Part I
Introduction

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Introduction

In December 2013, the *tribunal correctionnel* in Marseille delivered its verdict in a fraud case affecting an estimated 300,000 women across the globe, around 5 per cent of whom are breast cancer patients, and many of whom suffer mental ill health. The case concerns Jean-Claude Mas, whose business, Poly Implant Prothèse, manufactured breast implants sold either directly or re-branded by intermediaries such as Dutch Rofil Medical to clinics in some sixty-five countries. The *tribunal* found that Mas fraudulently substituted industrial grade silicone for medical silicone in the implants.[1] The production process (although not the industrial grade silicone) for the implants had been approved by a private German certification body, TÜV-Rheinland. The products duly carried a CE marking, to warranty their safety for the European market.

After the matter came to light, the Czech, French, German and Swedish pharmaceuticals and medical devices regulatory authorities advised precautionary removal of the implants. In England, NHS Medical Director Sir Bruce Keogh's 2012 report concluded that there was no need for such removal if the implants had not ruptured, although where a doctor certifies 'medical need' the NHS will pay for removal. The high media profile of the case, and the availability of social media, have given an outlet to women affected by Poly Implant Prothèse to describe their suffering and their sense of injustice, including at the failings of the law. Dominque Terrier[2] speaks for many:

> The pain we went through was psychological and physical . . . we were mutilated, re-operated on. It's not easy to survive that after cancer.

With its very human, but also legal and European, dimensions, the Poly Implant Prothèse story illustrates many of the questions that piqued our curiosity and which we explore in this book. Does European Union law on health products (like the implants in the Poly Implant Prothèse case) treat those products as essentially the same as any consumer product available in the European market?

[1] Mas was fined €75 000 and sentenced to 4 years in prison. His appeal is pending. The German certification body was ordered to pay compensation to victims by the civil *tribunal de commerce* on 14 November 2013. It has also appealed.

[2] Speaking to public TV channel *France 3*, reported in A Chrisafis, 'PIP breast implant bosses' trial for aggravated fraud begins in France', *The Guardian*, 16 April 2013.

Is the same true of European Union law on health services? To the extent that it is, what does that mean for how patients are conceptualized by European Union health law? Are patients essentially consumers, subject to rules such as *caveat emptor*, even if they are protected by law from at least some products and services that would harm their health? If that is so, which products or services does European Union health law decide are harmful to health, and through what processes are those decisions made? What about treatments that are ethically controversial, such as beginning or end-of-life health care? What are the implications for health care professionals? What happens to notions of a professional ethic of care, or provision of public service, if European Union health law understands the relationships between doctors and their patients through the lens of **consumerism**?

The women affected by Poly Implant Prothèse spoke of infringements of their dignity and bodily integrity, which have been associated with the human right to privacy. More generally, both nationally and internationally, health rights are often thought of as human rights. Is this the case in European Union health law? What about the **rights** of patients? Are patients' rights seen as *human* rights in European Union health law, or are they more like *consumer* rights? Which, if any, of such health rights are recognized and upheld by European Union health law? If European Union health law involves consumerization of health care, what does that mean for patient autonomy and patient choice, which are both related to human rights? What are the implications of the 'right to health care' in the EU's own Charter of Fundamental Rights, for substantive European Union health law? Is its significance more symbolic than practical? How does European Union health law deal with conflicting rights in health contexts? Might European Union health law strengthen, or weaken, claims to health care resources as claims of right? What might this mean for health care systems?

We tend to think of European Union law as reducing differences between national legal systems. Yet the health authorities in different countries came to very different conclusions about the Poly Implant Prothèse case. Under European Union health law, how much control do national authorities have over determining questions of quality, safety and efficacy of health care products, services and procedures? What is the extent of national autonomy: if the Swedes decide that alcohol is so harmful to health that it should only be sold through one state-controlled monopoly provider, or the Scots decide to change alcohol pricing rules, or the Greeks decide that infant formula milk should only be sold through pharmacies, is that allowed? Can such national decisions, made with a view to promoting good health of the population, be challenged if they disrupt patterns of trade in products or services across European Union borders? If the European Union is supposed to secure safe medical devices, why did Poly Implant Prothèse patients in different European Union Member States have such different experiences? Why doesn't European Union health law offer equivalent protection to all patients? If patients in different countries end

up with very different entitlements to treatment, what are the implications of European Union health law for equality of access to medical care?

National arrangements for health care provision in EU Member States allow monopoly, or near monopoly, providers of health care services. What if those providers abuse that position? Does European Union health law scrutinize such behaviour, or the concentration of market power through mergers of health care providers? If so, does this mean that European Union health law is moving health care systems towards market-based models of regulation? To the extent that it does, what are the implications for the organization and underlying ethos of national health systems? Or does European Union health law recognize health care as a 'special case', a type of service that is not subject to the ordinary rules that apply to anti-competitive behaviour of companies?

To the extent that European Union health law involves more patient choice, how does that increased choice affect the delivery of health care through health care systems that are predominantly funded either by taxation or through social insurance, rather than through private mechanisms? The fundamental basis of health care in European contexts is solidarity. Does European Union health law challenge, disrupt, or even destroy, those fundamentals? How does European Union health law balance **equality** and **solidarity** with fair and effective **competition**?

The Poly Implant Prothèse story suggests a very light touch approach to regulation of risk in health contexts – the medical device involved was allowed onto the European market following essentially the same marketing authorization procedure that applies to, say, toys. To what extent is that true of European Union law on other health products or services involving assessment of **risk**? What does European Union health law require in terms of pre- and post-market controls of health care products such as pharmaceuticals, bio- or nano-technology products, and medical devices? What does European Union health law require of other products that are or may be harmful to health, such as tobacco, food, alcohol? Where European Union law must balance risks to patients with freedom to run a business, how is such law made? Given that health industries make a major contribution to the European economy, what are the implications for the European economy, which so desperately needs to grow to escape from recession?

Poly Implant Prothèse operated in a global market for health products. In that case, the European Union legal standards were insufficiently stringent to prevent harm to thousands of women. What should we make of the oft-repeated claim that the European Union is *too strict* in its regulatory approach to risk, is significantly more risk-averse than, say, the USA? Are firms operating in the EU therefore saddled with competitive disadvantage when seeking to compete globally? Does this hamper innovation in European health industries? What does this mean for economic growth? What does it mean for patients who are waiting for a treatment for their currently incurable conditions? What does it mean for patients across the world, who are dying because the health industry

invests in novel products for the rich global North, not in products that are needed by patients in the poor global South? What, if anything, does EU law do to make health products affordable to the poorest in the world? To what extent does European Union health law affect such questions of global health ethics?

And, of course, it isn't only health products that move across borders globally. What, if anything, are the implications of European Union health law for global 'medical tourism'? And what about global movement of public health threats, both from products that have important health implications (food, alcohol, tobacco) and from communicable diseases? How does European Union health law interact with global health law?

These questions illustrate our research agenda. One colleague, to whom we presented our work before publication, suggested that an introduction with over forty questions might be somewhat overwhelming for our readers, and wondered whether we were really going to answer all the questions we ask here. For those who would like a brief answer to each question, we have provided that summary, with references to the relevant chapters, in an Appendix. The detailed legal analysis supporting those brief answers is found in the body of the book.

Our inquiry into European Union health law is organized thematically. The questions arising from the Poly Implant Prothèse story can be arranged into four key themes: consumerism; protection of (human) rights; interactions between equality, solidarity and competition; and risk regulation. Our premise, which we support through the substantive chapters in Parts II, III and IV of the book, is that these are the themes of European Union health law. Our research agenda is to illuminate the significance of each theme, and its implications, for European Union health law.

We organize our analysis of those themes as follows. In Parts II and III of the book, we focus on the EU's *internal* health law, that is, how EU health law applies within the European Union and its Member States. In Part IV, our focus is on EU *external* health law, that is, how EU health law applies outside of the EU, in relations between the EU and states which are not EU members, and other international organizations. As far as we are aware, coverage of both internal and external EU health law in a single analytical framework is unique in the literature to date.

In our approach to the themes, we distinguish between two broad perspectives: an *individual perspective* and a *systemic or collective perspective*. The themes of consumerism and rights apply predominantly to ways that *individuals* experience EU health law. Part II of the book therefore places the individual patient and health care professional in the centre of its analytical perspective. The themes of solidarity, equality, competition and risk engage predominantly with the *systemic* effects of EU health law, and on *collective* experience. Therefore, the analysis in Part III of the book is based upon a collective or systemic analytical perspective. Likewise, the discussion of the EU's *external* health law, in Part IV of the book, considers each perspective in turn.

Of course, there are limitations to this broad division of focus, perspectives and themes. The EU's internal health law can have important implications for its external health law, and vice versa. An example is the ways in which EU health law embodies and reinterprets the Council of Europe's law on human tissue or organs. Associating each theme with one of two perspectives may obfuscate aspects of that theme which are associated with the other perspective. For instance, equality, which we consider mainly within the collective perspective, can be individual focused, such as in the context of non-discrimination litigation. And of course the four themes are far from distinct; they overlap and cut across one another. For instance, a consumer also enjoys (human) rights, and must be protected from unacceptable risk of harm. By being attentive to the potential drawbacks of our thematic approach, we are able at least in part to mitigate them. Particularly in the Conclusions, but also in the substantive chapters of the book, part of our contribution is to draw out exceptions and overlaps between our focuses, perspectives and themes.

The research agenda we set for ourselves essentially requires us to use the methods of standard legal scholarship, to understand the meanings of legal texts and the modes of legal reasoning and conceptualizations that underpin them. We are interested in how EU health law has shaped or may shape the behaviour of relevant actors, such as patients, national governments, health care professionals, the pharmaceutical or medical devices industry, health researchers, those bodies which finance or otherwise regulate the provision of health care, or protection of human health, and so on. But in seeking to draw out the significance of EU health law, and to understand its themes and their implications, we also need to draw on at least some literature in cognate fields, such as health policy and EU studies. In terms of the way in which we understand the EU and its legal system (our 'methodology'[3]), without going into too much detail here,[4] we see the EU as a constitutionalized, pluralist legal order, within which EU, international and national legal rules, as well as processes of regulation or governance that are formally non-binding, but nonetheless have normative effects, interact with one another. Thus, our methodological approach means that we have included within the scope of our analysis some of the more important sources of soft law, and governance processes, which apply to the substantive topics under discussion. Nevertheless, this book is essentially a piece of *legal* scholarship. Our central focus is on the EU's *law*, in the sense of its formally binding legal rules, as found in its foundational Treaties (the Treaty on European Union and Treaty on the Functioning of the European Union), the legislation adopted by its institutions (the European Commission, Council and European Parliament) and the jurisprudence of its court (the Court of Justice of the

[3] On the distinction between 'method' and 'methodology' in (EU) legal research, see Cryer et al., *Research Methodologies in EU and International Law* (Hart 2011).

[4] There is a vast literature on the EU's legal order, and on the interfaces between law, regulation, governance and policy in EU contexts.

European Union (CJEU)). We recognize that legal rules emanating from national, EU or international institutions are not in hierarchical relationships within one another. However, we do concentrate on the ways in which EU legal rules, which bind the governments of Member States and are applicable to individuals within and beyond the EU, change or may change situations or relationships. This focus might be read as implying a hierarchy, but is unavoidable as our central concern in this book is EU law.

In this book, we do not try to defend the concept of 'EU health law'. We recognize that the book begins from an implicit position that 'EU health law' exists as an entity with respect to which one can discern themes, and that not everyone will agree with this assertion.[5] Neither do we try to determine whether there should be 'EU health law', or whether the EU should be involved in health law: our approach implies that, even if we could demonstrate definitively, from some kind of standpoint of external critique, that it should not be, it is too late for that kind of observation to make much difference to law or policy. Moreover, we are not offering an evaluative assessment of EU health law – for instance, determining whether it is an 'achievement, failure or missed opportunity', or what the 'added value' of EU law is to health policy. Others have already offered such evaluations.[6]

In approaching EU health law through four themes and two broad perspectives, we are contributing a new analytical framework to the existing literature in the field. The four themes enable us to draw together disparate areas of EU health law and to understand them as a meaningful whole. They liberate us from the cognitive constraints of the existing organizing structures deployed to set out and interpret health law and EU law. This book is organized neither along the lines of a book on health law nor along the lines of a book on EU law. Adopting a new organizing structure, or taxonomy, is a crucial move in developing a new field of study: EU health law. It has the added benefit of allowing us to consider each particular substantive topic in a holistic or relatively holistic way.

Organizing the themes into two broad perspectives (individual and collective) sharpens our analysis, by assisting us to draw out the implications and potential implications of each theme with more precision than we would otherwise be able to achieve. Focusing on the internal separately from the external provides added clarity. Furthermore, we are able to rely on our organization of the material to draw out tensions and contradictions in EU health law. These are

[5] This position is a departure from Hervey and McHale, *Health Law and the European Union* (CUP 2004), see p 4. We will develop the analysis supporting the assertion that 'EU health law' is a meaningful analytical category in a companion piece, probably a journal article.

[6] See, for instance, Rosenkötter, Clemens, Sørensen, 'Twentieth anniversary of the European Union health mandate: taking stock of perceived achievements, failures and missed opportunities: a qualitative study' (2013) 13 *BMC Public Health* 1074; Clemens, Michelsen and Brand, 'Supporting health systems in Europe: added value of EU actions' (2013) 9(1) *Health Economics Policy and Law* 49.

illuminated in several ways: by comparing and contrasting how the themes play out in the EU's internal health law and its external health law; by contrasting the different perspectives across the themes; and by considering the individual and the collective perspective within each theme.

Using our analytical framework, we are able to reinterpret the academic and policy-focused literature on a range of topics, which share a concern with how EU law affects, or has the potential to affect, human health. Essentially, and to oversimplify our overall findings, each theme is associated with one or more claims in the existing literature about its significance and implications for health. Some of these claims are stated or implied by the questions that we outlined above. For instance, it is claimed that EU law undermines national health systems based on solidarity, that EU law pushes competitive market models into health, that EU law supports the choices of (wealthy and relatively healthy) patients, that EU law stifles health innovations, that EU law makes it difficult for national authorities to protect the health of their populations, and so on. Our overall findings are that, while the strong version of each claim is not borne out, once we immerse ourselves in the details of law in its policy contexts, a weaker version may well be defensible.

But we are getting ahead of ourselves. Before we explore the first of our themes, the following two chapters provide an explanation of the scope of the enquiry. To that end, we consider first how we are defining 'health law' (chapter 2), and, second, how we are defining 'European Union health law' (chapter 3).

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What is health law?

Introduction

The development of health law as a discipline has been gradual and incremental. One of the complexities in ascertaining the nature and scope of health law is that, across the EU as a whole, health law is at different stages of development. As we shall see, the origins of health law stretch back for many centuries, but its evolution has been more rapid and concentrated over the last half-century. Secondly, even the words that describe the discipline are not consistently utilized across or within EU Member States, or indeed in the rest of the world. In some jurisdictions, the term used is 'medical law', whereas elsewhere it is 'health care law' or simply 'health law.' Understanding the evolutionary development of the discipline is critical to effective engagement with the discipline. Derek Morgan writing in 2001 suggested that

> Medical law is indeed not *just* a subject; it is also a responsibility. Whether medical law is a legal category in itself is beside the point. The framing of responses properly lying within medical law is part of an intellectual responsibility that lies at the heart of the academic obligation which, as John Fleming has otherwise observed, is to be 'sensitive to movement and direction . . . [being] concerned with whence, whither and most important, with why'.[1]

The fact that not many textbook writers, or indeed many academic commentators, across the EU have engaged explicitly with such development is a source of regret. It is also, more importantly, problematic for others attempting to understand the nature and scope of the discipline. Hence we begin our book by briefly examining what is understood by 'health'. In the second section of the chapter, we consider the disciplinary derivations of health law, and its legal evolution. This leads directly to a third section, in which we analyse the extent to which the evolution of health law is integrally connected to the development of biomedical ethics. There, we explore the relationship between biomedical ethics and professional ethics and the impact of both discourses upon health law itself. We conclude the chapter with a discussion of what we mean by 'health law' in the context of our research agenda in this monograph.

[1] Morgan, *Issues in Medical Law and Ethics* (Cavendish 2001) 3