

a number of historians have examined the development of oral contraceptives, especially in the United States. But what Marks does in this important book is to place the scientific development of the pill, together with its economic and regulatory dimensions, in a much-needed international perspective. In clear and convincing fashion, Marks lays out the influence of the European sex hormone industry in the interwar period, analyses the impact of the emigration of refugee scientists to American laboratories, and traces the myriad national contexts in which clinical trials of various oral formulations were conducted. In so doing, she significantly enhances our understanding of the pill's development and diffusion in comparing the British and North American experiences with the contraceptive.

One of the reigning historical interpretations that Marks challenges is the depiction of the women who participated in early trials of oral contraceptives as “unwitting guinea pigs” of male scientists. Marks joins other historians in noting that important research on an oral contraceptive was stimulated and funded by prominent American women, including the philanthropist Kathleen McCormick and the birth control advocate Margaret Sanger. McCormick's extensive funding made possible not only the animal studies to screen drugs for toxicity and efficacy, but also the clinical trials of the new formulations that necessarily involved large numbers of women to test the drug. But where could such women be found, especially for research that violated the societal norms about sexuality? Marks described how researchers recruited nurses to serve as volunteers (a good choice since they were able to follow the detailed instructions required in the early tests). But other women were also pressed into service, including patients suffering from severe mental disorders in a Massachusetts psychiatric hospital. Another major locus of clinical trials on the pill was the American controlled island of Puerto Rico, where large numbers of impoverished women participated in clinical studies. Marks mostly dismisses charges that Puerto Rican women represented a readily accessible pool of available research subjects. She argues that researchers

took considerable trouble to monitor the safety of these women and the wellbeing of the babies that resulted from the failure of the drugs (or from lack of compliance with the regimen). Perhaps because we hear so little from these women subjects or from activists who protested the exploitation of these women, Marks is less than persuasive that certain sociocultural factors, especially racism, did not make these women more attractive research subjects than middle-class white women. Unlike Marks, I don't find the lack of a signed consent form among the most troubling features of these early trials. Although some investigators in this period, including researchers who were infecting children with hepatitis virus, did obtain written permission, this was hardly conventional practice. More troubling was the risk, both short-term and long-term, that women experienced, despite the physicians' care to minimize dangers from the drugs.

Marks's extensive research and numerous interviews with participants in the development of the pill are impressive. She offers a nuanced analysis of the medical controversies that the pill created; her discussion of the relationship between oral contraceptives and cancer is especially useful for the light it sheds on the persistent uncertainties that have shaped medical and popular responses to the risks and benefits of the pill. In the 1960s the oral contraceptive was hailed as a “dream come true,” freeing women from the burdens of unwanted pregnancy. As Marks convincingly shows, freedom is seldom free or without risk.

Susan E Lederer,  
Yale University

Arthur A Daemmrich, *Pharmacopolitics: drug regulation in the United States and Germany*, Chapel Hill and London, University of North Carolina Press, 2004, pp. xiii, 203, £25.50 (hardback 0-8078-2844-0).

During the second half of the twentieth century the pharmaceutical industry made an increasingly significant contribution to the national economies not only of the two countries

figuring in this book, the USA and Germany, but also to those of many others, including Japan, Britain and France as well as to the growth of international trade and business. Over the same period, there was increasing government regulation concerning the safety and efficacy of pharmaceutical products in many countries. However, relatively few detailed explorations of the development of safety regulation have been published, so this comparative study of the development of the regulatory frameworks in the USA and Germany between 1950 and 2000 is very welcome.

The parameters of the study and its main focus—the politics of regulation—are established in the first chapter. Arthur Daemmerich sets out to explore regulation *vis-à-vis* therapeutic cultures, the term he uses to encompass the complexity of the relationships which have developed between those primarily, although in varying degrees, concerned: “the state (including legislatures and regulatory agencies), the pharmaceutical industry, the medical profession, and disease-based organizations” (p. 4). However, as the later chapters and the drug case studies evidence, the existence and role in the process of disease-based organizations is largely confined to the USA and there it is seen most clearly in the case of HIV/AIDS.

The study as a whole makes it clear that differences of history, of political systems, of ways of delivering healthcare and of professional medical approaches have resulted not only in a lack of disease-based organizations in Germany, comparable to those of the USA, but also in the development of the very different regulatory regimes revealed in this book. To summarize the major difference, in the USA regulatory authority rests solely with the state, whereas in Germany it is shared across a network of state, industry and the medical profession.

Case studies on the adoption and use of terramycin, thalidomide and propranolol are used to highlight and explain the development of different systems in the two countries over the period 1950 to 1980. Thalidomide was, of course, the trigger for increasing regulation in the shape of more stringent testing requirements before

new drugs could be launched on the market in the USA and in many European countries. Although the USA escaped the worst effects of thalidomide because the FDA did not license it, the new requirements imposed took a longer time to meet and that impacted significantly on the introduction of propranolol; the discussion of this provides a strong contrast with the use of propranolol in Germany.

By 1980 pre-clinical and clinical trials had become an institutionalized process in drug development, a phenomenon explored at work in the later chapters, which focus on the last two decades of the twentieth century. The cases of the cancer therapy, interleukin-2 and the anti-AIDS drug, indinavir are used to illustrate and explore the nature of post-market drug introduction surveillance as well as the changing nature of the major relationships. In the final chapter the attempts to create an internationally harmonized regulatory system and the implications of such a system are discussed. Given the strength of national differences in the politics of medicine and perceptions of the patient, highlighted in this book, as articulated through the regulatory systems, now deeply embedded, it is hardly surprising that international harmonization encounters resistance.

It is no criticism of this significant and highly readable comparison of regulatory development in the USA and Germany, to suggest that further studies extending the comparison to other significant drug-producing and consuming countries would enhance our understanding.

**Judy Slinn,**  
Oxford Brookes University

**Ralf Vollmuth,** *Traumatologie und Feldchirurgie an der Wende vom Mittelalter zur Neuzeit: exemplarisch dargestellt anhand der “Grossen Chirurgie” des Walther Herrmann Ryff,* Sudhoffs Archiv, Beiheft 45, Stuttgart, Franz Steiner, 2001, pp. 352, illus., €44.00 (hardback 3-515-07742-1).

The goal of this study is to present the state of the art in the field of what the author calls