EU Health Law & Policy

The Expansion of EU Power in Public Health and Health Care

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LIST OF ABBREVIATIONS

ARGUS	General European Rapid Alert System
ASHTI	Alerting System for Chemical Health Threats
AWG	Ageing Working Group
BISCHAT	Rapid Alert System for Biological and Chemical Attacks
BSE	Bovine Spongiform Encephalitis
CAP	Common Agricultural Policy
CASSTM	Administrative Commission on Social Security for Migrant Workers
CBHC	Cross Border Health Care
CEC	Commission of the European Communities
CECA	Communauté européenne du charbon et de l'acier
CEDAW	Convention on the Elimination of All Forms of Discrimination against
CELENEC	Women
CEN	European Committee for Electrotechnical Standardization
CERD	European Committee for Standardization
	International Convention on the Elimination of All Forms of Racial
CFREU	Discrimination
CHMP	Charter of Fundamental Rights of the European Union
CJEU	Committee for Medicinal Products for Human Use
COREPER	Court of Justice of the European Union
CRC	Committee of Permanent Representatives
CRPD	Convention on the Rights of the Child
DG	Convention on the Rights of Persons with Disabilities
DNA	Directorate General
ECR	Deoxyribonucleic acid
EAHC	European Court Reports
ECDC	Executive Agency for Health and Consumers
ECFIN	European Centre for Disease Control
ECHR	Directorate General Directorate General for Economic and Financial
ECOFIN	Affairs
ECPT	European Convention on Human Rights
	Economic and Financial Affairs Council
ECSC	European Convention for the Prevention of Torture and Inhuman or
EDPS	Degrading Treatment or Punishment
EEC	Treaty establishing Coal and Steel Community
EFSA	European Data Protection Supervisor
EFTA	European Economic Community
EGKS	European Food and Safety Agency
EMA	European Free Trade Association
EMCDDA	Europese Gemeenschap voor Kolen en Staal
ENVI	European Medicines Agency
EP	European Monitoring Centre for Drugs and Drug Addiction
EPC	Committee on the Environment, Public Health and Consumer Protection
EPIET	European Parliament
EPSCO	Economic Policy Committee
ESC	European Programme for Intervention Epidemiology Training
EU	Employment, Social Policy, Health and Consumer Affairs Council
EUCO	European Social Charter

EUPC	European Union
EURATOM	European Council
EUROFOUND	EU Poisons Centres
EWRS	The European Atomic Energy Community
FVO	European Foundation for the Improvement of Living and Working
GDP	Conditions
GMO	Early Warning and Response System (Communicable Disease)
HEDIS	Food and Veterinary Office
HIA	Gross Domestic Product
HLG	Genetically Modified Organism
HLPR	The Health Emergency & Disease Information System
HLY	Health Impact Assessment
HSC	High Level Group
ICCPR	High Level Process
ICESCR	Healthy Life Year (Indicator)
IHR	Health Security Committee
ILO	International Covenant on Civil and Political Rights
IMCO	International Covenant on Economic, Social and Cultural Rights
ISO	International Health Regulations
IVF	International Labour Organisation
MARKT	Internal Market and Consumer Protection
MEDDEV	International Organization for Standardization
MEP	In-Vitro Fertilisation
NGO	Directorate-General Internal Market and Services
OMC	Commission Guideline relating to medical devices directives
OSHA	Member Of the European Parliament
RAS	Non-Governmental Organisation
SANCO	Open Method of Coordination
SARS	European Agency for Safety and Health at Work
SCCS	Rapid Alert System
SCENIHR	Directorate General Health and Consumers
SCHER	Severe acute respiratory syndrome
TEU	Scientific Committee on Consumer Safety
TFEU	Scientific Committee on Emerging and Newly Identified Health Risks
UDHR	Scientific Committee on Health and Environmental Risks
UN	Treaty on European Union
US	Treaty on the Functioning of the European Union
VWG	The Universal Declaration of Human Rights
WHO	United Nations
WMA	United States
	Vaccine Working Group
	World Health Organisation
	World Medical Association

Chapter 1. THE SILENT REVOLUTION OF EU HEALTH LAW & POLICY

With health policy in Europe there has been an intrinsic development going on, a silent revolution. It's like grass, you don't see it grow, but you cut it every week.[1]

Seemingly unremarkable and unexceptional was the legal case of Mr. Kohll.[2] In the beginning of the '90s Mr. Kohll took his daughter to a doctor for dental treatment.[3] The doctor in Luxembourg recommended braces for the girl and, in order to avoid waiting times, advised to go across the border to Trier, Germany. The request by Mr. Kohll for reimbursement of the costs was refused by his national insurance body because the treatment was not deemed urgent. Mr. Kohll challenged this decision and the national Luxembourg court referred a question to the Court of Justice of the EU (CJEU). The question was if the EU law on free movement of services applied (Article 49 TFEU) and if the denial of reimbursement constituted breach of EU law.[4]

The CJEU determined that the denial of reimbursement of the costs of health care by the Luxembourgian authorities did indeed violate the principle of free movement of services, which meant that the costs of health care of Mr. Kohll had to be paid for by the home-state insurance authority. The outcome of this case became highly publicized and politicized. The EU was seen to ruin the slowly and carefully balanced-out national health care systems. Especially the Member States argued that the judgment was not in line with the European Treaties, which determine that the redistribution of access to health care – at the epicentre of national elections and taking up a high part of the national budget – is not in the purview of EU 'market-making' and does therefore not give the EU the power to make decisions about the reimbursements of costs (Art 168 (7) TFEU).[5]

The Kohll case is at the time of writing 14 years old already, but it illustrates one way that – as the statement by the EU civil servant at the top of the page states – the involvement of the

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[1] Respondent 2 (Deputy Permanent Representative for Health in the Council, 2010).

[2] T.K. Hervey, 'Re-Judging Social Rights in the EU', *Critical Legal Perspectives on Global Governance* (Hart Publishing 2014) 347.

[3] *Case C-158/96 Raymond Kohll v Union des caisses de maladie [1998] ECR I-1931.*

[4] Regulation (EC) No 883/2004, 'Regulation (EC) No 883/2004 of the European Parliament and of the Council on the Coordination of Social Security Systems (O.J. L166, 3-4-2004)'.

[5] 'Treaty on the Functioning of the EU (O.J. 115/49)' <13488829440080509en00470199.pdf>.A de Swaan, *In Care of the State: Health Care, Education and Welfare in Europe and the USA in the Modern Era* (Oxford University Press 1988); C. Newdick, 'Disrupting the Community-Saving Public Health Ethics from the EU Internal Market', *Health Care and EU Law* (Asser 2011).

EU in human health is expanding, notwithstanding limited legislative competence.[6] The paradoxical growth of EU health policy indicates that formal legal rules alone do not explain its involvement in health, because much of the activity of the EU in health is either ‘non-legislative’[7] or takes place under a different policy heading, such as agriculture or economic policy.

This book describes the growth of EU power in the field of *health care* and in the field of *public health* and it analyses the implications of this expansion in these distinct and ‘functional’ policy fields for EU health values and rights. The book is legal in that it uses a framework of EU fundamental rights to ascertain the qualitative impact in terms of rights and values of the growth of EU power in the field of human health. At the same time, in describing the growth of EU power, qualitative semi-structured interviews illustrate the legal and policy developments that are described in the book. Rather than choosing one theoretical narrative to explain the growth of EU power in the field of human health, several theoretical explanations are mapped and related to the functional divides that define the nature of certain choices that are made in EU human health policy and law – the connecting factor however is a *legal analysis* in terms of EU fundamental rights and values.

[6] The EU only has limited legislative competence in the area of public health, Article 168 TFEU; E. Randal *The European Union and health policy* (St. Martin's Press, New York: 2000); E. Mossialos *et al* (eds) *Health Systems Governance in Europe, the Role of European Union Law and Policy* (Cambridge University Press, New York: 2010); S. Boessen and H. Maarse 'The impact of the treaty basis on health policy legislation in the European Union: A case study on the tobacco advertising directive' (2008) *BMC Health Services Research* 8 (77); T.K. Hervey and J.V. McHale *Health Law and the European Union* (Cambridge University Press, Cambridge: 2004); M. Steffen (ed) *Health Governance in Europe: Issues, Challenges, and Theories* (Routledge, New York: 2005).

[7] D.M. Curtin *Executive Power of the European Union. Law, Practices and the Living Constitution* (Oxford University Press, Oxford: 2009) p. 3: ‘Non-legislation basically refers to executive action in one form or another from implementation and standard setting to operational decisions by both majoritan and non-majoritan actors.’

1. Human health, values, rights and the European Union

The denial or approval of authorisation of a specific controversial medication, or the payment for health care in another Member State than the home state of insurance – and many of the other questions and issues that are addressed in the EU with regard to human health – illustrate that the involvement of the EU in human health can involve controversial questions, where fundamental rights, bioethical issues and regulatory problems or redistributive choices may intertwine. This puts into question the power the EU has in this regard. Particularly if we take into consideration that human health law and policy are often seen in light of a special reciprocal relationship with fundamental rights.[8] Infringements of fundamental rights can harm human health, for instance in cases of torture or discrimination of people with a particular disease, such as HIV/Aids or mental disorders. At the same time health policy can affect fundamental rights, for instance when obligatory vaccination programmes or quarantines are ordered.[9]

The connection between fundamental rights and human health is integrated both into the law of numerous states and the legal framework of a number of international organisations.[10] Moreover, the relationship between health policy and fundamental rights is increasingly put forward by scholars as an 'inextricable connection', and is as an instrument to judge the *legitimacy* of the involvement of public and private authorities in health efforts.[11] In other words, fundamental rights are a benchmark for analysing the legitimacy of health policy: On the one hand, a rights-based approach to policymaking makes the values explicit that are affected by authoritative decisions of policymakers.[12] On the other hand, fundamental rights can define who is a rights holder and duty bearer and what is the nature of a particular

[8] Jonathan M Mann and others, 'Health and Human Rights' (1994) 1 Health and Human Rights 6.
[9] S. Gruskin *et al* 'Health and Human Rights: History, principles and practice of health and human rights' (2007) *The Lancet* 370 449-455; G.J. Annas 'Human Rights and Health: The Universal Declaration of Human Rights at 50' (1998) *The New England Journal of Medicine* 339 (24) 1778-1781.
[10] B. Toebes 'The right to health and other health-related rights, in Health and Human Rights in Europe' in B. Toebes *et al.* (eds) *Health and Human Rights in Europe* (Intersentia, Cambridge: 2012); E.D. Kinney and B.A. Clark 'Provisions for Health and Health Care in the Constitutions of the Countries of the World' (2004) *Cornell International Law Journal* 37 285-355.
[11] S. Gruskin *et al* 'Rights-based approaches to health policies and programs: Articulations, ambiguities, and assessment' (2010) Journal of Public Health Policy 31 (2) 129-145; S. Gruskin and D. Tarantola 'Health and Human Rights' in S. Gruskin et al. (eds) *Perspectives on Health and Human Rights* (Routledge, New York: 2005); World Health Organisation Europe *Health impact assessment: main concepts and suggested approach. Brussels: ECHP* (Gothenburg consensus paper: 1999); and for a global overview of some of these efforts, see A. Scott-Samuel and E. O'Keefe 'Health impact assessment, human rights and global public policy: a critical appraisal' (2007) *Bulletin of the World Health Organization* 85 212-217.
[12] L. London, 'What is a Human –Rights Based Approach to Health and Does it Matter?' (2008) *Health and Human Rights* 10(1) 65-80 at p. 72.

obligation. In this regard, fundamental rights create a range of legal mechanisms to assess the legitimacy of the exercise of public power.[13]

In the literature on the involvement of the European Union in human health, the connection with fundamental rights has been highlighted and a great deal of work is done in outlining the importance of EU fundamental rights applicable to Member States' health policies.[14] Yet, only 'limited attention has been devoted to the growth of EU legislation that has implications for the protection of fundamental rights'.[15] At the same time, fundamental rights are deemed of pivotal importance for EU in scholarship in a more abstract sense:

> [F]undamental values [...] may be said to underpin all health regimes within the EU although the interpretation of those values may differ considerably in practice. […] One key element of the EU's role may be seen in the protection of such 'European values' inherent in European national health systems in the context of increasing international economic pressures.[16]

Yet although the importance of the connection between fundamental rights and the growing involvement of the EU in health is recognised in the literature,[17] there is not a neatly circumscribed concept of EU health policy or law, nor a determination of the *de jure* and *de facto* power of the EU in human health. But as long as the existence of European Union health policy is a 'silent revolution' and remains undefined,[18] its possible implications for fundamental rights and values remain implicit. Health policy in that case does not require legitimation, even though our lives may depend on it.

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[13] Ibid at p. 68. In the EU there is the Fundamental Rights Agency, the policy objective of 'mainstreaming' fundamental rights in all EU public policies and there is of course the possibility for litigation and legislative review.

[14] The European Fundamental Rights Agency in particular has issued a number of studies on discrimination in health care settings across the EU: European Agency for Fundamental Rights, Involuntary placement and involuntary treatment of persons with mental health problems (June 2012); European Agency for Fundamental Rights, Inequalities and multiple discrimination in access to and quality of healthcare (March 2013); European Union Agency for Fundamental Rights, Legal capacity of persons with intellectual disabilities and persons with mental health problems (July 2013). Also see J.V. McHale 'Fundamental rights and health care' in E. Mossialos *et al* (eds) *Health systems governance in the EU: the role of EU law and governance* (Cambridge University Press, New York: 2012). In this regard, the European Journal for Health Law in particular has focused on EU fundamental rights. See e.g. H. Nys 'The Right to Informed Choice and the Patients' Rights Directive' (2012) *European Journal of Health Law* 19 (4); H.D.C. Roscam Abbing 'Patients' Right to Quality of Healthcare: How Satisfactory Are the European Union's Regulatory Policies?' (2012) *European Journal of Health Law* 19 (5) 415-422.

[15] E. Muir 'The Fundamental Rights implications of EU Legislation: Some Constitutional Challenges' (2014) *Common Market Law Review* 51 219-246 at p. 220.

[16] Hervey and McHale (2004) supra note 6 at p. 5. And see further T.K. Hervey 'The Right to Health in European Union Law' in T.K. Hervey and J. Kenner (eds) *Economic and Social Rights Under the Charter of Fundamental Rights* (Hart Publishing, Oxford: 2003); T.K. Hervey 'The "Right to Health" in European Union Law' in T.K. Hervey and J. Kenner (eds) *Economic and Social Rights under the EU Charter of Fundamental Rights* (Hart Publishing,Oxford: 2003) and see Council Conclusions on Common values and principles in European Union Health Systems(2006/C 146/01) (OJ 146/1).

[17] See ibid Hervey (2003) .

[18] Or merely captured in its 'contours', see T.K. Hervey 'Mapping the Contours of European Union Health Law and Policy ' (2002) *European Public Law* 8 (1) 69-105.

2. Expanding power of the EU in human health

The scope of power that can currently be exercised by the EU goes far beyond what was envisioned for the international organisation founded in the 1950s for the purpose of creating a common market.[19] The EU has powerful institutional actors: the Court of Justice of the EU (CJEU) and the European Commission, the EU's central executive and administrative body that can initiate legislation. The Member States are represented at ministerial level in the Council of the EU and the Heads of State are represented in the European Council. Besides the Council's central role in adopting legislation together with the European Parliament, it also holds significant executive powers.[20] Moreover, operating below the core institutions of the EU there are a number of actors that play an important role in the involvement of the EU in health, such as European agencies that work on various health issues and to which Member States and the EU have delegated tasks in this regard.[21] Furthermore, in the initiation and implementation stage of EU legislation and policy, there are numerous working groups, experts, committees and high-level groups that are involved in health in the EU.[22]

Leaving aside the difficulty of defining the nature of the EU's political system,[23] the European Union can be described as a political union that on the surface has developed through major treaty reforms and 'constitutional sedimentation' by way of authoritative and far-reaching treaty interpretations of the Court of Justice and the settlement of institutional mechanisms.[24] However, below the surface, there are numerous empirical policy practices that take place for instance in implementation phases, in the form of coordination between Member States'

[19] See Curtin (2009) supra note 7.

[20] Ibid; and see The Treaty on European Union (OJ 115/15).

[21] M.E. Busuioc *European Agencies: Law and Practices of Accountability* (Oxford University Press, Oxford: 2013); and see G. Permanand. and E. Vos 'EU regulatory agencies and health protection' in E. Mossialos *et al* (eds) *Health Systems governance in Europe: The role of EU Law and governance* (Cambridge University Press, New York: 2010).

[22] E. Vos *Institutional Frameworks of Community Health and Safety Regulation: Committees, Agencies and Private Bodies* (Hart Publishing, Oxford: 1999).

[23] See D.M. Curtin 'The Constitutional Structure of the Union: A Europe of Bits and Pieces' (1993) *Common Market Law Review* 30 (1) 17-69. The use of the term 'political system' refers to Easton's classic notion of institutions and processes that are involved in the authoritative allocation of values in a given society. D. Easton 'An Approach to the Analysis of Political Systems' (1957) *World Politics* 9 (3) 383-400 at p. 384. The concept of a "political system" is helpful as it is able to 'encompass pre-state/non state societies as well as roles and offices that might not be seen to be overtly connected with the state'; see S.E. Finer 'Almond's concept of the political system'(1970) *Government and Opposition* 5 (1): 3-21 at p. 5, in P. Mair 'Popular Democracy and the European Union Polity ' (2005) *European Governance Papers* C-05-03 p. 16; also see S. Hix *The political system of the European Union* (Palgrave Macmillan, London: 2005) ; also see Curtin (2009) supra note 7 at p. 40 et seq; in relation to health policy specifically, see G. Walt *Health Policy, an Introduction to Process and Power* 5th ed (Zed Books, London: 2001); and see further Chapter 2.

[24] See Curtin (2009) supra note 7 at p. 11; also see D.M. Curtin 'The Sedimentary European Constitution: The Future of 'Constitutionalisation' without a Constitution' in I. Pernice and E. Tanchev (eds) *Ceci n'est pas une Constitution - Constitutionalisation without a Constitution?* (Nomos, Baden-Baden: 2009).

policies in areas where there is little formal legislative competence, or merely as a matter of institutional dynamics.[25]

2.1 Limited legislative power…

The EU has limited legislative power in the field of human health as a result of Member States resistance to transferring any major powers to the EU. Article 168 TFEU is not very helpful in this regard, as it simply outlines: 'A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.'[26] On the basis of this article it could be inferred that either EU health policy is non-existent as an autonomous policy area, given that it is mainstreamed in all other policies, or it is basically everything, in that all EU public policy is also health policy. However, at the same time Article 168 TFEU in two places restates the limited role for the EU:

> The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health […] excluding any harmonisation of the laws and regulations of the Member States.[27]
>
> Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.[28]

One explanation for the resistance of Member States to EU power is that health services form the centre of nation states' welfare provisions and in most EU Member States, health spending is one of the largest single chunks of the national social welfare budget.[29] Moreover, equally significant, health care and public health provisions have 'state building' capacity,[30] in that the collectivising of arrangements and instruments to cope with health related adversity

[25] See Curtin (2009), supra note 7.
[26] Treaty on the Functioning of the EU (OJ 115/49); see further Article 6(a) TFEU which attributes supportive, coordinative or supplementary competence to the EU with respect to the protection and improvement of human health, also see Article 9 TFEU which also contains a mainstreaming provision of the protection of human health in the definition and implementation of all EU policies and activities.
[27] Article 168 (5) TFEU.
[28] Article 168(7) TFEU.
[29] B.Przywara 'Projecting future health care expenditure at European level: drivers, methodology and main results, Directorate General of Economic and Financial Affairs of the European Commission' (July 2010) *Economic Papers* 417 .
[30] Public health policy addresses the health of a population at large. See L.O. Gostin *Public Health Law: Power, Duty, Restraint* (University of California Press, Berkeley: 2000).
[30] Health care policy relates to public activity aimed at creating access and providing health care services to individuals, rather than for the population at large. Steffen (ed) (2005) supra note 6; also see K. Lenaerts and J.A. Gutierrez-Fons 'The Constitutional Allocation of Powers and General Principles of Law' (2010) *Common Market Law Review* 47 1629-1669 at p. 244.

interacts with a 'civilizing process' in which all citizens have come to expect care as an expression of solidarity, organised by the nation state.[31]

Precisely the persisting national welfare provisions as a legitimating factor for the nation state and the absence of popular support and solidarity felt across EU Member States makes the growing expansion of the EU's role for human health a politically charged issue.[32] In this respect it is not likely that Member States will transfer major powers in the field of health to the EU any time in the near future, nor is there any indication that a collectivising process is repeating itself at the European level. However, there are numerous accounts testifying that the role of the EU in health keeps expanding, slowly chipping away at the Member States' autonomy to arrange their public health and health care policies.[33] The EU's involvement in health then may not be as clear-cut as the Treaty or Member States' resistance would suggest.

2.2...but ever-growing policy-making authority

Although the precise nature of the EU political system may remain unclear, the 'bits and pieces' of the EU's institutional and political structure do present a 'living whole' that wields significant political and executive power over its citizens, including with respect to human health.[34] The EU involvement in health is often conceptualised as only amounting to an array of health *policies*.[35] This 'patchwork picture' of EU health policy makes it difficult to comprehensively analyse EU activity in the field. This picture is explained by the fact that in general, much of EU policy activity in health has evolved as a by-product of other policies; for instance food safety in the EU for a long time was regarded as part of the Common

[31] A.D. Swaan *In Care of the State: health Care, Education and Welfare in Europe and the USA in the Modern Era* (Oxford University Press, New York: 1988) at p. 246-257; also see G. Majone 'The European Community between social policy and social regulation' (1993) *Journal of Common Market Studies* 31 153-170, at p. 159.
[32] See Majone (1993) ibid at p. 161 (on the unlikelihood of the harmonization of health policy due to the vast differences in health policy arrangements across the EU Member States).
[33] See De Swaan, supra note 24 at p. 257; S.L. Greer 'Uninvited Europeanization: Neo-functionalism and the EU in Health Policy' (2006) *Journal of European Public Policy* 13 (1) 134-152; S.L. *et al* 'Mobilizing Bias in Europe: Lobbies, Democracy and EU Health Policy-Making' (2008) *European Union Politics* 9 (3) 403-433; Mossialos *et al* (eds) (2010) supra note 6; R. Hamalainen *The Europeanisation of occupational health services: a study of the impact of EU policies* (Juvenes, Tampere: 2008); A. de Ruijterand T.K. Hervey 'Healthcare and the Lisbon Agenda' in P. Copeland and D. Papadimitriou (eds) *The EU's Lisbon Strategy, Evaluating Success, Understanding Failure* (Palgrave MacMillan, New York: 2012); P. Minogiannis *European Integration and Health Policy: The Artful Dance of Economics and History* (Transaction Publishers, New Brunswick: 2003); A.P. van der Mei *Free Movement of Persons within the European Community: Cross-Border Access to Public Benefits* (Hart Publishing, Oxford: 2003); D.S. Martinsen 'The Europeanization of HealthCare: Processes and Factors' in T. Exadaktylos and C.M. Radaelli (eds) *Research design in European studies, establishing causality in Europeanization* (Palgrave MacMillan, Basingstoke: 2012); R. Baeten *et al* (eds) *The Europeanisation of National Health Care Systems: Creative Adaptation in the Shadow of Patient Mobility Case Law* (European Social Observatory paper series, European Social Observatory: 2010); M. McKee *et al* (eds) *Health policy and European enlargement* (World Health Organisation, European Observatory on Health Systems and Policies, New York: 2004).
[34] Curtin (1993) supra note 23; Curtin (2009) supra note 7.
[35] Majone (1993) supra note 31 at p. 154.

Agricultural Policy ('CAP'). Generally – although from its inception the EU was not supposed to have a central role in human health issues – its involvement grew due to different pressures and constraints and as a result of continuous reconciliations of market aspirations with health concerns.[36]

A particularly important explanation, even justification for some, of the increasing role of the EU in health was that the EU represented a shift in the functions of the state, whereby its main instrument for social change was formed by the regulation of health and safety rather than redistributing welfare entitlements with regard to health, which remained within the autonomy of the Member States.[37] The 'welfare aspect' of health policy could be separated by the 'regulatory aspect' and so the influence of the EU could grow relatively free from political influence, which in the end eroded the 'Member States ability to make authoritative political decisions' as a result of policy-making that was not explicitly recognised as health policy, but rather as an issue of market regulation.[38] At the same time the CJEU addresses the 'welfare aspects' of health policy, in the context of market integration rather than as a particular aspect of social welfare that may escape the influence of EU internal market law.[39] Moreover, on other welfare aspects of health issues Member States *did* coordinate health policies through a range of 'non-legislative' mechanisms and policy practices, which in some cases became formalised to a greater or lesser extent.[40]

As a result of the role of the Court and the various ways for addressing human health by the EU, its involvement in health is usually captured as a sum of its parts rather than as a whole: 'EU health policymaking is currently made up of the various extensions of bureaucratic

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[36] See Chapter 3.

[37] The concept of the EU as a 'regulatory state' as developed by Majone refers to the phenomenon in which the regulation of health and safety aspects are delegated to largely expert and non-majoritan authorities that have derived their legitimation from their relative independence and scientific output. Regulation usually refers to specialized and more long-term, specialized control (credible commitment) over activities that are socially valued, such as the safety of consumer products generally. G. Majone 'The regulatory state and its legitimacy problems' (1999) *West European Politics* 22 (1) 1-24 at p. 2; also see Majone (1993) supra note 31; and see E. Vos 'The Rise of the Committees' (1997) *European Law Journal* 3 (3) 210-229; on the relationship of the regulatory state and health policy, see further Chapter 2.

[38] J. Richardson (ed) *Constructing a Policy-Making State? Policy Dynamics in the EU* (Oxford University Press, New York: 2012) at p. 12; also see S.L. Greer 'EU Healthcare Services Policy' in J. Richardson (ed) *Constructing a Policy-Making State? Policy Dynamics in the EU* (Oxford University Press, New York: 2012). As a policy-making state the EU's political system is involved in the 'authoritative allocation' of values in regard to our health; ibid at p. 15 and see further Chapter 2.

[39] G. Davies 'The effect of Mrs Watts' Trip to France on the National Health Care Service' (2007) *King's Law Journal* 18 158-167; Greer (2006) supra note 33.

[40] See further Chapter 3.

models developed in other fields and for other fields.'[41] Even in relation to public health,[42] where there is a stronger legislative EU competence, the baseline is that:

> [..I]t is not possible to discern a distinctive all encompassing 'supranational' public health model that would apply to the EU. Rather what emerges is a series of partially connected EU laws and policies that have various effects on public health.[43]

> [W]e can expect an interaction, or set of interactions, between legislative and governance processes, […]. However, this set of interactions will never amount to policy that is 'a single all-encompassing woven tapestry.'[44]

At the same time, in the re-print of their seminal book on the EU and human health policy and law, Hervey and McHale have come to the conclusion that regardless of its precise nature, the existence of EU health law is an empirical fact, whether we agree with it or not.[45]
Politically the EU's increasing role in health is largely seen as the 'result of EU institutional actors' entrepreneurialism and ensuing Member State lobby, with very limited democratic feedback.'[46] The involvement of the EU in health develops in '[A] closed shop of high level civil servants, EU officials and experts and many governance practices are particularly poorly integrated into domestic policy processes.[47]

Hence, generally, although there is no single theoretical explanation for the increasing expansion of the EU's role in human health, there seems to be ample opportunity for policy-making despite limited legislative competence for health specifically. However, as long as legally the responsibility to protect and promote human health remains with the Member States, the EU's role does not become explicit. Although the increasing role of the EU in human health issues is widely acknowledged, because of the fact that EU health policy features in a number of different policies in the EU and escapes legal definition, its legitimacy

[41] See Greer (2009) supra note (he goes on to say: 'as a result, health policy making for the EU is less a product if design than of translation and transplantation').
[42] Public health is a sub-field of health policy with a focus on the health of the population at large; see further Chapter 2.
[43] M. McKee, M. *et al.* 'Public Health Policies' in E. Mossialos *et al* (eds) *Health Systems governance in Europe: The role of European Union law and policy* (Cambridge University Press, New York: 2010), at p. 232.
[44] See T.K. Hervey and B. Vanhercke 'Health care and the EU: the law and policy patchwork' in E. Mossialos *et al* (eds) *Health systems governance in Europe: the role of European Union law and policy* (Cambridge University Press, New York: 2010) p. 133
[45] Tamara K Hervey and Jean V McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press 2015).
[46] Greer (2009) at p. 160.
[47] Hervey and Vanhercke (2010) supra note 44 at p. 132. This problem of EU democratic deficit is widely acknowledged and also affects European public policy in other sectors. There is a long-standing debate on the EU's democratic deficit; see, among others, S. Hix *What's wrong with the European Union and how to fix it* (Polity, London: 2008).

has not explicitly been addressed before. Fundamental rights provide a powerful normative language for addressing the legitimacy of health policy.

3. Health Law: Rights and Functions

The EU's powers are silently increasing in a policy domain – EU health policy – on which we spend lots of public money,[48] and to which we sometimes literally owe our lives. The growth of the EU's role in the field of human health, hence, brings up the question of the nature of EU health law with respect to the protection of fundamental rights, ánd vis-a-vis the functions of national health law. Health law generally functions to ensure the protection of fundamental rights in the context of health policy. It is seen as a legal discipline that: '[I]]ntends to create an environment in which the promotion of health goes hand in hand with the protection of individual rights and the general principles of equality and justice.'[49] Loosely defined, health law encompasses legal rules that regulate the provision of health care and the protection of human health.[50]

Fundamental rights in this context are of such central importance for the regulation of health that some scholars have defined health law to be a part of fundamental rights law.[51] And

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[48] Funds for health programmes and health policies are very limited at EU level, whereas it 'is the second largest function of government spending, at 7.5 % of EU GDP in 2010 (14.7 % of total government expenditure)', Eurostat, available at <www.epp.eurostat.ec.europa.eu/statistics_explained/index.php/General_government_expenditure_statistics#General_government_expenditure_by_function>.

[49] J. Legemaate 'Integrating health law and policy: a European perspective' (2002) *Health Policy* 60 101-110 at p. 102.

[50] The use of the term 'health law' here is deliberately not health care law, or medical law, as these terms refer more particularly to the regulation of health care arrangements rather than public health, whereas the term 'health law' here is taken to encompass both the regulation of public health and health care. See Hervey and McHale (2004) supra note 6 at p. 15 et seq. (provides a good overview of the different terminology); also see H.T. Greely 'Some Thoughts on Academic Health Law' (2006) *Wake Forest Law Review* 41 391-409 at p. 392 (Greely also includes public policy in his definition, and writes in the context of American health governance); H.J.J. Leenen *et al Handboek Gezondheidsrecht, deel 1 rechten van mensen in de gezondheidszorg* 5de druk(Boom Juridische Uitgevers, Den Haag: 2011) at p. 19 (specifically refers to the horizontal cross-cutting character of health law, overarching other legal disciplines such as constitutional, private, administrative and criminal law); see further A.P. den Exter *Health Care Law-making in Central and Eastern Europe* (Intersentia, Antwerp: 2002) at p. 56;; H.J.J. Leenen 'Health Law in the Twenty-first Century' (1998) *European Journal of Health Law* 5 341-348 ('Essentially the role of health law in the future will not be different from the present one. The basic norms: humanity, human rights and equity have to be kept upright') at p. 348.

[51] 'The unifying legal theme is, to us, that of human rights. In our view, therefore, medical law is a subset of human rights law.' See I. Kennedy and A. Grubb *Medical Law* (Butterworths, London: 2000) at p. 3 (as the introduction states this textbook is 'firmly rooted' in English law and deals mainly with the legal relationships between doctors and patients); also E. Wicks *Human Rights and Health Care* (Hart Publishing, Oregon: 2007); but see J.K. Mason and G.T. Laurie *Law and Medical Ethics* (Oxford University Press, New York: 2006) at p. 41 (who put forward that too much emphasis on the human rights aspect of 'medical law' could lead to a problematic interpretation of the therapeutic relationships in health care, where paternalism or beneficence is an important pillar in conjunction to the safeguarding of patient autonomy); see further here S. Sheldonand M. Thomson (eds) *Feminist perspectives on health care law* (Cavendish Publishing, London: 1998) at p. 6 (who use the term 'health care law' in a reconstructive sense, expanding the scope of 'medical law' to include not only physicians, but also the myriad of health care workers that can impact on fundamental rights in the health care context). With regard to public health, human rights feature as an important balancing instrument in the 'state-patient' relationship, see Mason and Laurie (2006) supra at p. 29. On the relationship between (public) health and human rights, J.M. Mann *et al* 'Health and Human Rights' (1994) *Health and Human Rights: an International Quarterly Journal* 1 (1) at p. 6 ('health and human rights are complementary approaches for defining and advancing human well-being'); also see L.O. Gostin and J.M. Mann 'Towards the Development of a Human RIghts Impact Assessment for the Formulation and Evaluation of Public Health Policies' (1994) *Health and Human Rights: an International Quarterly Journal* 1 (1) 50-78; for a critical perspective on the development of health law and its connection to fundamental rights as a way of increasing the power of law and legal practice vis-à-vis the medical community, see K. Veitch *The Jurisdiction on Medical Law* (Ashgate, Aldershot: 2007).

although there are many aspects to the governance of human health that may not have immediate fundamental rights implications,[52] health law as a discipline generally functions as a legal paradigm that safeguards fundamental rights in the activities of either the state or health professionals in relation to the human body and mind. This function is usually seen as the consequence of the historically ever-increasing power of the medical profession in the field of health care and the power of the state in human health.[53]

Hence, at Member State level health law functions to protect fundamental rights in relation to health policy. In the EU, the relevance of fundamental rights for health is also acknowledged through the adoption of a number of rights that take into account the special importance of health considerations in public policy.[54] However, if the EU's involvement in health is expanding in practice without a formal competence in the field, this could affect the level of protection of fundamental rights at national level, thus leaving a gap with respect to the responsibility for upholding fundamental rights in the context of health policy. In other words, EU health policy by its mere existence may: '[I]ncidentally set fundamental rights standards and create mechanisms for their protection.'[55]

Therefore, if the growth of Union law and policy-making in the field of human health, 'with different degrees of visibility'[56] has implications for fundamental rights, this puts into question the legitimacy or even the constitutionality of the EU's role.[57] First, the involvement of the EU in health could have fundamental rights implications while at the same time going beyond the competences that are conferred by Member States to the EU in this regard. Second, if EU involvement in health is based on a competence other than health, the principle of subsidiarity that holds that the EU should only act in cases where Member States themselves cannot achieve a particular objective sufficiently,[58] is not an apt tool to balance the importance of values that underlie fundamental rights and at what level of governance these are best

[52] See H.E.G.M. Hermans and M.A.J.M. Buijsen *Recht en Gezondheidszorg* 2de druk (Elsevier gezondheidszorg, Amsterdam: 2010) at p. 45 (who take 'health' as an intrinsic value as the unifying principle for health law, not unlike the approach chosen in J.M. Mann *et al*, see ibid).
[53] See *e.g.* Gostin (2000) supra note 30; Leenen (1998) supra note 50; Mann *et al* (1994) supra note 51.
[54] See further Chapter 3.
[55] G. Davies 'Subsidiarity: The Wrong Idea, In the Wrong Place, at the Wrong Time' (2006) *Common Market Law Review* 43 63-84 at p. 244.
[56] See E. Muir (2014) supra note 15 at p.223.
[57] See ibid. at p. 240.
[58] Article 5(3) TFEU.

protected.[59] Last, if EU health policy impacts on fundamental rights as a result of non-legislative mechanisms or informal practices, neither the conferral nor the use of EU legislative competences can determine the legitimacy of the EU's role. Therefore, rights-based approach to EU health policy can provide a powerful 'normative set of criteria' for establishing obligations for guaranteeing the rights of EU citizens in an area that is legally largely still within the autonomy of the Member States.[60] These – internal to health law – values and rights, set the agenda for this book.

4. Structure of the book and methodology of the research

The approach that is chosen in this book for mapping the growth of EU power and its impact in terms of rights and values of in the field of human health is largely legal. At the same time, European health policy is a matter of Union law, regulation *and* empirical practices. Health policy is not exceptional in this respect. With the increasing internationalisation of law and legal rules, the decentralisation of both government and the actors representing public power, law itself has become more diffuse. The legal sources that once delineated what the law is and how it evolves may no longer reflect the whole context in which law develops.[61] With respect to health policy; markets, the economy, developments in medical science and changing demands of patients, the political landscape, the social interactions of policy makers, the involvements of agencies and other expert actors are all variables that shape the EU's involvement in health policy as well.[62]

Therefore the current research goes beyond the 'formal sources of law' by including qualitative research data relating the accounts of civil servants working on health policy in the EU institutional context. Furthermore, as to the institutional build-up of the EU institutional presence in health law and policy, many sources of the EU historical legislative archives have been used. In this respect the book is essentially multidisciplinary. The use of a qualitative research method together with a rights-based analysis follows from its generally shared underlying assumptions, namely that law is not separate, but forms part of a social

[59] G. Davies (2006) supra note 55 (subsidiarity as a tool for EU integration is a matter of assessing the effectiveness of law in view of a particular (legislative) objective, rather than balancing values).

[60] L. London, 'What is a Human Rights-Based Approach to Health and Does it Matter?' (2008) *Health and Human Rights* (10)1, at p. 68. Also see V. Kosta, *Fundamental Rights in Internal Market Legislation*, PhD Thesis on file at the EUI, Florence 2013 at p.237. F. Scharpf 'Perpetual momentum: directed and unconstrained?' (2012)*Journal of European Public Policy* 19 127-139; E. Muir (2014) supra note 15.

[61] R. Cryer *et al Research Methodologees in EU and International Law* (Hart Publishing, Oxford: 2011) at p. 45

[62] G. Walt *Health Policy, an Introduction to Process and Power* 5th ed (Zed Books, London: 2001); also see S.L. Greer *The Politics of European Union Health Policies* (Open University Press, Maidenhead/Philadelphia: 2009).

infrastructure and plays a role in the construction of the social world. Fundamental rights as expressions of shared values are an example of law as an expression with meaning beyond the narrower legal context. Legal methodology in this critical sense can be compared to social constructivism, as a particular school in the social sciences, with respect to its ontological approach: the law as a social construction is essentially value laden.[63] In this regard, the choice to employ a qualitative research method for obtaining the insights of experts fits with the underlying assumptions of the current legal research. These include the proposition that it is only possible to tell a convincing version of facts that correspond with a shared experience, such as the shared conviction that fundamental rights matter to us all.[64]

These underlying assumptions have certain consequences for the research design and the structure of the book. It is assumed that, to describe the growing power of the EU in health law and policy, reconstruction or interpretation needs to take place, much like the existence and 'finding' of law is a matter of legal interpretation.[65] However, a possible shared interpretation of social facts such as the role of law and policy in a particular field can make for a more or less convincing interpretation of this social construction.[66] In this sense a purely doctrinal legal approach – where only formal sources of law and their legal interpretation form the research material – would not take into consideration the contexts that shape the legal arrangements in European Union health policy, or conversely the way that legal norms shape the social context in which this policy plays out. In sum, in this book, a broad conceptualisation of EU power in the field of human health is developed, and coupled with a right-based framework for analysis for two case studies, one on *public health* and the other on *health care,* that go beyond strictly legal norms.

[63] D. della Porta and M. Keating 'How many approaches in the social sciences? An epistomological introduction' in D. della Porta and M. Keating (eds) *Approaches and Methodologies in Social Sciences, A Pluralist Perspective* (Cambridge University Press, Cambridge: 2008).

[64] Generally in quantitative research, realism is possible the assumption is that we can know the world as such and that objective fact-finding as to our social existence is possible; see L. Snape and L. Spencer 'The Foundations of Qualitative Research' in J. Ritchie and J. Lewis (eds) *Qualitative Research Practice* (Sage Publications, London: 2003).

[65] A quantitative research design however is characterised by the use of variables, the proposition of neutrality towards the objective reality, deductive reasoning, testing hypotheses, probabilities and prediction. As to methodology, in quantitative research one might use experiments, closed interviews, questionnaires and experiments

[66] See D. Snape and L. Spencer 'The Foundations of Qualitative Research' in J. Ritchie and J. Lewis (eds) *Qualitative Research Practice* (Sage Publications, London: 2003) at p. 15.

4.1 Legal framework for analysis: fundamental rights beyond justiciability

In Chapter 2, a normative legal framework is outlined that is used for analysing the legitimacy of the involvement of the EU in human health. This framework is comprehensive in that it allows for an analysis of the promotion and protection of fundamental rights through EU health policy, but also extends to the implications of fundamental rights as an expression of shared values. In the current literature, the importance of the creation of a rights-based framework for addressing the legitimacy of the EU's involvement in health has been addressed and important contributions have been made in this respect.[67]

The framework of analysis developed in this book creates a broad scope that goes beyond fundamental rights that are justiciable in a 'formal' sense.[68] On the one hand fundamental rights function as a benchmark in the analysis of the legitimacy of EU power in the field of health as a way of defining the rights of individuals and populations and the respective obligations at EU and Member State level. On the other hand, fundamental rights function to express shared European values in relation to health policy, to aid the analysis of the exercise of EU power in the field of health that may not create legal obligations; where fundamental rights may not necessarily be justiciable.

The subsequent chapters 3 and 4 address the growth of EU power in the field of health. Chapter 3 looks at EU health law and policy substantively and Chapter 4 addresses the institutional expansion. Both chapters aim to, in the end, conceptualize EU health law and policy by use of legal and historical materials and through analysing and comparing a number of explanatory theories.

4.2 Case studies: Public health and health care

In chapters 5 and 6 two broad case studies are conducted: one in the field of EU public health and the other in the field of health care. The cases are chosen to explore the fundamental rights implications of the growing power of the EU in health policy to do justice to the complexity of the 'real world' of European health policy.[69] The selected cases primarily illustrate the

[67] T.K. Hervey ''We don't see a connection: the "right to health" in the EU Charter and European Social Charter' in G. de Burca and B. de Witte (eds) *Social Rights in Europe* (Oxford University Press, Oxford: 2005); Hervey (2003) supra note 16; Hervey and McHale (2004) supra note 6; McHale (2012) supra note 14. Also see V. Kosta, supra note 60 who concludes that a rights-based approach for certain legislation would in practice not have made a big difference in its outcome.
[68] The particular scope of the framework of for analysis in terms of fundamental rights as will be developed in this research will be addressed in detail in Chapter 3.
[69] R.K. Yin *Case Study Research: Design and Methods* (Sage Publications, Thousand Oaks: 2003).

various ways EU health policy expands and examine the relationship between EU health policy and fundamental rights. The use of case studies also gives the book a narrower focus in two functional areas of EU health policy and how these interlink with formal legislative procedures and legal rules.

Generally a case study is an appropriate tool for narrowing an otherwise broad scope for a research: A case study is a more 'intensive study of a single unit wherever the aim is to shed light on a question pertaining to a broader class of units'.[70] Accordingly, a case study is especially apt for exploring and describing a relatively newly defined policy area with some depth without attempting to be exhaustive,[71] particularly as it allows for the exploration of a 'unit' using a variety of data sources.[72] This means that beyond the narrower focus, case studies allow for the study of European health policy in an interdisciplinary manner without the assumption that there would be an exhaustive analysis of all EU health policy. In other words, in outlining two specific cases within the functional policy fields, the way European health policy is expanding both legally and empirically and what its impact is on fundamental rights can be explored in more detail.

A primary starting point for the book is a perspective from health 'policy-making' rather than 'law-making' in a stricter sense through the formal legislative process. In the background, the reason for this perspective is the puzzle that more is going on with respect to EU health policy than can be explained by the legislative competence in Article 168 TFEU. Therefore generally the selected cases in chapter 5 and 6 study examples or illustrations of the different ways EU power for human health expands and the roles of institutional actors therein. More specifically, the first (procedural) criterion for selection of the case studies is the ability to illustrate different aspects of the (legal) practice of EU of health policy making. These different aspects include institutional actors involved in health policy making at the European level, the legislative or policy-making processes involved and the (legal) nature of the policy that is created. This criterion is important as fundamental rights function partly to legitimately limit public powers. In this regard the illustration with cases based on this criterion helps

[70] J. Gerring 'What is a Case Study and What is it Good for?' (2004) *American Political Science Review* 98 (2) 341-354 at p. 344.
[71] J. Gerring *Case Study Research, Principles and Practices* (Cambridge University Press, Cambridge: 2007) at p. 39; Yin (2003) supra note 69 at p. 13.
[72] Ibid.

provide an understanding of the breadth of institutional involvement of the EU, where a rights-based analysis can provide insight into the legitimacy of EU health policy.

A second (substantive) criterion for the selection of the case studies is that the case illustrates an important aspect of health policy substantively with respect to its possible impact on fundamental rights. This second criterion is important, as the cases in this regard illustrate the other function of fundamental rights as input into legitimate objectives of the European political system. The rights-based analysis in this regard illustrates where rights and values are impacted as a result of EU health policy both on EU or Member State level.

4.2.1 Public health: communicable disease outbreak

The case study in Chapter 5 on EU public health policy and law looks at the event of the outbreak of a communicable disease and the response to this outbreak at the European level. Specifically, the case focuses on the countermeasures taken to curb the spread of swine flu (influenza A H1N1) over the course of 2009-2010. Communicable disease control is a classic and central aspect of public health policy generally.[73] At EU level, a variety of policy instruments come into play in a response to a public health emergency, particularly when responding to a communicable disease. In primary Union law, Article 168(1) TFEU establishes that the EU has a role to play in a public health response:

> Union action […] shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

This is translated in secondary Union law, and also involves the European Centre for Disease Control (ECDC). However, response to a disease outbreak at EU level also engages the European Medicines Agency (EMA) and particular provisions in the central regulation of medicines. At the same time, Member States tend to coordinate informally as well as in crisis meetings in the Council and under Commission auspices. Hence, the case study illustrates that a response to a public health emergency may create a basis for expanding EU health policy legally, through interlinking policy practices with law.

[73] S. Greer and P. Kurzer (eds) *European Union Public Health Policy, Regional and global trents* (Routledge, New York: 2013); also see G. Rosen *A History of Public Health* (John Hopkins University Press, Baltimore: 1958).

As to the second (substantive) criterion, the swine flu case shows the potential fundamental rights implications in both in terms of the right to health and individual rights. In a public health emergency, public authorities generally have an obligation to 'do something' and safeguard the population. The provision in Article 168 TFEU cited above is an example of this. In general terms communicable disease control has the potential to touch on the right to health broadly, and the response to a public health emergency can touch on the right to access health care more specifically. An example where the right to access health care is implicated is when public authorities decide on what groups of the population are able to obtain access to particular life-saving medicines or treatment in case of a pandemic. Furthermore, in order to protect the population, countermeasures can impact individual rights, such as the mandatory vaccinations or quarantines. Accordingly, the case of the swine flu outbreak illustrates the implications of EU health policy through a rights-based analysis of a response to a public health emergency.

4.2.2 Health care: access to medical care

The second case in chapter 6 illustrates legally how the course of a formal legislative process may provide breeding ground for further policy-making and – eventually – law. In the field of EU health a prime example in this regard is the adoption of the Patients Rights Directive,[74] which presents the controversial case of creating access to health care at EU level. The creation of access to health care affects the delivery of care and the ability of a political system to make health care available to the population at large as a welfare entitlement, which is a highly charged political issue.[75] Health care policy at Member State level involves the creation of access to doctors, hospitals and other health care services. The organisation and management of social insurance and cost-containment strategies is what national health care systems are all about.

In particular, chapter 7 focuses on the processes and dynamics surrounding the adoption of the Patients Rights' Directive, on the involvement of different EU institutional actors and on the policy mechanisms that were used. Therefore with regard to the first (procedural) criterion for case selection, the case study of the EU's involvement in cross-border health care may illustrate how in the context of a formal legislative process a policy discourse develops. The

[74] Commission Proposal for a Directive of the European Parliament and of the Council on the Application of Patients' Rights in Cross-Border Healthcare (COM(2008)414 final).

[75] A. de Swaan *In Care of the State: Health Care, Education and Welfare in Europe and the USA in the Modern Era* (Oxford University Press, New York: 1988).

chapter shows not just the legal aspects of access to health care cross-border as such, but also hones in on the institutional processes around the creation of access to health care at the European level. The adoption of the cross-border health care directive includes a number of different Directorates General of the Commission, different (in)formal coordination groups of Member States under Commission auspices, and institutional actors within the Council.

In terms of the second (substantive) criterion, the cross-border health case shows generally that the legal possibilities of accessing and obtaining reimbursement for medical care can impact the right to access health care. However, in terms of quality and safety of medical care, the right to health could also be impacted by the adoption of a Cross-Border Healthcare Directive. Moreover, with respect to individual rights informed consent, human dignity, the right to life and the right to privacy are of potential relevance in the context of the delivery of medical care.

4.3 Data sources: beyond law

The data sources in this book are standard to legal research.[76] They include legislative instruments, both primary and secondary EU legislation, as well as non-legislative Union acts and case law of the CJEU and the ECtHR, policy documents of international organisations such as the WHO if relevant. In order to give as in-depth an account as possible, other sources are policy studies of the EU agencies and other (national) actors, EU statistical information, Commission Communications and Council deliberations, inasmuch as these are publicly accessible.

Additionally, data is included from expert interviews as part of a qualitative social research method in the case studies. Expert interviews provide a deeper insight into the context and processes that shape EU health policy.[77] The expert interviews aim to reconstruct specific specialised knowledge about a particular aspect of EU health policy. For the case studies the selected experts have the ability to contribute the kind of exclusive knowledge of EU health policy-making that is largely geared towards problem solution and its causes.[78] Hence, the

[76] M. McConville and W.H. Chui (eds) *Research Methods for Law* (Edinburgh University Press, Edinburgh: 2007); and see Cryer *et al* (2011) supra note 61.
[77] The expert interview is a particular interview that has its own methodological purpose. Interviews with experts are geared for qualitative research in that it is their purpose to reconstruct particular 'knowledge stocks.' See B. Littig. 'Interviewing elites – interviewing experts: Is there a difference? Methodological considerations' in A. Bogner, B. Littig and W. Menz (eds) *Expert Interviews* (Palgrave/MacMillan, London: 2009).
[78] Ibid.

selected respondents have specialised knowledge on a particular subject, which helps to understand the real world of health policymaking with respect to one of the case studies, but also because of their position in a particular institution or actor, so as to provide a broad representation of respondents across EU institutional actors. Therefore the book included the data of a number of experts in the Commission, the Council, Parliament and the EU agencies. Preferably, the experts were true EU 'health specialists' able to talk on all of the case studies.[79]

5. Balancing subsidiarity and fundamental rights

The concluding Chapter 7 brings together the different chapters as it analyses the expansion of EU power in the field of human health - both the case of health care and in public health - in terms of fundamental rights. Particularly it concludes that the EU is de-facto balancing fundamental rights and values relating to health, *implicitly* taking on obligations for safeguarding fundamental rights in the field of health and affecting individuals' rights sometimes without an *explicit* legal competence to do so. This brings to light instances where EU health policy has implications for fundamental rights without the possibility to challenge the exercise of power of the EU in human health.

The chapter also focuses our attention on the role of the EU principle of subsidiarity in dividing the tasks and functional powers of the EU Member States versus the EU. The legal function of principle of subsidiarity in the Treaty stands in contrast with the expansion of de facto EU power in the field of human health, and the impact this has for health related fundamental rights and values. This begs the question if subsidiarity is still the most relevant legal principle for the division of powers and tasks between the Member States, particularly when EU policy and law involves a politically sensitive area such as health care and public health. This question draws out the parameter for continuing the debate on the role of the European Union in promoting its own values and the well-being of its peoples,[80] in light of its ever-growing role for human health issues.

[79] See further notes on the interview protocol in the bibliography section under sources.
[80] Article 2 TEU.