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Article:
Hervey, T.K. (2011) The European Union, Its Court of Justice, and "Super-Stewardship" in Public Health. Northern Ireland Legal Quarterly, 62 (5). 633 - 658 . ISSN 0029-3105

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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 EU's 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 European Union

'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)

Practitioners and academics within the health community have routinely been critical of involvement of the European Union and its Court of Justice ('the Court') in policy areas concerning healthcare systems and public health, such as caffeine and vitamin-enhanced foodstuffs, alcohol and tobacco, as the quotations above, taken from the press,[1] 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.[2]

* I am grateful to the participants at the UACES-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 ESRC 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.

[1] The Independent, 7 February 2004, 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 http://www.thelocal.se/7508/20070605/; Beveridge Daily 9 March 2010 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' BMJ 2010; 340:c1498 http://www.bmj.com/content/340/bmj.c1498; EurActiv.com http://www.euractiv.com/en/food/food-industry-wins-battle-traffic-light-labels-news-495324 (all accessed Jan 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' 18 European Journal of Public Health (2008) 392-398; G Hermans, A F Casparie and J H Paelinck, eds, Health care in Europe after

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 process, and, where disputes arise, through adjudication. Where states have chosen to become members of an international organization based on free trade, such as the European Union or the World Trade Organization, that balancing exercise must take place within the rules of such an organization. In the case of the EU, the direct effect[3] and supremacy[4] of EU law, and the role of the Court in interpreting EU law, as set out in the EU Treaties,[5] 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[6] and the Court's jurisprudence[7] recognize 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 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

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1992 (Leiden: Dartmouth, 1992); M McKee, E Mossialos and P Belcher, 'The influence of European Union law on national health policy' 6 Journal of European Social Policy (1996) 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 University Press, 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' 28 West European Politics (2005) 1035-56; C Newdick, 'Citizenship, free movement and health care: cementing individual rights by corroding social solidarity' 43 Common Market Law Review (2006) 1645-68; S Greer, The Politics of European Union Health Policies (Maidenhead: Open University Press, 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 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 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), p 269-93; C Barnard, The Substantive Law of the EU: The Four Freedoms (Oxford: OUP, 2010) p 165-187, 241-2, 510-8; V Hatzopolous, 'Recent Developments of the case law of the ECJ in the field of services' 37 CMLRev (2000) 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).

'intervention ladder',[8] be used to assess whether the European Union'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 '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[9] of the notion as developed in the Nuffield Report on Public Health: Ethical Issues,[10] can be characterized 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.'[11]

This conception echoes the World Health Organisation's World Health Report, 2000, which considers that stewardship consists in the 'ultimate responsibility' of governments for health within a state.[12] Brownsword et al's conception of stewardship lies somewhere between 'libertarian paternalism' and paternalism.[13] 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,[14] especially to those who would otherwise be disproportionately

[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' 2 (1) Public Health Ethics (2009) 113-119.
[10] London: Nuffield Council on Bioethics, 2007.
[11] Baldwin et al, supra n 9, p 115-116; Nuffield Report, supra n 8, p 25.
[12] WHO, World Health Report 2000, (Geneva, WHO, 2000), p xiv, 119-140.
[13] Nuffield Report, supra n 8, p 17-25.
[14] Nuffield Report, supra n 8, p 25.

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.[15]

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.[16] 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.[17] The Member States, and in practice the EU,[18] also share this responsibility with international organisations, in particular the World Health Organisation.[19] 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.[20]

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'[21] 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

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[15] WHO, supra n 12, 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), p 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. Collaborative initiatives include, for instance, the Global Health Security Initiative, launched 2001 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' 325 British Medical Journal 19 Oct 2002, 846-7; the Framework for Alcohol Policy in the WHO European Region 2006 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, 'Refining EU preparedness through supra-stewardship' in this issue. The EU also works with the OECD and the Council of Europe on a range of health issues, see http://ec.europa.eu/health/eu_world/international_organisations/index_en.htm (accessed Jan 2011).

[20] Article 168 (4) (a) (b) (c) TFEU.

[21] Nuffield Report, supra n 8, p 42.

- 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',[22] and Majone, for instance, has described the EU as 'a regulatory state'.[23] 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.

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

The concept of stewardship implies processes that legitimate public action.[24] For Brownsword et al, and for the WHO,[25] 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 European Union is a 'process of creating an ever closer union among the peoples of Europe', in which the Member

[22] R Brownsword, Rights, Regulation and the Technological Revolution (Oxford, OUP, 2008), 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 emphasizes 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 ELRev (2008) 457-481. For another perspective on the EU as (potentially) a state, see G Mancini, 'Europe: The Case for Statehood' 4 ELJ (1998) 29-42.
[24] Nuffield Report, p 23, 26, 43-45, 46. The idea is also implicit in R Brownsword, Rights, Regulation and the Technological Revolution (Oxford, OUP, 2008).
[25] WHO, supra n 8.

States give competence, in the Treaties, to attain common objectives, but is not a state.[26] 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 legitimation 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'[27]); 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.[28] 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.[29] 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,[30] nor even a telos or 'end game' that is a unitary community,[31] 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

[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, eg, 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 (accessed Jan 2011); the discussion of the Constitutional Treaty and its rejection in P Craig, The Lisbon Treaty: Law, Politics and Treaty Reform (Oxford: OUP, 2010) p 6-25; the conversation between L Siedentop 'A Crisis of Legitimacy' and A Moravcsik 'Europe without Illusions: a category error' at http://www.prospectmagazine.co.uk/2005/07/europewithoutillusions/ (accessed Jan 2011).

[27] See, eg N MacCormick, 'Beyond the Sovereign State' 56 Modern Law Review (1993) 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' 6 International Journal of Constitutional Law (2008) 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' 11 New Left Review (2001) http://www.newleftreview.org/A2343 (accessed Jan 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 et al European Union Law (Cambridge, CUP, 2010), p 6-7. For a defence of a more modest version of 'constitutional patriotism' for the EU, which however recognises the EU as having multiple demoi, see, J-W Müller, 'A European Constitutional Patriotism? The Case Restated' 14 ELJ (2008) 542-557.

[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 (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 ELJ (2008) 147-67.

[31] See, eg, 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 Jan 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), p 522-3, cited in I Ward, A Critical Introduction to European Law (Oxford: OUP, 2009), p 211-2.

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.[32] 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 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

[32] Much of the relevant literature on this subject pertains to the ill-fated Treaty establishing a Constitution for Europe. See, eg, P Eleftheriadis, 'Constitution or Treaty?' (2004) The 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?' 33 European Law Review (2008) 619-42. However, it also has a much longer pedigree, and involves more general reflection on EU constitutionalisation: see, eg, E Stein, 'Lawyers, Judges and the Making of a Transnational Constitution' 75 American Journal of International Law (1981) 1; G Bermann, 'The Single European Act: A New Constitution for the European Community?' 27 Columbia Journal of Transnational Law (1989) 529-87; J Weiler, 'The Transformation of Europe' 100 Yale Law Journal (1991) 2403; D Curtin, 'The Constitutional Structure of the Union: A Europe of Bits and Pieces' 30 Common Market Law Review (1993) 17-69; P Eleftheriadis, 'Aspects of European Constitutionalism' 21 European Law Review (1996) 32-42; N Walker, 'European Constitutionalism and European Integration' 1996 Public Law 266-90; J Shaw, 'Postnational Constitutionalism in the European Union' 6 Journal of European Public Policy (1999) 579-97; J-C Piris, 'Does the European Union have a Constitution? Does it need One?' (1999) 24 ELRev 557-85; J Shaw, 'Process and Constitutional Discourse in the European Union' 27 Journal of Law and Society (2000) 4-37; P Craig, 'Constitutions, Constitutionalism and the European Union' 7 European Law Journal (2001) 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' 9 European Law Journal (2003) 45-68; V Breda, 'A European Constitution in a Multinational Europe or a Multinational Constitution for Europe' 12 European Law Journal (2006) 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' 16 European Law Journal (2010) 511-550.

1980s and 90s,[33] or the EU's blood[34] or organ and tissue donation[35] law and policy. The fact that, at the height of the BSE/vCJD crisis, 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,[36] 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[37] and Human Tissue and Organs Directives[38] provide for accreditation, authorisation and licensing of establishments that collect human blood, organs or tissues, and establish inspection and quality control requirements with respect to those establishments.[39] 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

[33] Eg 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 beef burger to his 4 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.

[39] For discussion of the EU's regulation of blood and human tissue, see S Hennette-Vauchez, 'Biomedicine and EU law: Unlikely Encounters?' EUI Working Papers, RSCAS 2010/46, http://cadmus.eui.eu/handle/1814/14174 (accessed Jan 2011); A-M Farrell, 'The Politics of Risk and EU Governance of Human Material' 16 Maastricht Journal of European and Comparative Law (2009) 41-64; A-M Farrell, 'Is the Gift still Good? Examining the Politics and Regulation of Blood Safety in the European Union 14 Medical Law Review (2006) 155-79; M Favale and A Plomer, 'Fundamental Disjunctions in the EU Legal Order on Human Tissue, Cells and Advanced Regenerative Therapies' 16 Maastricht Journal of European and Comparative Law (2009) 89-111; T Hervey and H Black, 'The European Union and the Governance of Stem Cell Research' 12 Maastricht Journal of European and Comparative Law (2005) 3-40; J McHale, 'Nanomedicine and the EU: Some Legal, Ethical and Regulatory Challenges' 16 Maastricht Journal of European and Comparative Law (2009) 65-88; M Flear, 'The EU's Biopolitical Governance of Advanced Therapy Medicinal Products' 16 Maastricht Journal of European and Comparative Law (2009) 113-137.

HIV-contaminated blood in the 1980s and 90s.[40] 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,[41] 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,[42] and indeed, that it does not require all necessary information for consumers to make informed choices.[43] Given the inequalities inherent in obesity as a public health problem in European societies,[44] 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

[40] T Hervey and J McHale, Health Law and the European Union (Cambridge: CUP, 2004), p 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' 10 Professional Negligence (1994) 2; Y Englert, ed, Organ and Tissue Transplantation in the European Union (Dordrecht: Martinus Nijhoff, 1995) A-M Farrell (2006), supra n 39, 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' 45 Common Market Law Review (2008) 1147-65; H Unberath and A Johnston, 'The Double-Headed Approach of the ECJ Concerning Consumer Protection' 44 Common Market Law Review (2007) 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?' 16 European Law Review (1991) 391-415; S Weatherill, 'Recent Case Law concerning the Free Movement of Goods: Mapping the Frontiers of Market Deregulation' 36 CMLRev (1999) 51; O Brouwer, 'Free Movement of Foodstuffs and Quality Requirements: Has the Commission Got it Wrong?' 25 Common Market Law Review (1988) 237-67.

[42] Ibid.

[43] In spite of regular calls for its introduction from the public health community, the EU has not been able to introduce mandatory food labelling requirements that give 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 http://www.eatwell.gov.uk/foodlabels/trafficlights/#cat334844 (accessed Jan 2011). See 'Traffic light food labelling: a position statement', UK Faculty of Public Health http://www.fph.org.uk/uploads/ps_food_labelling.pdf (accessed Jan 2011); House of Commons Health Committee Obesity Third Report of session 2003-04 London: Stationery Office, 2004; EurActiv.com http://www.euractiv.com/en/food/food-industry-wins-battle-traffic-light-labels-news-495324. The Commission's Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers COM(2008) 40 final, does not include the requirement to give information about the health impact of food.

[44] Obesity is linked to social class, see UK Office for National Statistics http://www.statistics.gov.uk/STATBASE/Product.asp?vlnk=11130&More=Y (accessed Jan 2011) and to poverty, see J Sobal and A J Stunkard, 'Socioeconomic status and obesity: a review of the literature' 105 Psychology Bulletin (1989) 260-75; A Drewnowski and S E Specter, ' Poverty and Obesity: the role of energy density and energy costs' 79 American Journal of Clinical Nutrition (2004) 6-16; L McLaren, 'Socioeconomic status and obesity' 29 Epidemiological Review (2007) 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 (accessed Jan 2011).

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 immunization, 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 'base line', and the further from the base a proposed intervention, the higher the justification involved. What is the appropriate base line for our 'multi-level ladder of intervention'? One possible base line, provided within EU law itself, is the doctrine of subsidiarity.[45] 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.[46] 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 World Health Organization attests, the starting 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.[47] In other words,

[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 harmonizes such policies must be justified.
[47] This is also supported by the post-Lisbon 'mainstreaming' obligation with respect to human health, see Article 9 TFEU.

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, e.g., WHO policy, 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, which seeks to coordinate responses to communicable diseases[48] 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.[49] 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,[50] as well as the EU's internal market in goods, justifies the elements of EU-level food law and policy that protect and promote public health.[51]

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[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 2011 Journal of Health Politics, Policy and Law.

[50] See, eg, M Cardwell, The European Model of Agriculture (Oxford: OUP, 2004).

[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 Jan 2010, http://ec.europa.eu/food/food/foodlaw/guidance/docs/guidance_rev_8_en.pdf (accessed Jan 2011). See, eg, 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 and 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' 23 Journal of Consumer Policy (2000) 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,

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 European Union.

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.[52] 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 European Union.

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 activities, Brownsword himself deals (implicitly) with how stewardship obligations apply to courts at length in Rights, Regulation and the Technological Revolution.[53] 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'.[54] For

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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 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.

[52] For instance, Baldwin et al 2009 assert that, under a stewardship model, 'public health programmes should …' – in other words stewardship is a tool for assessing programmes, not adjudication.

[53] R Brownsword, Rights, Regulation and the Technological Revolution (Oxford: OUP, 2008) (RRTR), Chapter 6 'The Challenge of Regulatory Connection'

[54] Brownsword, RRTR, supra n 53 p 166-7; 184.

Brownsword,[55] '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.[56] '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'[57] and 'unproductive'.[58] Otherwise, courts should maintain the disconnections, as these will produce a realignment of the regulatory arrangements through legislative activity.[59] Whether courts adopt a purposive approach depends upon how they judge the 'regulatory tilt'[60] – in other words the default position set by regulators.[61] 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).[62] The EU legislative processes have been widely criticized as being insufficiently legitimate, including where the EU legislates in areas such as public health, where law interfaces with science and society.[63] 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[64] or the protracted, highly

[55] Relying on Lon Fuller's work, especially L Fuller, The Morality of Law (New Haven: Yale University Press, 1969), p 209-10; L Fuller, 'Positivism and Fidelity to Law – A Reply to Professor Hart' (1957-58) 71 Harvard Law Review 630, cited in RRTR, p 161 and 167.
[56] RRTR, supra n 53, p 167.
[57] Where the descriptions in law or policy decisions no longer correspond to developments in science and/or society, RRTR, supra n 53, 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, RRTR, supra n 53, p 167, see also p 183.
[59] RRTR, supra n 53, p 184
[60] RRTR, supra n 53, p 172-3
[61] RRTR, supra n 53, 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' 40 Journal of Common Market Studies (2002) 283-307; F Scharpf, 'The Joint Decision Trap: Lessons from German Federalism and European Integration' 66 Public Administration (1988) 239-278.
[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, Haltern and Mayer, supra n 30; S Jasanoff, Designs on Nature. Science and Democracy in Europe and the United States (New Jersey, Princeton University Press, 2005).
[64] Directive 98/44/EC on the legal protection of biotechnological inventions OJ 1998 L 213/13. For discussion see, eg, E Cloatre, 'From International Ethics to European Union Policy: A case study on biopiracy in the EU's Biotechnology Directive' 28 Law and Policy (2006) 345-67; T Hervey and H Black, 'The European Union and the Governance of Stem Cell Research' 12 Maastricht Journal of European and Comparative Law (2005) 11-

contested (and ongoing[65]) legislative process concerning EU-level regulation of tobacco[66] and its advertisement.[67] Because of these 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.[68] But 'super-stewardship', and an obligation to consider a recalibrated choice between

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48, at 32-8; E R Gold and A Gallochat, 'The European Biotech Directive: past as prologue' 7 European Law Journal (2001) 331-366; 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, T Hervey, eds, Health Systems Governance in Europe: The Role of European Law and Policy (Cambridge: CUP, 2010), p 262-5; D Wyatt, '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' 26 European Law Review (2001) 101-125; T Hervey, 'Community and National Competence in Health after Tobacco Advertising' 38 Common Market Law Review (2001) 1421-1446.

[68] Probably the best-known area for critique of the CJEU as a forum for making these kinds of judgments concerns the CJEU's human rights jurisprudence. See, seminally, J Coppell and A O'Neill, 'The European Court of Justice: Taking Rights Seriously?' 29 Common Market Law Review (1992) 669-92; and J H H Weiler and N Lockhart, ' "Taking Rights Seriously" Seriously: The European Court and its Fundamental Rights Jurisprudence' 32 Common Market Law Review (1995) 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' 55 Modern Law Review (1992) 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).

'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 DG Health and Consumers (SANCO). DG SANCO seeks to work with various EU agencies[69] with responsibilities for specific public health fields, such as food safety,[70] environmental protection[71] and communicable diseases[72]. 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[73] and HIV/AIDS[74]. Although the programmes have extremely modest budgets, they have provided guidelines and positive incentives for change at the national health policy level.[75] Nevertheless, as 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

[69] For discussion of the roles of agencies in the EU see, e.g., D Geradin, R Muños and N Petit, eds, Regulation though agencies in the EU: a new paradigm of European governance (Cheltenham: Edward Elgar, 2005); Vos, supra n 51 (Hart, 1999); O De Schutter, N Lebessis and J Paterson, eds, Governance in the European Union (Luxembourg: European Communities, 2001).

[70] The European Food Safety Authority http://www.efsa.europa.eu/ (accessed Jan 2011). See Vos and Wendler, supra n 51, (Intersentia, 2006); C Ansell and D Vogel, supra n 51.

[71] The European Environment Agency http://www.eea.europa.eu/ (accessed Jan 2011). See D A Westbrook, 'Environmental Policy in the European Community: Observations on the European Environment Agency' 15 Harvard Environmental Law Review (1991) 257; D Chalmers, 'Inhabitants in the field of European Community Environmental Law' 5 Columbia Journal of European Law (1998-99) 39-79.

[72] The European Centre for Disease Prevention and Control http://www.ecdc.europa.eu/en/Pages/home.aspx (accessed Jan 2011). See Greer, supra n 49 and H Elliott, S L Greer, D K Jones, supra n 49.

[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' 26 Wisconsin International Law Journal (2008) 804-43.

[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, Nance and Hervey, supra n 73; 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' (August 25, 2010) 14 Journal of Health Care Law and Policy, (2010); University of Wisconsin Legal Studies Research Paper No. 1128. Available at SSRN: http://ssrn.com/abstract=1665187 (accessed Jan 2011).

developed within its policy on 'freedom, security and justice'.[76] Responsibility for the European Union'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,[77] has been developed through the common agricultural policy, and responsibility for food safety now resides with the European Food Safety Authority.[78] 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.[79] Health and safety at work is covered by DG Employment.[80] The EU's long-standing environmental policy, with a significant body of environmental law involving matters such as air and water quality;[81] waste disposal;[82] and noise pollution,[83] 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,

[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 Jan 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 above n 70.

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

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

[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.

internal market law exerts a major influence on public health.[84] 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[85] has had profound implications for national laws, regulations and administrative practices and policies dealing with those products, and the advertisement of these products, as part of national public health policies.[86]

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 market law.[87] 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[88] internal market law. Being part of the Treaty on the Functioning of the European Union, these measures of EU law cannot be amended except by Treaty revision, and in fact the core provisions have not been amended[89] in the entire lifetime of what is now the EU.[90] Treaty revision involves an even more difficult process than adoption of EU

[84] Recently, for instance, the CJEU 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 Franzén [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 Ahokainen 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 supra n 7, 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, K Poikolainen, 'Alcohol tax cuts and increase in alcohol-positive sudden deaths: a time-series intervention analysis' 102 (3) Addiction (2007) 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' British Medical Journal 2009;338: b1191.

[87] Article 36 TFEU; Articles 52 and 62 TFEU; Case 120/78 Cassis de Dijon, supra n 7; 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

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,[91] 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 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 World Trade Organization, 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 IVF 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

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'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' EUI Working Paper RSC 96/44; F Scharpf, 'The European Social Model: Coping with the Challenges of Diversity' 40 Journal of Common Market Studies (2002) 645-670; F Scharpf, 'The Joint-Decision Trap Revisited' 44 Journal of Common Market Studies (2006), 845-864; F Scharpf, 'Legitimacy in the Multilevel European Polity' FPIfG Working Paper 09/1 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 Rödl, 'On the 'Social Deficit' of the European Integration Project and its Perpetuation through the ECJ judgments in Viking and Laval' RECON Online Working Paper 2008/06 www.reconproject.eu/projectweb/portalproject/RECONWorkingPapers.html; C Offe, 'The European Model of 'Social' Capitalism: Can it Survive European Integration?' 11 Journal of Political Philosophy (2003), 437-469; L Moreno & 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', Jean Monnet Working Paper, No. 02/06, 1-64.

> could have been found to support the Authority's refusal to allow Diane Blood to export the sperm.[92]

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.[93] 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 the Court 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 European Union in determining the balance between free trade/fair competition and public health, discussed in this article, relates to the point above. 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 …'[94]

> '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[95] … The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured …'[96].

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')

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[92] T Hervey, 'Buy Baby: the European Union and regulation of human reproduction' 18 Oxford Journal of Legal Studies (1998) 207-233, at 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 p 7; 10-11; p 82-137; 184-199; A Somek, 'The Owl of Minerva: Constitutional Discourse Before its Conclusion' 71 MLRev (2008) 473-89, at 485, and ftn 38.
[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, Oregon: Hart, 2008), p 47.
[95] Article 1 TEU.
[96] Article 26 (2) TFEU.

'community of rights' (a state). The main addressees of stewardship are public authorities[97] 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 criticize 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'.[98] The very nature of public health goods is such that they can often outweigh liberal ideas about protecting individual liberties and freedoms,[99] including those pertaining to the creation and maintenance of the EU's internal market. So, just as '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.

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[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, 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) 111–168; 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, supra n 9, p 114.

[99] Baldwin et al, supra n 9, p 114.

Obviously the examples discussed here are selective. They are based on a review of the Court's case law in public health fields, from the 1950s-2009.[100]

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.'[101]

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 goods,[102] 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.[103] There are essentially two versions of the proportionality test (a stronger and a weaker test),[104] and the

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[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.

[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' 33 European Law Review (2008) 167-193. In the weakest version, a measure that is prima facie suitable to protect public health, and is not

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,[105] or from certain levels of active coliform bacteria and active micro-organisms in milk products,[106] 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'.[107]

The weaker version of proportionality also applied in cases where the science was less clear. For instance, in Rewe-Zentralefinanz eGmbh v Landwirtschaftskammer,[108] 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.[109] There was no need to prove the risk – it was enough to show that it was reasonable for the national administration to believe it existed. This softer version of proportionality continued in cases throughout the 1980s.[110]

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

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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, supra n 101,.

[107] Case 54/85 Mirepoix, supra n 105, para 15.

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

[109] Para 8.

[110] See, e.g., Case 174/82 Sandoz supra n 101; Case 53/80 Eyssen [1981] ECR 409; Case 247/84 Motte, supra n 101, and Case 304/84 Muller, supra n 101. In Case 174/82 Sandoz, supra n 101, the CJEU 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, italics added). Similar reasoning is found in Case 53/80 Eyssen [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).

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;[111] the nutrient L-Carnitine;[112] and the nutrient Co-enzyme Q10,[113] the Court's position moved towards a stricter version of proportionality, by scrutinizing 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.[114] Originally following decisions taken by Member States, the EU began to develop its own idea of scientific knowledge[115] 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.[116] But is there sufficient commonality between the Member States of the EU in terms

[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, supra n 51), 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, supra n 51, p 55-56.
[115] Such knowledge being not only scientifically, but also socially and politically constructed, see S Jasanoff, Designs on Nature: Science and Democracy in Europe and the United States (Princeton, NJ, Princeton University Press, 2005).
[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 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) http://www.mtcr.info/english/index.html; the Wassenaar Arrangement (with 40 members) http://www.wassenaar.org/controllists/index.html; the Nuclear Suppliers Group (with 46 members) http://www.nuclearsuppliersgroup.org/Leng/03-member.htm; and the Australia Group (with 41 members) 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 http://www.fco.gov.uk/en/global-

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,[117] 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 intervention'. In a large number of cases concerning food and alcohol labelling,[118] 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.[119] Labelling of food or

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issues/weapons/arms-trade-treaty/. The UN's Single Convention on Narcotic Drugs 1961 http://www.unodc.org/unodc/en/treaties/single-convention.html?ref=menuside 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 http://www.unodc.org/unodc/en/treaties/psychotropics.html?ref=menuside 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' 24 Fordham International Law Journal (2000) 317-70; J Scott, 'European Regulation of GMOs and the WTO' 9 Columbia Journal of European Law (2003) 213-39; J G Carrau, 'Lack of Sherpas for a GMO Escape Route in the EU' 10 German Law Journal (2009) 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), 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).

[118] See, for instance, Case 120/78 Cassis de Dijon supra n 7; Case 261/81 Rau [1982] ECR 3961; Case 94/82 De Kikvorsch Groothandel-Import-Export [1983] ECR 947; Case 178/84 Commission v Germany (Beer Purity) supra n 7; 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), supra n 112; 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 Judgment of 29 April 2010 nyr in ECR. For critique, see Weatherill, supra n 41; von Heydebrand u d Lasa, supra n 41; Brouwers, supra n 41; MacMaoláin, supra n 41; Unberath and Johnston, supra n 41.

[119] Nuffield Report, supra n 8, p 40, citing D Acheson (1998) Independent Inquiry into Inequalities in Health: Report (London: The Stationery Office); A Gepkens and LJ Gunning-Schepers (1996) 'Interventions to reduce

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,[120] 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.[121]

However, both in cases where the detriments to public health arising from the product or service relating to the product are contested[122] and in those, such as with respect to tobacco, where they are known and agreed upon,[123] the Court's reasoning remains trapped within the (liberal) frame of constitutional asymmetry, where the individual is conceptualized 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 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.

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[120] Nuffield Report, supra n 8, p 41.

[121] See, for instance, the Swedish rules on the sale of alcohol, Case C-434/04 Ahokainen and Leppik, supra n 85.

[122] See, for instance, Case C-24/00 Red Bull, supra n 112.

[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 Autria (Tobacco Retail Prices) 4 March 2010, nyr in ECR; Case C-221/08 Commission v Ireland (Tobacco Retail Prices) 4 March 2010 nyr in ECR; Case C-571/08 Commission v Italy (Tobacco Prices) 24 June 2010 nyr in ECR.

‘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 European Union does not always successfully play its role as a ‘super-steward’ of public health in the European Union.