and inspired perspective interested in empowering citizens.

I use the term *supra-stewardship* to emphasise the EU’s *sui generis* or *supra-national* nature and focus on the public bioethics aspect of its stewardship responsibilities towards its citizens.<sup>42</sup> In adopting a human rights-oriented approach, I suggest only some of the contours for empowerment of citizens as they bring out the normative in technical through engagement around the boundaries of responsibility and the production of governance distortions and failures. This engagement is facilitated by attention to framing, distribution, vulnerability and learning. I stop short of establishing criteria for assessing preparedness or prescribing the precise features of supra-stewardship. In an empowering way, it is for

34 “Stewardship and governance”: [www.euro.who.int/en/what-we-do/health-topics/Health-systems/stewardship-and-governance](http://www.euro.who.int/en/what-we-do/health-topics/Health-systems/stewardship-and-governance) (last accessed 5 September 2011).

35 “Message from the Director General, Gro Harlem Brundtland” in WHO, *World Health Report 2000* (Geneva: WHO 2000), p. viii.

36 Ibid. Also see: WHO, *World Health Day: International health security: invest in health, build a safer future* (Geneva: WHO 2007).

37 Nuffield Council on Bioethics, *Public Health: Ethical issues* (London: Nuffield Council on Bioethics 2007).

38 T Baldwin, R Brownsword and H Schmidt, “Stewardship, paternalism and public health: further thoughts” 2(1) *Public Health Ethics* (2009) 113, p. 115 (emphasis added). Citing Nuffield Council, *Public Health*, n. 37 above, p. 25.

39 R Brownsword, “So what does the world need now? Reflections on regulating technologies” in R Brownsword and K Yeung (eds), *Regulating Technologies: Legal futures, regulatory frames and technological fixes* (Oxford: Hart 2008), p. 47.

40 R Ashcroft, “Could human rights supersede bioethics?” (2010) 10(4) *Human Rights Law Review* 639, p. 645.

41 Moore, “Public bioethics and public engagement: the politics of ‘proper talk’”, n. 22 above.

42 Cf. S Holm, “From steward to Stuart: some problems in deciding for others” and T Hervey, “The European Union, its Court of Justice and ‘super-stewardship’ in public health” (containing an extensive review of the EU’s deeply contested nature), both developing the EU’s stewardship role in this special issue.

citizens to explore further the protean, open-textured and polyvalent nature of stewardship so that they might hone a tool for their participation in governance.

As an indication, in terms of framing, when informed by the WHO, supra-stewardship could ensure a focus on “*improving overall levels of population health*”<sup>43</sup> and “oversight of the entire system, avoiding myopia, tunnel vision and the *turning of a blind eye* to a system’s *failings*”.<sup>44</sup> References to pandemic planning in the WHO and Nuffield versions of stewardship do emphasise essential infrastructures, but they are part of a broader attention to population and the conditions that support it. Importantly, Nuffield uses pandemic influenza as a jumping-off point for considering cross-border obligations, noting how it is “also reasonable” to apply stewardship at a “much higher level”.<sup>45</sup> The central example given – duplicated by the EU and noted as problematic below – is that countries should notify others of a serious infectious disease outbreak, following WHO procedures. Yet, since such cross-border obligations require an efficient surveillance system and some countries lack such capabilities, richer countries become obligated to “seek to enhance the capacities of developing countries to conduct effective surveillance of infectious diseases”.<sup>46</sup> Surveillance is “not simply a national matter”.<sup>47</sup> Interestingly, the ECDC is referred to here, alongside the WHO and the Centers for Disease Prevention and Control in the United States, as “international partners”.<sup>48</sup>

As elaborated below, a focus on pandemics in cross-border governance has implications for distribution and vulnerability, both within the EU and in its external relations, and they could be teased out by stressing wider public health objectives. For instance, similar to Nuffield, the WHO notes the objectives of stewardship “are likely to be framed in terms of equity, coverage, access, quality, and patients”<sup>49</sup> rights. Baldwin et al. note that stewardship means taking account of “different needs arising from factors such as age, gender, ethnic background or socio-economic status”.<sup>50</sup> Bolstering this is a focus on supporting population through the “*conditions* that allow people to be healthy, *focussing attention, in particular, on reducing health inequalities*”.<sup>51</sup> Finally, learning means using engagement around the other focal points to open up space for collective and especially institutional learning by the EU around uncertainty and ambiguity, the delineation of its responsibility, the production of governance distortions and failures, and ways of promoting the uptake and use in decision-making of the knowledge produced by citizen participation.

In drawing on stewardship models, supra-stewardship could derive power from their foundation in human rights and bioethics. While others have discussed the advantages and disadvantages of the link between them,<sup>52</sup> it is more important here to recognise its presence in several international declarations,<sup>53</sup> and the scholarly discussion of what that

43 “Governance”: [www.who.int/healthsystems/topics/stewardship/en/index.html](http://www.who.int/healthsystems/topics/stewardship/en/index.html) (emphasis added) (last accessed 5 September 2011).

44 “Message”, n. 35 above, p. ix (emphasis added).

45 Nuffield Council, *Public Health*, n. 37 above, p. 68 (emphasis added).

46 Ibid.

47 Ibid. p. 67.

48 Ibid. p. 68.

49 “Governance”, n. 43 above.

50 Baldwin et al., “Stewardship”, n. 38 above, pp. 115–16. Cf. Nuffield Council, *Public Health*, n. 38 above, p. 25 (emphasis added).

51 Ibid. (emphasis added).

52 See, generally: Ashcroft, “Could human rights supersede bioethics?”, n. 40 above.

53 For instance, the Universal Declaration on Bioethics and Human Rights (2005), and in the European context in, for instance, the Convention on Human Rights and Biomedicine (the Oviedo Convention 1997) and its protocols.

entails. That is, as Ashcroft summarises, whether human rights might “subsume or replace bioethics, at least at the level of the public governance of medicine and the life sciences”.<sup>54</sup> Most notable for present purposes is human rights’ capacity, also noted by Ashcroft, and highlighted by Montgomery in his discussion of Nuffield,<sup>55</sup> to facilitate communication between governance and citizens – as Black explains it, “putting the views of each set of participants [in governance] into a language that the others can understand”<sup>56</sup> – and to provide a rhetorical opening for participation.

Ashcroft describes the point of particular interest:

[The potential of human rights in the] hands of activists, at least to disrupt . . . by *challenging the language*, the *types of problem recognised* . . . and the working methods of the public bioethics process. This might particularly be the case where the challenge to bioethics comes from groups which have tried – and failed – to *challenge the policy consensus* by other methods.<sup>57</sup>

In relation to preparedness, and as detailed further in the next section, the groups that might benefit most include those whose biology or social status renders them particularly vulnerable to infection by pandemic influenza and who have a special interest in public health interventions, especially vaccination and social distancing. Figured as “risk groups”, they include those with underlying medical conditions, pregnant women, children and itinerants. Such individuals and groups might exploit human rights<sup>58</sup> to generate “politics of life itself”.<sup>59</sup> This potential is recognised in terms such as “moral pioneers”,<sup>60</sup> “genetic citizens”<sup>61</sup> or “biocitizens”.<sup>62</sup> These highlight how people come to know and understand themselves and relate to others through knowledge of their biological and medical status – but nevertheless sometimes demonstrate “biosociality”<sup>63</sup> as they work together to reshape governance in order to address their concerns.

In the EU context, the empowering potential of human rights and bioethics has been traced more extensively by Flear and Vakulenko.<sup>64</sup> Yet, that potential is stressed as replete with paradoxes and pitfalls that might reproduce and reinforce the deficit model of citizens – which might in turn stymie supra-stewardship. For instance, even as human rights promises and delivers results when deployed to combat social difference and its attendant

54 Ashcroft, “Could human rights supersede bioethics?”, n. 40 above, at p. 640.

55 Cited as a work in progress and discussed in: J Coggon, “What help is a steward? Stewardship, political theory and public health law and ethics”, in this special issue.

56 J Black, “Regulation as facilitation: negotiating the genetic revolution” (1998) 61(5) *Modern Law Review* 621, p. 623.

57 Ashcroft, “Could human rights supersede bioethics?”, n. 40 above, p. 645 (emphasis added).

58 W Brown, *States of Injury* (Oxford: Princeton UP 1995); W Brown, “Suffering rights as paradoxes” (2000) 7 *Constellations* 230.

59 N Rose, *The Politics of Life Itself: Biomedicine, power and subjectivity in the 21st Century* (Oxford: Princeton UP 2007).

60 R Rapp, *Testing Women, Testing the Fetus: The social impact of amniocentesis in America* (London: Routledge 2000).

61 D Heath, R Rapp and K-S Taussig, “Genetic citizenship” in D Night and J Vincent (eds), *A Companion to the Anthropology of Politics* (Oxford: Blackwell 2004).

62 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 2005).

63 P Rabinow, *Essays on the Anthropology of Reason* (Princeton NJ: Princeton UP 1996); S Gibbon and C Novas (eds), *Biosocialities, Genetics and the Social Sciences* (London: Routledge 2007).

64 Flear and Vakulenko, “A human rights perspective”, n. 16 above.

injustices,<sup>65</sup> it can also produce and reinforce social position as identity.<sup>66</sup> In moves that reinforce the deficit model, conferred top-down in the EU,<sup>67</sup> human rights also depoliticises and naturalises the social origins of problems, and emphasises and abets moves towards self-management and individualisation that deny the potential of collective action to reshape governance. More broadly, Somsen queries the wisdom of developing a precautionary approach within human rights, arguing it effectively provides “governments with a blank cheque for limiting individual liberties”.<sup>68</sup> Similarly, stewardship might also limit individual autonomy through paternalistic interventions in citizens’ lives.

Still, given the predominance of risk (and safety and security), human rights’ efforts to engage and demonstrate its efficacy – here by instrumentalising public bioethics for citizen participation – is surely valuable. Further, safeguards against excessive action and paternalism in stewardship that might be deployed in supra-stewardship to resist disempowerment are envisaged by the WHO (especially in terms of patients’ rights) and Nuffield. In the latter report, public health programmes are constrained by an intervention ladder that attempts to minimise “significant limitations on individual freedom”.<sup>69</sup> For example, while compulsory vaccination can override individual consent, its use should be minimised and come with procedural justice arrangements (such as democratic decision-making procedures) which provide adequate mandate and justification of public health governance. This sort of requirement provides resources for participation that could underpin supra-stewardship. Yet, since the focus is on aligning governance with public opinion through scrutiny and expression of views, and there are no guarantees for a substantive input into decision-making, participation is limited and there seems to be a denial of citizens’ potential to contribute knowledge.<sup>70</sup>

To focus on (public) bioethics in the EU, it is prominent through the introduction of ethics committees in the MSs by the Clinical Trials Directive<sup>71</sup> and the European Group on Ethics. The latter provides the Commission with a comprehensive range of opinions on “all areas of the application of science and technology”,<sup>72</sup> which have been used to support controversial research funding<sup>73</sup> and produce “whereas” clauses bolstering the recitals of

65 For instance, Article 6 amended TEU gives the previously non-binding Charter of Fundamental Rights of the European Union the same status as the treaties. Further, not only is the European Convention on Human Rights noted as a source for the general principles of EU law in Article 6(3) amended TEU, but the EU’s accession to the Council of Europe is required under Article 6(2) amended TEU. It might even be said the EU – now with its own Fundamental Rights Agency – has become *the* human rights organisation in Europe. On this and key cases see: Flear and Vakulenko, “A human rights perspective”, n. 16 above.

66 Flear and Vakulenko, “A human rights perspective”, n. 16 above.

67 Ibid.

68 H Somsen, “Regulating human genetics in a neo-eugenic era” in T Murphy (ed.), *New Technologies and Human Rights* (Oxford: OUP 2009), p. 116.

69 Nuffield Council, *Public Health*, n. 37 above, p. 26.

70 Ibid. p. 26: stewardship “recognises the importance of open and transparent participatory processes as a necessary condition for public health policy making, but it is also clear that these are not sufficient by themselves. Stewardship is not exercised simply by following the public vote, especially where issues involve complex scientific evidence. Under the stewardship model, public health policy should be compatible with the views of the public, and the government should create conditions that allow the public to scrutinise and judge the appropriateness of proposed policies.”

71 Directive 2001/20/EC.

72 Decision 2005/383/EC.

73 Opinion 10 – 11 December 1997 – Ethical Aspects of the 5th Research Framework Programme; Opinion 22 – 13 July 2007 – The Ethics Review of hESC FP7 Research Projects.

legislation.<sup>74</sup> In addition, the ethical content of the latter is removed from citizen contestation to be determined by *committees* and *MS governments*.<sup>75</sup> Bioethics is designed “to ensure that the general public is kept properly informed”<sup>76</sup> and to “keep the rapidly advancing progress in science in harmony with the *ethical values of all Europeans*”.<sup>77</sup> Yet, since those values are merely represented in expert discourse, the deficit model of citizens re-emerges along with expert domination of governance. In short, bioethics has tended to be used less to facilitate citizen participation and more as a way of legitimating EU governance of life. Even so, as Flear and Vakulenko point out, bioethics has an empowering potential by opening up knowledge domains and facilitating discussion – and this could be enhanced by the link with human rights and references to mandate and participation.<sup>78</sup>

Overall, while stewardship models are, as Coggon asserts, neat but problematic labels,<sup>79</sup> despite their problems and paradoxes, I stick to the basic proposition that supra-stewardship is of much use as a tool to facilitate a discursive space for citizen participation in preparedness. Indeed, supra-stewardship might be most useful when deployed with critical self-consciousness to develop its content and meaning in light of ongoing concerns and immediate exigencies – and resist reproduction of the deficit model.

## EU preparedness: responsibility, governance distortions and failures

### THE FRAME AND RATIONALITY OF PREPAREDNESS

This will become apparent as I suggest how supra-stewardship could produce supplementary knowledge for existing technologies of hubris and contribute towards institutional learning and decision-making. As a first step, it is necessary to unpack the frame and rationality of preparedness in order to then suggest the contours of engagement on its delimitation of EU responsibility and some of its broad governance distortions and failures, which are brought out by attention to framing, distribution and vulnerability. In the second sub-section, I take a closer look at the boundaries of responsibility and distortions and failures relating to two key essential infrastructures favoured by preparedness: surveillance and interventions.

The frame is assembled from EU law and policy. As an indicative overview, in EU law public health is recognised and protected through express derogations to the free movement of goods, persons and services, which are supplemented by justifications created through the jurisprudence of the Court of Justice of the European Union.<sup>80</sup> As such public health is central to the EU’s internal market, defined as “an area without internal frontiers in which the *free movement* of goods, persons, services and capital is ensured”.<sup>81</sup> Public health

74 For instance, Directive 2004/23/EC on Human Tissue and Cells and Regulation 1394/2007 on Advanced Therapies.

75 M Tallacchini, “Governing by values. EU ethics: soft tool, hard effects” (2009) 47 *Minerva* 281, pp. 293–95.

76 [http://ec.europa.eu/bepa/european-group-ethics/archive-mandates/mandate-1991-1997/index\\_en.htm](http://ec.europa.eu/bepa/european-group-ethics/archive-mandates/mandate-1991-1997/index_en.htm) (emphasis added) (last accessed 5 September 2011).

77 *Taking European Knowledge Seriously: Report of the Expert Group on Science and Governance* (Luxembourg: European Commission 2007), p. 49 (emphasis added).

78 Flear and Vakulenko, “A human rights perspective”, n. 16 above.

79 Coggon, “What help is a steward?”, n. 55 above.

80 For instance: Case 120/78 *Rewe-Zentrale AG v Bundesmonopolverwaltung (Cassis de Dijon)* [1979] ECR 649; Case 178/84 *Commission v Germany (Beer Purity Laws)* [1987] ECR 1227; Case C-76/90 *Säger v Denemeyer* [1991] ECR I-4221; Case C-55/94 *Gebhard* [1996] ECR I-4165; Case C-237/94 *O’Flynn v Adjudication Officer* [1996] ECR I-2617. See further: C Barnard, *The Substantive Law of the EU: The four freedoms* (Oxford: OUP 2010), pp. 165–87, 241–2 and 510–8.

81 Article 26(2) TFEU (emphasis added). The establishment of the internal market is required by Article 3(3) amended TEU.

is increasingly aligned to security concerns in the traditional understanding of them as being about containment, defence and protection, *and* also in a more Foucauldian vein as being about optimising the circulation of people and things and regulating the attendant dangers. This is apparent in, for instance, references that the MSs are “resolved to facilitate the free movement of persons, while ensuring the *safety and security* of their peoples, by establishing an area of *freedom, security and justice*”.<sup>82</sup>

This concern with security is inflected in Article 168 of the Treaty on the Functioning of the EU (TFEU),<sup>83</sup> the treaty base for preparedness, which states a “high level of *human health protection* shall be ensured in the definition and implementation of all Union policies and activities”.<sup>84</sup> EU action cannot harmonise and is only complementary to that of its MSs,<sup>85</sup> which maintain responsibilities over “the *definition* of their health policy and for the *organisation and delivery* of health services and medical care”.<sup>86</sup> However, the MSs are required to work in liaison with the Commission to coordinate among themselves their policies and programmes in the areas referred to in Article 168(1).<sup>87</sup>

Article 168(2) provides for the adoption of measures including guidelines and indicators, exchange of best practice, and mechanisms for periodic monitoring and evaluation. Under Article 168(1) and (2) such action must be “directed towards improving public health . . . *obviating sources of danger to physical and mental health*”, and covers “health information and education, and monitoring, early warning of and combating serious cross-border threats to health”.<sup>88</sup> The addition of the final italicised portion to the text of the former Article 152 EC seems intended to reflect and provide a concrete basis for EU action. Further, Article 168(3) provides both the EU and its MSs “*shall* foster cooperation with *third countries* and the *competent international organisations* in the sphere of public health”.<sup>89</sup>

With EU law as its foundation, and grounded on a more general scientific approach to decision-making established in the EU White Paper *European Governance* as a response to the regulatory failures noted above,<sup>90</sup> it is in policy that preparedness is elaborated.<sup>91</sup> The focus on some of the most important steps in the tightening of the link between public health and security, 9/11<sup>92</sup> and subsequent terrorist attacks prompted the EU’s “all hazards”

82 Recital 12 amended TEU (emphasis added). Cf. Article 3(2) amended TEU. See further (including summary of legislation): [http://europa.eu/pol/justice/index\\_en.htm](http://europa.eu/pol/justice/index_en.htm) (last accessed 5 September 2011). For discussion: N Walker (ed.), *Europe's Area of Freedom, Security and Justice* (Oxford: OUP 2004).

83 Formerly Article 152 EC.

84 Article 168(1) TFEU (emphasis added).

85 Harmonisation is precluded by Article 168(5) TFEU. In accordance with principles of subsidiarity and proportionality in Article 5 amended TEU.

86 Article 168(7) TFEU (emphasis added)

87 A concrete expression of the principle of sincere cooperation in Article 4(3) amended TEU.

88 Emphasis added. Previously Article 152(1)(1)–(2) EC emphasised “obviating sources of danger to human health” and it did not include a reference to cross-border threats to health.

89 Emphasis added.

90 For the EU’s general approach to risk regulation see: European Commission, “European Governance: A White Paper”, COM(2001) 428 final. Cf. Flear and Vakulenko, “A human rights perspective”, n. 16 above.

91 The documents are available at: [http://ec.europa.eu/health/preparedness\\_response/policy/index\\_en.htm](http://ec.europa.eu/health/preparedness_response/policy/index_en.htm) (last accessed 5 September 2011). On the link made globally see: Murphy and Whitty, “Is human rights prepared?”, n. 19 above.

92 F Lentzos, “Rationality, risk and response: a research agenda for biosecurity” (2006) 1(4) *BioSocieties* 453.

approach to biosecurity.<sup>93</sup> With public health security established as a priority by the EU’s Health Council on 15 November 2001, there followed a *Programme of Cooperation on Preparedness and Response to Biological and Chemical Attacks [Health Security]*,<sup>94</sup> dealing with deliberate human release of chemical, biological, radiological and nuclear (CBRN) agents within the EU and aimed at “bridging security and health”.<sup>95</sup> One of the objectives of this plan was the establishment of the Health Security Committee (HSC), which meets twice yearly and is composed of high-level representatives from health ministries of the MSs, the Commission, the ECDC and the European Medicines Agency (EMA).<sup>96</sup>

On 27 November 2001, the Commission began its first notable foray into pandemic preparedness planning with a conference to link pandemic influenza with security (titled “Preparedness Planning in the Community: Influenza and Other Health Threats”) and providing the impetus for next steps.<sup>97</sup> With the concern around severe acute respiratory syndrome (SARS) and avian influenza in 2003, the link between public health and security came to encompass previously unknown diseases whose rapid transmission was facilitated by free movement. The importance of such measures was highlighted by the support and guidance of the WHO.<sup>98</sup> In the wake of this, the remit of the Early Warning and Response System (EWRS) established in 1999<sup>99</sup> was extended to cover a wide range of communicable diseases, including H1N1.<sup>100</sup> The EWRS is “a confidential computer system allowing Member States to send alerts about events with a potential impact on the EU, share information, and coordinate their response”<sup>101</sup> (consistent with the

93 Cf. European Commission, “Green Paper on Bio-preparedness”, COM(2007) 399 final. For discussion: S Brem and S Dubois, “Different perceptions, similar reactions: biopreparedness in the European Union” in P Katona, J P Sullivan and M D Intriligator (eds), *Global Biosecurity: Threats and responses* (London: Routledge 2010). More generally: D P Fidler and L O Gostin, *Biosecurity in the Global Age: Biological weapons, public health, and the rule of law* (Stanford: Stanford UP 2007); A Lakoff, “Preparing for the next emergency” (2007) 19(2) *Public Culture* 247; S Hinchcliffe and N Bingham, “Securing life: the emerging practices of biosecurity” (2008) 40(7) *Environment and Planning A* 1534.

94 European Commission, “Programme of Cooperation on Preparedness and Response to Biological and Chemical Attacks [Health Security]” G/FS D(2001) GG.

95 See: [http://ec.europa.eu/health/preparedness\\_response/policy/index\\_en.htm](http://ec.europa.eu/health/preparedness_response/policy/index_en.htm) (last accessed 5 September 2011). Subsequently, see: European Commission, “Communication on Cooperation in the European Union on Preparedness and Response to Biological and Chemical Agent Attacks (Health Security)”, COM(2003) 320 final. Also see: European Commission, “Communication on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union – an EU CBRN Action Plan”, COM(2009) 273 final; European Commission, “Commission Staff Working Document on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union – an EU CBRN Action Plan. Impact Assessment”, SEC(2009) 790; European Commission, “Commission Staff Working Document on Strengthening Chemical, Biological, [n. 95 cont.] Radiological and Nuclear Security in the European Union – an EU CBRN Action Plan. Summary of Impact Assessment”, SEC(2009) 791; European Commission, “Commission Staff Working Document Bridging Security and Health: Towards the Identification of Good Practices in the Response to CBRN Incidents and the Security of CBR Substances”, SEC(2009) 874.

96 Especially representatives of Directorate-General for Health and Consumers: [http://ec.europa.eu/dgs/health\\_consumer/index\\_en.htm](http://ec.europa.eu/dgs/health_consumer/index_en.htm) (last accessed 5 September 2011).

97 [http://ec.europa.eu/health/ph\\_threats/com/Influenza/influenza\\_conference\\_1.htm](http://ec.europa.eu/health/ph_threats/com/Influenza/influenza_conference_1.htm) (last accessed 5 September 2011).

98 European Commission, “Communication on Strengthening Coordination on Generic Preparedness Planning for Public Health Emergencies at EU Level”, COM(2005) 605 final, p. 3.

99 Decision 2119/98/EC Establishing Network for the Epidemiological Surveillance and Control of Communicable Diseases and Decision 2000/57/EC11 on the EWRS.

100 [http://ec.europa.eu/health/communicable\\_diseases/diseases/index\\_en.htm#A](http://ec.europa.eu/health/communicable_diseases/diseases/index_en.htm#A) (last accessed 5 September 2011).

101 [http://ec.europa.eu/health/communicable\\_diseases/early\\_warning/comm\\_legislation\\_en.htm](http://ec.europa.eu/health/communicable_diseases/early_warning/comm_legislation_en.htm) (last accessed 5 September 2011).

International Health Regulations).<sup>102</sup> Surveillance data from the EWRS is collated into a report by the ECDC.<sup>103</sup> This move strengthened the knowledge available to MSs and enhanced their ability to limit contagion.

On 26 March 2004, the Commission began to step up its engagement with pandemic influenza planning, and as an “important step” established a Public Health Preparedness and Response Planning Group (PHPRPG) in the HSC to advise it on the actions to be taken in the event of an imminent pandemic threat.<sup>104</sup> On 28 November 2005, there followed the *Communication on Pandemic Influenza Preparedness and Response Planning in the European Community*,<sup>105</sup> which updated planning in light of WHO recommendations and the establishment of the ECDC, also in 2005. This uses “the principles and components of . . . generic preparedness planning”,<sup>106</sup> such as in the *Communication on Strengthening Coordination on Generic Preparedness Planning for Public Health Emergencies at EU Level*<sup>107</sup> and the *Interim Document: Technical Guidance on Generic Preparedness Planning for Public Health Emergencies (interim document)*.<sup>108</sup> As such, I draw on generic preparedness only where it helps to elaborate on pandemic preparedness. The Commission and the ECDC have also been actively engaged with the WHO, joint international workshops<sup>109</sup> and global meetings to discuss planning with third countries,<sup>110</sup> including the Global Health Security Initiative (GHSI), an informal, international partnership that works to strengthen health preparedness and response globally.<sup>111</sup>

Importantly, in February 2007, the Health Council agreed on a transitional prolongation and extension of HSC’s mandate to encompass the threads traced above: public health preparedness and response to CBRN attacks; generic preparedness and response for public

102 The *International Health Regulations* (IHR) require WHO MSs to notify the WHO of any potential international public health emergency (World Health Assembly, *International Health Regulations* (2005), available at [www.who.int/csr/ihr/IHRWHA58\\_3-en.pdf](http://www.who.int/csr/ihr/IHRWHA58_3-en.pdf) (last accessed 5 September 2011)), and are rendered applicable to the EU under Article 57(1) IHR, which states the IHR and EU Treaties “should be interpreted so as to be compatible”. The Commission “believes the EU and its [MSs] can and should work together to optimise IHR implementation in the context of the EU policies and health related actions and initiatives” (see press release: <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/1276> (last accessed 5 September 2011)).

103 For instance, *Annual Epidemiological Report on Communicable Diseases in Europe 2009* (Stockholm: ECDC 2010), available at [http://www.ecdc.europa.eu/en/publications/Publications/1011\\_SUR\\_Annual\\_Epidemiological\\_Report\\_on\\_Communicable\\_Diseases\\_in\\_Europe.pdf](http://www.ecdc.europa.eu/en/publications/Publications/1011_SUR_Annual_Epidemiological_Report_on_Communicable_Diseases_in_Europe.pdf) (last accessed 5 September 2011).

104 See [http://ec.europa.eu/health/ph\\_threats/com/Influenza/influhome/influenza\\_level\\_en.htm](http://ec.europa.eu/health/ph_threats/com/Influenza/influhome/influenza_level_en.htm) (last accessed 5 September 2011).

105 European Commission, “Communication on Pandemic Influenza Preparedness and Response Planning in the European Community”, COM(2005) 607 final.

106 *Ibid.* p. 7.

107 European Commission, “Generic Preparedness”, n. 98 above.

108 European Commission, “Interim Document: Technical Guidance on Generic Preparedness Planning for Public Health Emergencies”, 2005. This addresses in martial tones, “*threats and emergencies* which are affecting or are likely to affect public health in more than one Member State” (*ibid.* p. 65, emphasis added). The guidance includes checklists “as a guide that may be used to assist in the development, revision or assessment of comprehensiveness of preparedness plans” (*ibid.* p. 3) and facilitate the “*inter-operability of national plans*, mainly by the creation of *co-ordination mechanisms* and analysis and *communication* tools that *enhance co-operation* between key Member States and Commission players” (*ibid.* p. 2, emphasis added), and lay the basis for “reviews, validations and tests and making recommendations for improvements and fine-tuning of national plans and EU procedures to *reduce vulnerabilities and incompatibilities*” (*ibid.* emphasis added).

109 2–3 March 2005 in Luxembourg, 24–26 October 2005 in Copenhagen, 15–17 May 2006 in Uppsala, and 25–27 September 2007 in Luxembourg. See further: [http://ec.europa.eu/health/ph\\_threats/com/Influenza/influhome/influenza\\_level\\_en.htm](http://ec.europa.eu/health/ph_threats/com/Influenza/influhome/influenza_level_en.htm) (last accessed 5 September 2011).

110 For instance, “Vienna Senior Officials Meeting on Avian and Human Pandemic”, 6 and 7 June 2006. See [http://ec.europa.eu/health/ph\\_threats/com/Influenza/SOM\\_Vienna.pdf](http://ec.europa.eu/health/ph_threats/com/Influenza/SOM_Vienna.pdf) (last accessed 5 September 2011).

111 See [www.ghsi.ca/english/index.asp](http://www.ghsi.ca/english/index.asp) (last accessed 5 September 2011).

health emergencies; and, most significantly, influenza preparedness and response.<sup>112</sup> The link between public health and security was augmented further by the identification of “protecting people from health threats” as one of three key objectives of 2007’s *Together for Health: A Strategic Approach for the EU 2008–2013*.<sup>113</sup> This encompasses communicable, non-communicable and rare diseases, vaccination, and preparedness and response to health threats.

Preparedness operationalises, and is framed by, this dense link between public health and security in order to deal with a pandemic, which is constructed as a medical emergency. It is a useful supplement to public health’s traditional focus on prevention, which relies on archival–statistical knowledge, but which by definition becomes of limited use in contexts of high uncertainty. Unsurprisingly, then, preparedness is the pervasive governance response for dealing with highly ambiguous and uncertain (low-probability, high-harm) risks,<sup>114</sup> engendering a “policy revolution”,<sup>115</sup> propelling us into “the age of preparedness”.<sup>116</sup> As Collier and Lakoff put it, generally preparedness requires imaginative enactment and “demands that experts *constantly assess the vulnerability of vital systems and the readiness to respond to, and recover from, events that threaten them*”.<sup>117</sup> This is echoed by the Commission, which uses previous experience to imagine pandemic scenarios<sup>118</sup> and notes “the ability to respond to an international threat to health is profoundly influenced by the extent to which the issues have been *considered in advance and plans are in place for co-ordinated action*”.<sup>119</sup>

Yet, as Collier and Lakoff go on to say, generally the goal of preparedness “is *not* necessarily to prevent events from happening but to *mitigate their consequences* – in other words, to keep a disaster from turning into a catastrophe”.<sup>120</sup> This is reflected in statements by the Commission. For example, preparedness is “directed towards identifying and addressing the current impact and subsequent threat potential of the influenza outbreak in order to *limit its consequences*”<sup>121</sup> – especially to the internal market.<sup>122</sup> Still, in producing a “synergy” to the mutual benefit of public health and security such as in relation to surveillance and interventions, preparedness might have some use in bolstering efforts and resources to deal with pandemics as a medical emergency.<sup>123</sup> Indeed, as Rothstein et al. point out, a focus on so-called “institutional risk” (the “government of governments”) can

112 In response to: European Commission, “Communication on Transitional Prolongation and Extension of the Mandate of the Health Security Committee in View of a Future General Revision of the Structures Dealing with Health Threats at EU Level”, COM(2006) 699 final.

113 European Commission, “White Paper, Together for Health: A Strategic Approach for the EU 2008–2013”, COM(2007) 630 final; European Commission, “Commission Staff Working Document Accompanying White Paper, Together for Health: A Strategic Approach for the EU 2008–2013”, SEC(2007) 1376. For an overview of initiatives, see European Commission, “Commission Staff Working Document, Report on European Governance (2003–2004)”, SEC(2004) 1153. Also see: [http://ec.europa.eu/health/strategy/policy/index\\_en.htm](http://ec.europa.eu/health/strategy/policy/index_en.htm) (last accessed 5 September 2011).

114 R Ericson and A Doyle, *Uncertain Business: Risk, insurance and the limits of knowledge* (Toronto: University of Toronto Press 2004); S J Collier, “Enacting catastrophe: preparedness, insurance, budgetary rationalization” (2008) 37(2) *Economy and Society* 224; A Lakoff, “From population to vital system” in A Lakoff and S Collier (eds), *Biosecurity Interventions* (Chichester: Columbia UP 2008); P O’Malley, *Risk, Uncertainty and Government* (London: Glasshouse Press 2004).

115 Fidler and Gostin, *Biosecurity*, n. 93 above, p. 145.

116 Murphy and Whitty, “Is human rights prepared?”, n. 19 above, pp. 230 and 232.

117 S Collier and A Lakoff, “Vital systems security” (2007) ARC Working Paper No 2, p. 3 (emphasis added).

118 For instance, European Commission, “Interim Document”, n. 108 above.

119 *Ibid.* p. 3 (emphasis added).

120 *Ibid.*

121 European Commission, “Pandemic Influenza Preparedness”, n. 105 above, p. 8 (emphasis added).

122 *Ibid.* and European Commission, “Interim Document”, n. 108 above.

123 See further, Fidler and Gostin, *Biosecurity*, n. 93 above, ch. 5.

figure the approach taken to “societal risks” (like H1N1).<sup>124</sup> Advantages of this include the sensitisation of the EU to pandemic influenza, more and coordinated research, professionalisation of the problem and a stronger basis for decision-making.

However, such potential benefits are what de Larrinaga and Doucet call “part of the wager” of securitisation of public health by and through the construction of a pandemic as a medical emergency.<sup>125</sup> Securitisation is a speech act and force that redounds below, especially in relation to distribution and vulnerability concerns around interventions. Security provides the “conditions of possibility for liberalism’s central tenet of freedom”,<sup>126</sup> what Foucault describes as “the possibility of movement, change of place, and processes of circulation of both people and things”.<sup>127</sup> As such, optimisation of freedom creates demands for increased security and an all too easy resort to the exceptional measures it favours – that is, more preparedness through a focus on protection of essential infrastructures, especially surveillance and interventions.<sup>128</sup> Balzacq summarises the point: 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”.<sup>129</sup>

Moreover, as de Larrinaga and Doucet explain, the governmentalisation of security means it is increasingly understood in neoliberal terms as being about the optimisation of the health and wealth of (non-state) populations and “assessment of threats . . . pays particular attention to the global and transboundary *circulation of threats* to [them]”.<sup>130</sup> In a reflexive way this is to be achieved through the protection of vulnerable governance rather than vulnerable populations. As already apparent, and detailed further below, this is accomplished by assembling, linking together and leveraging support from various discourses, knowledges, scientific and bureaucratic techniques and practices from a range of national, supranational and global actors and sources.<sup>131</sup> References to inter alia the Commission, HSC, ECDC, MSs, WHO and GHSI, and their gathering and deployment of pandemic and risk knowledge, highlight the securitisation of public health and governmentalisation of security as being underpinned by an expert rationality.

To clarify, the broadest governance distortion is the emphasis on and distribution of resources towards protecting essential infrastructures – planning and coordination, monitoring and assessment, prevention and containment, health system response and communication – which attempt to mitigate catastrophe in the face of a pandemic medical emergency and ensure the EU is only indirectly formally responsible for population. To quote Black, this also sets in train “decisions as to which *types of failures an organisation* is willing to tolerate” – failures in the direct protection of population – “and

124 H Rothstein, M Huber and G Gaskell, “A theory of risk colonization: the spiralling regulatory logics of societal and institutional risk” (2006) 35(1) *Economy and Society* 91.

125 M de Larrinaga and M G Doucet, *Security and Global Governmentality: Globalisation, governance and the state* (London: Routledge 2010), p. 1.

126 Ibid. p. 7.

127 Foucault, *Security*, n. 26 above, pp. 48–9.

128 Generally, see De Larrinaga and Doucet, *Security and Global Governmentality*, n. 125 above.

129 T Balzacq, “Preface” in *Securitisation Theory: How security problems emerge and dissolve* (London: Routledge 2011), p. xiii.

130 De Larrinaga and Doucet, *Security and Global Governmentality*, n. 125 above, p. 17 (emphasis added).

131 J Huysmans, *The Politics of Insecurity: Fear, migration and asylum in the EU* (London: Routledge 2006).

which it is *not*<sup>132</sup> – failures in the protection of essential infrastructures in order to optimise the economy.

As Black continues, these choices “are linked to attempts to define the *parameters of blame*. Through risk-based frameworks, regulators are attempting to define what, to their minds, *are the acceptable limits of their responsibility and hence accountability*”.<sup>133</sup> It does not appear that improvisation<sup>134</sup> is to be avoided or eliminated even as interoperability of MS plans is the focus, and given that, as traced below, it is built into planning. However, improvisation does seem to be constrained – and responsibilities limited to protection of essential infrastructures in order to optimise the economy, governance distorted and certain failures envisaged – by the construction of preparedness. Requiring far more discussion, below I focus only on pharmaceutical interventions as the key medical emergency triage choice. Clearly, attention to *framing* reveals the pandemic “threat”, the governance planning response, and its attendant distortions and failures as fabrications with profound normative implications. Yet, as Balzacq states, “those who *define* a threat can be held accountable, as threats” – *and* planning, its attempted limitation of responsibility and production of governance distortions and failures – “are also the *product of their entrepreneurship*”.<sup>135</sup>

Reference to the alert phases helps to bring out the centrality and importance of the focus on the protection of essential infrastructures. To overview the phases, they are based on EU generic planning alert phases, which are in turn based explicitly on WHO Phases 1–6. The inter-pandemic period is at Phases 1 and 2. At this stage no new influenza virus subtypes have been detected in humans, but they might be present in animals. The main public health goal at this stage is to “strengthen influenza pandemic preparedness at the global, regional, national and sub-national levels”<sup>136</sup> and minimisation of the risk of transmission to humans. This requires rapid detection and reporting of any such transmission. The Commission and the ECDC work in consultation with the HSC, and in cooperation with the WHO, to assess, review and organise “exercises concerning national pandemic plans, with a special focus on their interoperability”.<sup>137</sup>

Phases 3 to 5 are the pandemic alert period. At Phases 3 and 4, there are no human cases in the EU, but a risk of sporadic *importation* of isolated cases in MSs. Rapid characterisation of the new virus subtype and early detection, notification and response to new cases are the main public health objectives. At Phase 4, containing the new virus within a limited area or delaying its spread in order to implement preparedness counter-measures, such as the development of vaccine, is the main public health objective. At Phase 5, there are larger clusters of cases outside the EU, but human-to-human contagion is still limited in area. The main public health objective is to “maximize efforts to contain or delay spread, to possibly avert a pandemic, and to gain time to implement pandemic response measures”.<sup>138</sup>

132 J Black, “The emergence of risk-based regulation and the new public risk management in the United Kingdom” (2005) *Public Law* 512, p. 513 (emphasis added). On failure cf. J Downer, “Anatomy of disaster: why some accidents are unavoidable” (2010) CARR Discussion Paper 61.

133 *Ibid.* p. 514 (emphasis added).

134 Cf. G Gorgoni, ““(Pre)caution Improvisation Area’: Improvisation and responsibility in the practice of the precautionary principle” (2010) 6(1) *Critical Studies in Improvisation* at: [www.criticalimprov.com/article/view/1086/1727](http://www.criticalimprov.com/article/view/1086/1727) (last accessed 5 September 2011). Thanks to Thérèse Murphy and Sara Ramshaw for these insights.

135 Balzacq, “Preface”, n. 129 above, p. xiii (emphasis added).

136 European Commission, “Pandemic Influenza Preparedness”, n. 105 above, p. 16.

137 *Ibid.*

138 *Ibid.* p. 21.

Phase 6 is the pandemic period in which there is now an increased and sustained transmission of cases around the world and in the EU's general population. The main public health objective is minimising the pandemic's impact in the EU. In order to do so, the EU adopts its own Alert Levels 1–4. These take into account specifics such as the absence of internal borders, and differences between MSs (southern and eastern MSs have higher susceptibility). At EU Alert Level 1 there are no human cases in the EU, but there is a very high risk of sporadic imported cases. At EU Alert Level 2 there is a single human case inside the EU. EU Alert Level 3 occurs when there is an isolated cluster in one EU MS or sustained transmission between humans with several clusters inside the EU. EU Alert Level 4 is when there are cases in one or more MSs.

This phasing serves to modulate and shape preparedness by further specifying and limiting responsibilities and (improvisation of) actions in response to events towards, and establishing the boundaries of accountability and blame for failures in, the protection of essential infrastructures. For example, planning and coordination is aimed at “improving coordination and communication” to ensure the EU is of “added value”.<sup>139</sup> The PHPRPG is required to review MS preparedness plans and ensure the identification and dissemination of “expertise and good practice”<sup>140</sup> and the EWRS must be used for notification of cases and exchange of information on measures taken.

The ECDC sets the terms of reference for Outbreak Assistance Teams (OATs).<sup>141</sup> These participate in “outbreak investigation *inside and outside* the Community ensuring coherence and synergies with the EU's *external response in co-operation* with the WHO”.<sup>142</sup> Generally, the Commission is responsible for reviewing its own internal contingency and coordinating guidance to national authorities so that they can review and update their plans in light of evidence.<sup>143</sup> More specifically, at Phase 5, Commission staff surge capacity must be ensured, and at Phase 6 a centre to coordinate EU and international level actions and evaluate effectiveness must be established. Surveillance is dealt with in monitoring and assessment, and it provides the information upon which hinges the alert threat-level and the use of countermeasures such as vaccines. Indeed, “early detection and characterisation of pandemic strains”<sup>144</sup> is the “most important”<sup>145</sup> task. I elaborate on this, and interventions dealt with in prevention and containment, in the second sub-section.

To reflect further, the limitation of responsibility to the focus on, and distribution of resources towards, protecting essential infrastructures, such as surveillance, surge capacity and, as emphasised below, interventions like pharmaceuticals as the preferred triage choice, masks and is detrimental to wider public health objectives and increases the vulnerability of those who lose out as a consequence. Francis et al. point out how, while the “apparent assumption that devoting resources to pandemic planning is just” might be explained by the openness of the “triage choices in pandemic planning”, nevertheless

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139 European Commission, “Pandemic Influenza Preparedness”, n. 105 above, p. 8.

140 Ibid.

141 Ibid.

142 Ibid.

143 Ibid. p. 17.

144 Ibid. p. 8.

145 Ibid.

“there are *serious questions of justice* to be asked about the allocation of extensive resources to pandemic threats.”<sup>146</sup>

Indeed, Fidler and Gostin note that preparedness might skew resources towards rare events like pandemic influenza “at the expense of tackling health problems that cause the great death and illness in populations daily”.<sup>147</sup> Similarly, others stress that preparedness might skew resources towards communicable diseases at the expense of non-communicable diseases and persistent public health problems.<sup>148</sup> This is perhaps of greater concern in terms of external relations. There are efforts at international collaboration, especially with poorer countries, such as in relation to pharmaceuticals, elaborated below, and the ECDC’s organisation and deployment of OATs abroad. Yet the EU’s focus on protection becomes nuanced to being about *its* essential infrastructures. This could be mirrored in external effects by skewing resource allocation in countries with already poorly equipped health-care systems towards protection of *their* essential infrastructures, but in order to protect the EU. This is ultimately to the detriment of their already strained public health capacities and vulnerable populations.

Moreover, it is noteworthy that prior to Phase 6 the EU is deemed free of pandemic infection. This amounts to an externalisation of public health problems caused by failures of law, policy and medical practice in the EU, such as so-called MRSA and *C difficile*,<sup>149</sup> which are naturalised as part of the order of things, and consequently there is no one to blame. Despite efforts at international cooperation there remains a bias towards EU needs and the idea that, rather than being endemic to the operation of the EU’s privileging of free movement, the “threat” comes from “out there”. In short, there is much need for highlighting concerns around framing, distribution and vulnerability in order to avoid “myopia”.<sup>150</sup> As Murphy and Whitty explain, without attention to broader social conditions and public health concerns, such as sufficient staff and resources overall and reducing inequalities, “global surveillance, surge capacity and, more generally, preventing and coping with a pandemic will be all the more difficult”.<sup>151</sup>

Four main imbricating forces are worthy of attention given they might work to undergird and reinforce the delineation of responsibility and production of governance distortions and failures. A first force is a more specific valence of securitisation. To quote de Larrinaga and Doucet, security is increasingly prevalent and powerful, as indicated by the way in which “‘greater security’ has come to *trump* so easily other available political discourses”.<sup>152</sup> Linked closely to this is a second force: the dissemination of the wider zero-sum relationship between human rights and risk (and safety and security). Lazarus and Goold observe the power of “the idea that certain human rights can be ‘turned off’ when necessary” has become a “thoroughly reasonable reaction to the dangers allegedly faced by

146 L P Francis, M P Battin, J A Jacobson and C B Smith, “Pandemic planning and distributive justice in health care” in M Freeman (ed.), *Law and Bioethics* (Oxford: OUP 2008), p. 433 (emphasis added). Cf. consideration of social justice in pandemic planning in: “Bellagio Statement of Principles”, available at: [www.unicef.org/avianflu/files/Bellagio\\_Statement.pdf](http://www.unicef.org/avianflu/files/Bellagio_Statement.pdf) and [www.bioethicsinstitute.org/web/page/905/sectionid/377/pagelevel/3/interior.asp](http://www.bioethicsinstitute.org/web/page/905/sectionid/377/pagelevel/3/interior.asp) (last accessed 5 September 2011).

147 Fidler and Gostin, *Biosecurity*, n. 93 above, p. 8.

148 D Yach, S R Leeder, J Bell and B Kistmasamy, “Global chronic diseases” (2005) 307 *Science* 317.

149 S Jenkins, “Swine flu? A panic stoked in order to posture and spend”, *The Guardian*, 29 April 2009.

150 Cf. Francis et al., “Pandemic planning and distributive justice in health care”, n. 146 above, p. 446.

151 Murphy and Whitty, “Is human rights prepared?”, n. 19 above, at 243.

152 De Larrinaga and Doucet, *Security and Global Governmentality*, n. 125 above, p. 1 (emphasis added).

democratic societies”.<sup>153</sup> Abetting this is a broader tendency stressed by Hunter in which “all aspects of health emergency policy have shifted towards the framework of *enhanced* executive authority”.<sup>154</sup> Going so far as to describe this zero-sum game as part of the “new ‘rights revolution’”,<sup>155</sup> Murphy and Whitty note “there are no guarantees that the securitisation of public health, the right to security or human security will be good for human rights”.<sup>156</sup>

What Rothstein et al. term “institutional risk” also has another valence and it is the third force. That is, a focus on institutional risk might transform and reduce preparedness techniques into instrumental tick-box exercises and be detrimental to the efficient management of the societal risk of pandemics. Wider moves towards reflexive governance – a focus on *inter alia* institutions and their means of action – might exacerbate and underpin this focus on institutional risk. Since the object of these various moves is economic optimisation, they might also ensure governance openly serves the economy. Below I suggest this is apparent in the preference for protection of pharmaceutical interventions.

To tease out the point about legitimation, this final main force is especially important in light of *inter alia* the failures noted above leading to the EU’s renewed interest in risk governance in *European Governance*, successive democratic rejections of Treaty amendments, and a wider “democratic deficit”.<sup>157</sup> Preparedness helps to constitute and project the EU’s identity as authoritative and useful to its citizens, MSs, international actors and private actors like corporations, especially given worldwide moves towards “greater security”. Preparedness and its attendant distortions and failures might be augmented and facilitated by the resources and openings for action and the production of “output” legitimacy<sup>158</sup> it provides.

In other words, constructing pandemic influenza as a “threat” in a medical emergency model, and then a “risk” that must be governed in the present,<sup>159</sup> enlarges power and the possibility of action<sup>160</sup> – and, as noted, it conditions and legitimates the means used. As a twist, Power observes that democratic ideals “are increasingly positioned within ideals for good governance of the *risk analysis process*”.<sup>161</sup> This highlights preparedness as being partly about rendering the EU auditable and inspectable – *and* relating to and managing

153 L Lazarus and B J Goold, “Security and human rights: the search for a language of reconciliation” in B J Goold and L Lazarus (eds), *Security and Human Rights* (Oxford: Hart 2007), p. 4. Also see: G J Annas, *American Bioethics: Crossing human rights and health law boundaries* (Oxford: OUP 2005); L O Gostin, “When terrorism threatens health: how far are limitations on personal and economic liberties justified?” (2003) 55 *Florida Law Review* 1105; I Loader and N Walker, *Civilising Security* (Cambridge: CUP 2007); B Von Tigerstrom, *Human Security and International Law: Prospects and problems* (Oxford: Hart 2007).

154 N Hunter, “Public–private’ health law: multiple directions in public health” (2007) 10 *Journal of Health Care Law and Policy* 101, p. 106 (emphasis added).

155 Murphy and Whitty, “Is human rights prepared?”, n. 19 above, p. 231. Also see T Murphy, “Taking revolutions seriously: rights, risk and new technologies” (2009) 16(1) *Maastricht Journal of European and Comparative Law* 15–39.

156 Murphy and Whitty, “Is human rights prepared?”, *ibid.* p. 232.

157 In general, see C Scott, “Accountability in the regulatory state” (2000) 27 *Journal of Law and Society* 38; F Scharpf, *Governing in Europe. Effective and democratic?* (Oxford: OUP 1999); A Arnall and D Wincott, *Accountability and Legitimacy in the European Union* (Oxford: OUP 2002).

158 Scharpf, *Governing in Europe*, *ibid.*

159 Cf. Lentzos, n. 92 above, p. 461. F Ewald, “Insurance and risk” in G Burchell, C Gordon and P Miller (eds), *The Foucault Effect. Studies in governmentality* (Chicago: University of Chicago Press 1991).

160 S Sontag, *Illness as Metaphor and AIDS and its Metaphors* (London: Penguin 1991), especially p. 175.

161 M Power, *Organized Uncertainty* (Oxford: OUP 2007), p. 20 (emphasis added).

“public expectations”.<sup>162</sup> More specifically, risk – and preparedness – is partly an exercise in governing “unruly perceptions” and maintaining the “*production of legitimacy* in the face of these perceptions”.<sup>163</sup>

Relating to and managing public expectations occurs principally through communication, itself an essential infrastructure. This draws on the general approach established in *European Governance* in which openness, transparency, and accountability are to be ensured, and governance legitimated, by inter alia the provision of up-to-date and easily available (principally online) information on EU law and policymaking and, in preparedness, pandemic news media “status” updates.<sup>164</sup> Each alert phase has its own communication plan, reflecting the seriousness of the threat, and based on information gathered through surveillance. For example, throughout the alert phases it is for MS authorities to communicate arrangements for vaccination and distribution of antiviral agents to health professionals and the public.

Further, at Phase 3 the Commission, the ECDC and MSs must work together in order to coordinate the sharing of “accurate messages” about, inter alia, the global epidemiological situation (including spread and effectiveness of counter-measures). At Phase 4 (and similarly at Phases 5 and 6) the Commission and ECDC must work to promote “sharing of templates for general health education materials”<sup>165</sup> and the MSs must share their intended “public and educational material”.<sup>166</sup> The ECDC is charged with providing “the scientific appraisal of recommended measures”<sup>167</sup> and, as stressed at Phase 6, it has a central role in making briefings from the EU to other actors, including the public.

Fast exchange of information and:

prompt notification during the first stages of a pandemic influenza are essential in enabling [MSs], the Commission, the ECDC, WHO and other bodies to respond with common positions in *public communications*, and *alert properly their structures, so that measures can be implemented in a timely manner*.<sup>168</sup>

As such, MS public authorities should “communicate effectively with the public and the media *before and in anticipation of events* that *may* lead to public health emergencies”.<sup>168a</sup> Messages are to be coordinated,<sup>169</sup> and this should occur early on in any major incident, so as to ensure they establish “themselves as the leading, if not the only, source of authoritative information”,<sup>170</sup> and so as to avoid an “information void”<sup>171</sup> and subsequent speculation, rumour and confusion. This is facilitated through a “range of ready to use media briefing

162 Power, *Organized Uncertainty*, n. 161 above, pp. 20–1.

163 Ibid. p. 21 (emphasis added). Of course, besides citizens other addressees of the demonstration of action afforded by the rhetoric of preparedness include the MSs and international actors such as the WHO and GHSI (all leveraging support from EU action).

164 For instance, [http://europa.eu/press\\_room/press\\_packs/influenza/index\\_en.htm](http://europa.eu/press_room/press_packs/influenza/index_en.htm); [www.ecdc.europa.eu/en/healthtopics/influenza/Pages/index.aspx](http://www.ecdc.europa.eu/en/healthtopics/influenza/Pages/index.aspx); [http://ec.europa.eu/health/communicable\\_diseases/diseases/influenza/h1n1/index\\_en.htm](http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm) (all last accessed 5 September 2011).

165 European Commission, “Pandemic Influenza Preparedness”, n. 105 above, p. 20.

166 Ibid. p. 21.

167 Ibid.

168 Ibid. p. 14 (emphasis added). Cf. European Commission, “Generic Preparedness”, n. 98 above, p. 6.

168a European Commission, “Generic Preparedness”, *ibid.* p. 7 (emphasis added).

169 For instance, the Commission’s October 2005 technical guidance document on *Procedure for Communication to Member States, the Commission and the ECDC about Highly Pathogenic Avian Influenza Events in Humans*, cited in European Commission, “Pandemic Influenza Preparedness”, n. 105 above, p. 14.

170 European Commission, “Generic Preparedness”, n. 98 above, p. 7.

171 Ibid. p. 13.

materials about influenza”,<sup>172</sup> including, basic information about the disease and the response systems in place, and clear and timely flows of information facilitated by 24/7 “operational contact points in the Member States and in the Commission”,<sup>173</sup> and encompassing “text, voice, and video”.<sup>174</sup>

In relating to and managing public expectations, communication is concerned with establishing and limiting the boundaries of EU responsibility and blame in the public imagination to failures in the protection of finite and easily identifiable essential infrastructures and legitimating governance and the means used to deal with a pandemic medical emergency. The *rhetoric* of risk is, to quote Black, a “useful legitimating device”.<sup>175</sup> The EU is able to produce legitimacy through its centrality to communication, and in a neoliberal vein it does so through ensuring the output of an optimised and secure internal market: the “distribution of accurate and timely information . . . is critical in order to minimise unwanted and unforeseen *social disruption and economic consequences* and to maximise the *effective outcome* of the response”.<sup>176</sup> Such a focus might reinforce the zero-sum relationship between human rights and risk (and safety and security) and the legitimacy of using means favoured by security.

A focus on output legitimacy is also abetted by the limited construction of citizens within the deficit model as key addressees of communication. That is, consistent with Article 168(1)(2), preparedness relates to, animates and manages citizens through health information and education materials. It is noted that it:

will help *reinforce public confidence* in the response strategy if Member States and the Commission can demonstrate that the national strategies across the EU are *consistent and based on a common assessment* of the relevant science.<sup>177</sup>

This statement also reveals the limited nature of democratic ideals within risk governance. Communication is used to produce limited “input” in order to support and authorise preparedness. As such, this public rationality complements and buttresses the expert rationality, its depoliticisation and naturalisation of preparedness, the limited boundaries of responsibility, and the production of governance distortions and failures. Citizens do, however, have some input through surveillance and information-gathering. Yet, even then citizens are only one source among many,<sup>178</sup> and participation does not appear to extend to shaping and directing the form and broader focus of governance, or to identifying its distortions and failures.

This betrays an inflection with PUS which is also found in documents constituting the EU’s overarching approach to risk governance, especially *European Governance and Science and Society*.<sup>179</sup> PUS is an instrument used to support the overarching agenda of producing

172 European Commission, “Generic Preparedness”, n. 98 above, p. 13.

173 *Ibid.* p. 7.

174 *Ibid.* p. 6.

175 J Black, “The emergence of risk-based regulation and the new public risk management in the United Kingdom”, n. 132 above, p. 519. Also see: J Black, “Constructing and contesting legitimacy and accountability in polycentric regulatory regimes” (2008) 2 *Regulation & Governance* 137.

176 European Commission, “Generic Preparedness”, n. 98 above, p. 6.

177 European Commission, “Pandemic Influenza Preparedness”, n. 105 above, p. 14 (emphasis added).

178 *Ibid.*

179 European Commission, “Science and Society Action Plan”, COM(2001) 714. See also European Commission, “Commission Staff Working Paper, Science, Society and the Citizen in Europe”, SEC(2000) 1973; European Commission, “Science and Technology, the Key to Europe’s Future: Guidelines for Future European Union Policy to Support Research”, COM(2004) 353 final.

economic optimisation.<sup>180</sup> Perhaps the most notable PUS technique used in preparedness is the *Eurobarometer* on attitudes to pandemic planning.<sup>181</sup> Another is questionnaires, for instance, through the *Stakeholder Consultation on Strengthening European Union Preparedness on Pandemic Influenza*.<sup>182</sup> These are used to produce statistics and reports on strengthening governance. They conjure citizens, their understanding of pandemic science, and therefore the appropriate relationship between citizens and governance (which reinforces the importance of “tooling-up” through supra-stewardship). So-called “absent presences”,<sup>183</sup> citizens are represented and imagined by EU actors in order to provide a democratic basis for their decisions. Importantly, PUS is controlled by experts who attempt to shape and define citizen and “public” identities and attitudes within the deficit model as being in need of education.<sup>184</sup> Such a prior framing of public understanding denies the normative dimension of preparedness and attempts to “mark off” governance from popular control and contestation.

Overall, the complementary expert and public rationalities in preparedness highlight how, to quote Walklate and Mythen’s observation, “expert institutions deploy discourses of risk to filter information, buttress dominant norms and to muffle political opposition”.<sup>185</sup> This tendency might be reinforced by the way in which preparedness literally governs and attempts to quiet citizens through their feelings of insecurity.<sup>186</sup>

#### A CLOSER LOOK AT SURVEILLANCE AND INTERVENTIONS

Citizens could also hone supra-stewardship to take a closer look at surveillance and interventions. Here, I focus on some further contours for engagement that highlight how the framing of preparedness as being about dealing with a medical emergency impacts on distribution and vulnerability. Beginning with and elaborating on surveillance, throughout the alert phases, the ECDC works with the Commission, other EU agencies and MS authorities to coordinate epidemiological surveillance, especially through the EWRS.<sup>187</sup> Surveillance information is used to identify the circumstances of infection and to produce “risk groups”. These might be subject to containment and control measures, discussed below as interventions. At Phase 4, the risk groups and counter-measures are put under enhanced surveillance, and this attention heightens at Phase 5 when there might be importation of cases, and again at Phase 6 with the circulation of the pandemic in the EU.

180 Jasanoff, *Designs on Nature*, n. 11 above, p. 251.

181 See [http://ec.europa.eu/health/communicable\\_diseases/diseases/influenza/h1n1/docs/eurobarometer\\_summary\\_20100224.pdf](http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/docs/eurobarometer_summary_20100224.pdf) (last accessed 5 September 2011).

182 See [http://ec.europa.eu/health/preparedness\\_response/consultations/preparedness\\_cons\\_01\\_en.htm](http://ec.europa.eu/health/preparedness_response/consultations/preparedness_cons_01_en.htm) (last accessed 5 September 2011). Answers are sought to two key questions: how useful was the 2005 plan both during the pandemic preparedness phase and during the response to pandemic (H1N1) 2009 and how should it be improved? What should be done at EU level to improve EU pandemic preparedness? However, the focus is on: preparedness and co-ordination, surveillance, containment and mitigation (including vaccines and antivirals), health system response, international communication and communication with citizens. The final section is about multi-sectoral preparedness, which has been highlighted as an area for development. Overall, apart from the final section, the questionnaire is prefigured by what went before – and the questions asked do not seek to elicit a substantive input into preparedness besides this standalone consultation. The impression is that the deficit model is being reproduced. See further <http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=pandemicinfluenzan> (last accessed 5 September 2011).

183 *Taking European Knowledge Society Seriously*, n. 77 above, p. 58.

184 M Leach and I Scoones, “Science and citizenship in a global context” in M Leach, I Scoones and B Wynne (eds), *Science and Citizens: Globalization and the challenge of engagement* (London: Zed Books 2005), p. 16.

185 S Walklate and G Mythen, “Agency, reflexivity and risk: cosmopolitan, neurotic or prudential citizen?” (2010) 61(1) *British Journal of Sociology* 45, p. 50.

186 Cf. Lentzos and Rose, “Governing insecurity”, n. 8 above, p. 235.

187 European Commission, “Pandemic Influenza Preparedness”, n. 105 above, p. 9.

As Jasanoff explains, generally the production of risk groups is an “effort to produce policy-relevant assessments”<sup>188</sup> of those thought to be differently and most affected by the threat in question and to attune governance to them and their needs. This might work to protect the vulnerable and interrupt a pandemic.<sup>189</sup> One concern addressed shortly is how preparedness reshapes the value and use of risk groups. Another concern, discussed further below, is whether risk groups made subject to governance interventions have their human rights protected or in fact become, as an example, “at risk” of stigmatisation and excessive use of counter-measures.<sup>190</sup> Here, I focus on the production of risk groups from supposedly neutral scientific knowledge. This works with moves towards self-management and individualisation of responsibility to depoliticise and naturalise governance, and it reinforces the expert rationality underpinning preparedness and undermines democratic contestation.<sup>191</sup>

The latter is assisted by the re-emergence of the complementary public rationality through the use of physical and biological indicators to construct those at risk. Requiring further attention in relation to preparedness, Jasanoff notes how generally such “classifications tend to overlook the *social foundations* of vulnerability, and to *subordinate individual experiences* of risk to aggregate numerical calculations”.<sup>192</sup> The at-risk human is treated as a “passive agent”<sup>193</sup> whose sociality and sources of vulnerability are masked. This increases the need for citizens to “regain their status as *active subjects*, rather than remain undifferentiated objects in yet another expert discourse”.<sup>194</sup>

Turning to interventions, these fall within the essential infrastructure of prevention and containment. Vaccines and social distancing are central and are modulated throughout the alert levels. It is noted that “hand-washing and social distancing will play important roles in reducing the impact of pandemic influenza”,<sup>195</sup> vaccination is the key counter-measure, and since the production of vaccines usually takes between six and eight months,<sup>196</sup> anti-virals are “the *first pillar* of medical prevention and intervention”.<sup>197</sup> While competence ensures the EU has limited involvement in health system response, the Commission and ECDC coordinate and review non-pharmaceutical measures. For instance, at Phase 5 this involves guidance on how “to optimize use of scarce facilities (triage, modified clinical guidelines, modified hospital infection guidelines . . . etc.)”.<sup>198</sup>

To focus on vaccines, preparedness uses a variety of means, including support for research,<sup>199</sup> a public-private partnership between public authorities and the vaccine industry to stimulate production, and an expedited market-authorisation procedure, all to deliver vaccine to the EU in the “shortest possible time”.<sup>200</sup> Preparedness attempts to ensure equitable distribution of scarce resources and reduce vulnerability. For example,

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188 Jasanoff, “Technologies of humility”, n. 10 above, p. 241.

189 Cf. J. Upperman, “Vulnerable populations in disaster planning: children are different” in Katona et al. (eds), *Global Biosecurity*, n. 93 above.

190 Cf. Murphy and Whitty, “Is human rights prepared?”, n. 19 above, p. 237.

191 Jasanoff, “Technologies of humility”, n. 10 above, p. 241.

192 *Ibid.* (emphasis added).

193 *Ibid.*

194 *Ibid.* p. 241.

195 European Commission, “Pandemic Influenza Preparedness”, n. 105 above, p. 12.

196 *Ibid.* p. 10.

197 *Ibid.* (emphasis added).

198 *Ibid.* p. 22.

199 See [http://cordis.europa.eu/fp7/home\\_en.html](http://cordis.europa.eu/fp7/home_en.html) (last accessed 5 September 2011).

200 European Commission, “Pandemic Influenza Preparedness”, n. 105 above, p. 10.

while again externalising the pandemic, the Commission helps to promote the “mutualisation” of stocks to fight the disease at *source*” given “the lack of manufacturing capacity in many countries and the perceived imbalance between rich and powerful countries that collect strains through collaboration programmes with poor and affected ones but benefit from (their) manufacturers’ production only themselves”.<sup>201</sup> Also, threaded through the alert phases is the responsibility of the Commission, ECDC and MS authorities to target – and improvise as they review and retarget in light of the unfolding pandemic – limited stocks of anti-virals and vaccines to key health personnel and the most vulnerable defined in risk groups.<sup>202</sup>

However, a key concern is the apparent focus of responsibility and skewing of attention and resources towards the protection of pharmaceuticals. This highlights the limitation of triage choices: pharmaceuticals are seemingly *the* means to deal with (and pre-selected by) the medical emergency model, but such that other, cheaper and perhaps more effective options are not so readily used. This is not necessarily to the advantage of risk groups since the normative direction of preparedness ensures pharmaceuticals are the focus of protection efforts – rather than those at risk. As such, preparedness reshapes the value and use of such classifications, essentially because they are aimed at mitigating adverse consequences to the economy and ensuring its optimisation, in part through resort to pharmaceuticals. In other words, it appears improvisation in triage choices is constrained, and the vulnerability of population increased, by the frame of medical emergency.

Added to this, even as wider preventive measures such as hygiene are governed by preparedness, the focus is still on protecting them, in order to optimise the economy, rather than protecting population.<sup>203</sup> More widely, since the focus is on *triage* in medical emergency, broader public health interventions in population as part of a more concerted and long-term response are further undermined. Overall, the focus on pharmaceuticals implies the boundaries of responsibility and blame are effectively limited to failures in their protection as the preferred triage choice within the medical emergency model.

The prominence of pharmaceuticals has been explained by the close relations between the WHO and industry and the suggestion that the pandemic threat is talked up in order to generate orders.<sup>204</sup> Some note that changes to the WHO’s alert phases were prompted by, and privilege, industrial ties.<sup>205</sup> This is pertinent to the EU given how its alert phases are aligned to the WHO’s. Further, the clear bias of the EU’s pharmaceutical regime is towards getting (high-cost) products to market, regardless of their comparative efficacy, in order to support and optimise an innovative economy.<sup>206</sup> This highlights the use and dissemination of market rationality in public health and open servicing of market needs as facilitated by preparedness and the wider exacerbating forces noted above.

201 European Commission, “Pandemic Influenza Preparedness”, n. 105 above.

202 Ibid.

203 Staying at home and taking regular pain killers has been highlighted as the best option for most people infected with H1N1: Jenkins, “Swine flu?”, n. 149 above. For discussion of triage choices in relation to humanitarian responses to emergency, see T Murphy, “Public health *sans frontières*: human rights NGOs and ‘stewardship on a global scale’”, this special issue.

204 D Cohen and P Carter, “WHO and the pandemic flu ‘conspiracies’” (2010) *British Medical Journal* 340.

205 Such as when to declare a pandemic: *ibid.*

206 The emphasis is on quality, safety and efficacy rather than “comparative therapeutic efficacy” and genuine need: Hervey and McHale, *Health Law and the European Union*, n. 1 above, pp. 317–18. On the neoliberal orientation of EU pharmaceutical governance and biopolitics, see M Flear, “The EU’s biopolitical governance of advanced therapy medicinal products” (2009) 16(1) *Maastricht Journal of European and Comparative Law* 113.

Moving to social distancing, the ECDC must provide “scientific advice on *non-pharmaceutical* public health interventions”,<sup>207</sup> and it works with the Commission and affected MSs, who must report on the effectiveness of their efforts through the EWRS in order to inform national and international planning. Social distancing becomes particularly important at Phase 6, when its use to regulate the internal market is highlighted. Indeed, the Commission must work with the MSs to:

coordinate . . . the position on *movement of persons* and goods and cooperate with appropriate international organizations and associations and transportation companies to implement standard measures for *travellers* on board international conveyances, consistent with the alert level.<sup>208</sup>

Returning to the point introduced above, these are of special concern for risk groups who are produced as especially vulnerable and made subject to specific actions aimed at interrupting a pandemic, since it might make them vulnerable to repression. Medicine, law and governance work with metaphors of disease carriers to produce them as different from “normal” members of society.<sup>209</sup> This production can work to provide the rationale for interventions, and they are highly susceptible to abuse. In other words, those deemed at risk of infection are also at risk of human rights infringements beyond the failure to ensure that they rather than pharmaceuticals are the focus of protection efforts. Wider exacerbating tendencies include the criminalisation of disease transmission, the wider securitisation of public health,<sup>210</sup> and working with these, the figuration of disease carriers as active agents, aggressors and even “evil criminals” who must take responsibility for their condition and endangerment of others.<sup>211</sup> Particularly vulnerable groups include those coming from outside the EU, the zone where the threat is deemed to arise, and typically itinerant and already marginalised groups within the EU, such as the Roma or travelling communities.<sup>212</sup>

Overall, as Murphy and Whitty stress, such interventions can “provoke or compound discrimination and stigmatisation of particular individuals and groups”.<sup>213</sup> Yet, as they go on to explain, the efficacy of such social distancing might also be undermined given that individuals might avoid diagnosis and treatment where quarantine seems a realistic possibility.<sup>214</sup> In addition, such techniques and practices directly infringe personal liberty and privacy rights, and could lead to healthy individuals being put at serious risk of infection should they be mistakenly quarantined. Yet, since only certain risk groups are targeted for specific interventions, there is an absence of burdens on all.<sup>215</sup> This combined with the individualisation and responsabilisation attendant to risk mean such actions could be further depoliticised and left largely uncontested.

207 European Commission, “Pandemic Influenza Preparedness”, n. 105 above, p. 20 (emphasis added).

208 Ibid. p. 25.

209 Sontag, *Illness as Metaphor*, n. 160 above, p. 171.

210 S Elbe, “Pandemics on the radar screen: health security, infectious disease and the medicalisation of security” (2011) 59(4) *Political Studies* 848; S Elbe, *Security and Global Health: Toward the medicalization of insecurity* (Cambridge: Polity Press 2010).

211 J Montgomery, “Medicalizing crime – criminalizing health? The role of law” in C A Erin and S Ost (eds), *The Criminal Justice System and Health Care* (Oxford: OUP 2007). Cf. N Reis, “The 2003 SARS outbreak in Canada: legal and ethical lessons about the use of quarantine” in J Balint, S Philpott, R Baker and M Strosberg (eds), *Ethics and Epidemics* (Amsterdam: Elsevier Press 2006).

212 S Žižek, “Liberal multiculturalism masks an old barbarism with a human face”, *The Guardian*, 3 October 2010.

213 Murphy and Whitty, “Is human rights prepared?”, n. 19 above, at 235.

214 Ibid.

215 L Zedner, “Seeking security by eroding rights: the side-stepping of due process” in Goold and Lazarus (eds), *Security and Human Rights*, n. 153 above, p. 272, cited in Murphy and Whitty, n. 19 above, p. 235. Cf. M K Wynia, “Ethics and public health emergencies: restrictions on liberty” (2007) 7(2) *American Journal of Bioethics* 1.

The wider linked forces traced above – greater security, the zero-sum relationship between human rights and risk (and safety and security), a focus on institutional risk and broader shifts towards reflexive governance, and the production of legitimacy – might reinforce the tendency towards (investment in<sup>216</sup> and) protection of pharmaceuticals and (admittedly currently to a lesser extent) social distancing. This is because, as indicated, in one way or another they seem to condition and reinforce a preference for the use of such interventions within a medical emergency model.<sup>217</sup>

To focus on legitimacy, the preference for pharmaceuticals might also be explained by their cultural resonance and use for legitimisation purposes. That is, pharmaceuticals are now central to well-being and health, and are dominant in marketing strategies that favour self-management and which are underpinned by the individualisation of risk.<sup>218</sup> This makes pharmaceuticals useful for governance as a way of relating to and managing public expectations, and especially for setting and limiting the boundaries of responsibility and blame in the event of failure. The cultural resonance of pharmaceuticals helps to legitimate both the preference for them as a response to medical emergency and, through protection of their production and deployment, the preparedness regime.

This use of pharmaceuticals also undermines the political salience *and* use of other triage choices and broader public health interventions in population as part of a more concerted and long-term response. Put differently, it appears that a preference for pharmaceuticals (and constrained improvisation in triage choices) is politically useful as a way of relating to and managing public expectations in the face of what is constructed as a medical emergency in order to mitigate adverse consequences. However, this undermines resilience in that it also reinforces the distraction of attention away from, and use of responses that could deal with, the *social* conditions producing pandemics. Another aspect of legitimisation is apparent in the EU’s involvement in international pandemic planning to assist non-MSs as it seeks to govern its periphery and beyond. This helps to constitute the EU as an international actor, mark and secure its borders and identity, externalise the threat and limit the boundaries of its responsibility and accountability, *and* produce legitimacy by and through the demonstration of preparedness and response.<sup>219</sup>

Adding to these concerns, preparedness contains only background references to the legal and ethical implications of interventions. In the *Interim Document*,<sup>220</sup> the focus is more on ensuring minimal disruption to the internal market through assessment exercises and prior communication of counter-measures so as to ensure interoperability.<sup>221</sup> For example,

216 Furedi highlights a twist: a “culture of fear” is used by those in authority and in the welfare and security industries to promote investment in security. See F Furedi, *Culture of Fear Revisited* 4th edn (London: Continuum 2006).

217 Cf. C Caduff, “Public prophylaxis: pandemic influenza, pharmaceutical prevention and participatory governance” (2010) 5(2) *BioSocieties* 199.

218 A Petryna and A Kleinman, “The pharmaceutical nexus” in A Petryna, A Lakoff and A Kleinman (eds), *Global Pharmaceuticals: Ethics, markets, practices* (Durham: Duke UP 2006). Also see: S R Whyte, S Van der Geest and A Hardon, *Social Lives of Medicines* (Cambridge: CUP 2003), especially “Drug vendors and their market: the commodification of health”. More generally, see G C Gray, “The responsabilisation strategy of health and safety: neo-liberalism and the reconfiguration of individual responsibility for risk” (2009) 49 *British Journal of Criminology* 326.

219 Furedi, *Culture of Fear*, n. 216 above.

220 For instance, “full respect for ethical standards, human rights, national and local laws and cultural sensitivities and traditions” in interventions is noted (European Commission, “Interim Document”, n. 108 above, Annex 8, p. 78). It is supposedly a question of checking that “[n]ational plans include a leading ethical framework for responses to public health crisis and national plans include a verification processes to assure that the ethical aspects of policy decisions to be used during the response to an outbreak balance individual and population rights” (ibid. p. 35). The identity of the “leading” framework remains unclear.

221 As required for compliance with EU free movement law, see: Barnard, *The Substantive Law of the EU*, n. 80 above.

“[e]thical issues are closely related to the legal issues . . . and are *part* of the normative framework needed to *assess the cultural acceptability* of measures like *quarantine or selective immunisation of pre-defined risk groups*”.<sup>222</sup> Of course, cultural acceptability is determined in part by the broader framing in governance and the forces sketched above. Even so, responsibility for the management of the ethical and legal implications of interventions – including blame in the event of failure – is located at MS level.

Such a minimal concern for risk management highlights the EU’s eschewal of responsibility for the distortions and failures in relation to interventions *produced* by, at least in part, *its* discourse on preparedness. This move also enhances depoliticisation and naturalisation of preparedness and helps to shield the EU from adverse public perceptions in the event of controversy and failure. Again, these perceptions are managed and contained by the boundaries of responsibility and accountability. These boundaries are communicated as being limited to the protection of essential infrastructures and especially the pharmaceutical response, but in order to mitigate consequences of a pandemic and optimise the economy.

Further, the public rationality of the deficit model re-emerges, this time in making the ethical and legal implications of interventions matters of expert discourse and deliberation at MS level. This also reflects a broader observation that the complementary expert and public rationalities are used to authorise and legitimate certain preparedness response strategies, such as through use of pharmaceuticals, and reinforce existing power relations towards the objective of economic optimisation.<sup>223</sup>

### Conclusion: towards learning, enhanced responsibility and resilience

The analysis of preparedness highlights the operation of complementary expert and public rationalities in its constitutive discourses of risk, security, PUS, and which are undergirded by neoliberalism. While producing knowledge in an attempt to govern pandemics, the rationalities and discourses also delineate the boundaries of responsibility, and produce and mask governance distortions and failures. The rationalities also undermine participation because citizens are cast within a deficit model as being incapable of sharing in power to shape governance. In particular, citizens are limited through communication strategies to engage in hygiene efforts aimed at reducing contagion and pursuing their daily social and economic lives. Overall, the rationalities deny the normative within preparedness and essentially try to “mark off” governance from popular control and contestation.

In section 2, I nominated and made an initial sketch of supra-stewardship as a tool to resist the deficit model and facilitate citizen participation around framing, distribution and vulnerability in order to highlight the normative in the technical, especially the boundaries of EU responsibility, and the production of governance distortions and failures. In section 3, I suggested some of the contours for engagement by supra-stewardship to show how citizens might use it to become active subjects as they open up knowledge domains, contribute towards decision-making and expand EU responsibility and accountability to include the definition of the pandemic threat as a medical emergency and its attendant governance distortions and failures.

<sup>222</sup> European Commission, “Interim Document”, n. 108 above, p. 35 (and pp. 34–5 for legal implications). (emphasis added). For definitions, see Annex 3, pp. 64–6, available at [http://ec.europa.eu/health/ph\\_threats/Bioterrorisme/keydo\\_bio\\_01\\_en.pdf](http://ec.europa.eu/health/ph_threats/Bioterrorisme/keydo_bio_01_en.pdf) (last accessed 5 September 2011). On EU support for ethics in national plans, see in the workshop “Ethical issues in European national preparedness for pandemic influenza”, [www.eu2008.fr/webdav/site/PFUE/shared/import/1120\\_pandemie\\_de\\_grippe/Pandemie\\_grippe\\_Pandemic\\_influenza\\_Programme\\_FR\\_EN.pdf](http://www.eu2008.fr/webdav/site/PFUE/shared/import/1120_pandemie_de_grippe/Pandemie_grippe_Pandemic_influenza_Programme_FR_EN.pdf) (last accessed 5 September 2011).

<sup>223</sup> Caduff, “Public prophylaxis”, n. 217 above.

Perhaps most important is using these insights to widen triage choices within the current frame of preparedness as being about dealing with a medical emergency and to guard against excessive and repressive measures. More difficult, given the limitations of that frame, is using the insights to inflect preparedness with a wider set of public health concerns in order to look beyond mitigating consequences and bolster interventions in the social conditions producing pandemics – and ensuring that pandemic governance is not to the detriment of wider public health objectives. Yet, in re-emphasising uncertainty, and although it requires further honing, supra-stewardship could highlight the need for a substantive input from those who are most affected by decision-making that cannot be based on the dominant hubristic technologies of risk and science alone.

Citizen participation and institutional learning could be fostered further by exploiting the rhetorical openings provided by the discourses constituting preparedness. For example, while used to construct the deficit model, PUS, especially as inflected through communication, could also be used to stimulate citizens’ awareness, attitudes and preferences. Claims for violations of human rights and ethical obligations, especially in relation to broader public health objectives or societal risk, and built around framing, distribution and vulnerability, could exploit reflexive governance and the sensitisation of governance to the institutional risk of human rights linked to bioethics. This includes the potential for a human rights consciousness understood as being about empowerment to use bioethics in order to disrupt the interests and standing of the EU.<sup>224</sup>

A particularly useful platform could be the European Citizens’ Initiative, “the first transnational instrument of participatory democracy in world history”.<sup>225</sup> Further reinforcement could come from moves towards organisational accountability and exploitation of the EU’s legitimacy needs. Overall, the citizen input provided by supra-stewardship could contribute towards better outputs and understanding of the limits of governance to organise uncertainty, helping to make preparedness and wider public health governance more secure and resilient in the event of failure.

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224 Cf. “legal risk+” proposed by Murphy and Whitty, “Is human rights prepared?”, n. 19 above, p. 233.

225 See [www.citizens-initiative.eu/?page\\_id=2](http://www.citizens-initiative.eu/?page_id=2) (last accessed 5 September 2011). Established by Article 11(4) TEU and Article 24(1) TFEU. The practical arrangements and procedures are provided by Regulation 211/2011. Article 11(4) TEU provides “[n]ot less than one million citizens who are nationals of a significant number of Member States may take the initiative inviting the Commission, within the framework of its powers, to submit any appropriate proposal on matters where citizens consider that a legal act of the Union is required for the purpose of implementing the Treaties”. This could produce a legal act under Article 168 TFEU.

