

of fully assessing public safety risk in advance of use. Indeed, such assessment can only be undertaken dynamically, by evaluating the risk (and benefit) of the 'thing in use' as the creation of ongoing "interactions between hazards, people with all their behaviours and the ever-changing environment"<sup>6</sup>.

The book gives clear insight into the latent processes of decision making and the assumptions and philosophies that lie un-explored beneath the surface of contemporary ways of thinking and talking about risk and safety. The authors call for greater attention to narrative-based assessment of risk, and a move away from abstract schematic checklists and matrices. They consider (and draw upon recent developments in the psychology of decision making to support their argument) that safety can only be evaluated as part of sense-making of the entirety of a proposal or project. Safety and risk must be blended into the story – there must be clear policy goals against which to evaluate the safety risks and other (perhaps even more significant) benefits that accepting those risks will accrue. Here the authors invoke Margolis' conceptualisation of the 'fungibility' of risks<sup>7</sup> – that the public and managers of public safety must live and breathe the evaluation of trade-offs that the quest for ever greater levels of safety may entail.

The current UK coalition Government (like the socialist Labour Government that preceded it) sees a move away from 'excessive' safety regulation as a necessary step in formation of a risk-embracing and entrepreneurial national mind-set<sup>8</sup>. Time will tell whether the 'Health & Safety Culture' which the authors oppose, can be countered through deregulation and reform of regulatory guidance. As the authors acknowledge, the use and management of public spaces, and the tacit knowledge informing those practices is both complex and dynamic<sup>9</sup>.

6 Ball & Ball-King at p. 116.

7 Howard Margolis, *Dealing with risk – Why the public and the experts disagree on environmental issues*, (London: University of Chicago Press, 1996), at pp. 76–77.

8 For recent policy reviews in the U.K. echoing the authors' point of view see: Lord Young, *Common Sense Common Safety*, (London: Cabinet Office, 2010), Ragnar Löftstedt, *Reclaiming health and safety for all: An independent review of health and safety legislation Cm 8219*, (London: HM Government, 2011) and Department for Work & Pensions, *The Government response to the Löftstedt Report*, (London: DWP, 2011).

9 See Luke Bennett "A pub, a field and some signs – a case study in the pragmatics of proprietorship and legal cognition", paper presented to the Royal Institution of Chartered Surveyors' COBRA 2011 conference, Manchester, UK in September 2011, available on the Internet at <<http://shura.shu.ac.uk/3754>> (last accessed 28 January 2012).

*Medical Devices: European Union Policymaking and the Implementation of Health and Patient Safety in France*

by Christa Altenstetter

Piscataway, NJ: Transaction Publishers, 2007, 302 pp., \$ 49.95, Hardcover

*Nupur Chowdhury\**

This book is a welcome addition to the political science literature on medical product policymaking. Most researchers see medical devices as a poorer and perhaps less glamourized neighbour of the pharmaceutical regulation. Of course, pharmaceutical regulation has been besieged with academic debates on public health concerns and access. Similar lines of arguments also persist in the medical devices, but one aspect remains unique, that of the design of the regulatory regime itself – which is a *sui generis* to Europe (and therefore a truly European experiment) characterised by public roles played by private actors within a distinctly federal structure (allows for a well formulated role of member states). Therein lies the reason why the book brings in a distinct and largely missing voice in the academic literature on medical products. The book primarily looks at the evolving institutional scene of French medical device regulation and links this up with the regulatory developments in Europe. The choice of frame here is very important. Professor Altenstetter chooses to focus on France. The adoption of a state lens allows her to focus on regulatory cultures, major national events and domestic institutional dynamics in the ways in which they converge or diverge at certain points in history to influence the European policymaking. The other part is to see how European policy decisions are in a certain way indigenised (for lack of a better word) when implemented in member states. One does always suspect that this would happen, but this book provides a rich and detailed analysis in terms of motivations of individual actors and brilliantly displays the complexity of both arriving at and then implementing those policy outcomes. Further, its choice of adopting a national lens, allows it to provide an overview of developments in all the device sectors (general medical devices, in vitro diagnostics and also active implantable devices), and also focus

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attention on one of the principal actors (the others being UK and Germany) in negotiating a European regulatory regime.

The book includes thirteen chapters. The first three chapters provides a detailed background of the industry profile of medical devices in Europe, in terms of the players, products and geographical distribution of products across the three main markets – Germany, U.K. and France. The European policy context is also delved into this section. The focus of these sections is three fold. First, it discusses the unique characteristics of medical devices as an industry and discusses the European policy imperatives that have influenced its unique regulatory architecture. Second, connection is made between the industrial developments and the realignment of state-business relationships within the French government. Third, the HIV-contaminated blood scandal is discussed as a policy spur that had a long lasting impact on French attitudes, negotiating positions and ultimately influences on European policy. Chapters 4 to 6 primarily discuss the impact of the health crisis in France. The focus is on understanding the concept of *securité sanitaire* that forms the bedrock of the French health policy and how has it evolved eventually clashing with the European regulatory philosophy of the single market that was driving the medical device regulations. Other resulting influences of the health crisis – referred to as “judicialization” – simply put the culture of litigation has been growing in France and this also may have an impact on health policymaking in terms of taking a more risk-averse stance. Chapter 8 discusses the European negotiations on the IVDD and the successful push by the French delegation to include vigilance as a mandatory requirement for all medical devices. However by no means, this was a pan French policy position – it was a result of a hard fought battle, won by the ministry of health on one side and the ministries of finance and industry on the other. Thus reflecting the inter agency conflicts and the public pressure that propelled the former to win a rare victory.

The subsequent chapters (chapters 9 and 10) focuses attention on the setting up and operations of the French health agency AFSSAPS that has policing powers over all healthcare and medical products. Chapter 11 and 12 explores the local dimension of the implementation of vigilance systems by a number of administrative and professional stakeholders.

It highlights the intricate (and sometimes disconnected) network of doctors, hospital administrators, clinicians, local vigilance officials that have to operationalize rules that they inherit via a command and control structure of the Paris bureaucracy. Despite the challenges, the last chapter in fact manages to pull together several strands of arguments discussed in the earlier chapters. It highlights the impacts of modernization and institutional engineering that have characterised the public administration reforms agenda in the nineties in France. More importantly, the book argues that despite positively steering European policy towards higher standards of patient safety, nationally, France lacks the implementation capacity to effectively see through the same reforms that it has been advocating at the European level.

The author adopts an effective tool to discuss the overall picture in France, by discussing them in the context of eight public health principles drawn up by the WHO (World Health Organization). Another important aspect discussed briefly but illuminatingly in the book is the rapid global harmonization of regulatory practices through the GHTF (Global Harmonization Task Force).

The book is a result of painstaking research and is based on more than eighty expert interviews of the principal actors which the author held in the late nineties and early 2000. This book is rich in detail and allows the reader to get an in-depth look into the modern history and development of the regulatory apparatus and the actors that are involved in medical devices in France. Medical devices regulation is a largely understudied but an exciting area, and this book provides an absorbing account of the national dynamics and its impact on European regulation. The book also provides a rich material for future research on the national imperatives for global harmonization, impact and influence of a range of local actors on regulatory implementation, the influence of disciplinary backgrounds in interpreting and implementing regulatory rules, etc. The only quibble, which I had with the book, was in terms of organization. Chapters should have been grouped together under sub-headings. The book would have benefitted immensely from a clearer differentiation of either thematic areas or geographical coverage – in terms of national and European dynamics. Nevertheless, this book would appeal to both generalists and specialists alike from political science, law and regulatory studies and sociology.