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Arthur A. Daemmrich. *Pharmacopolitics: Drug Regulation in the United States and Germany.* Chapel Hill and London: University of North Carolina Press, 2004. xi + 203 pp. $21.95, cloth, ISBN 978-0-8078-2844-1.

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At the end of August 2005, Universal pictures released *The Constant Gardner*, a big-budget adaptation of John le Carré's latest novel, bringing the world of international drug testing into the limelight. The story condemns both the perfidy of drug manufacturers who test experimental drugs on unwitting subjects in East Africa and, in a larger sense, neo-colonial exploitation by multinational corporations. While the movie raised the level of debate over the ethics of drug regulatory regimes in a globalizing world, the issue is, as Arthur A. Daemmrich shows in his book, *Pharmacopolitics: Drug Regulation in the United States and Germany*, far from new. Concerns over how to regulate drugs have a long and complicated history.

With rapidly aging populations on both sides of the Atlantic, increasing life expectancies, rising numbers of pharmaceutical preparations for any number of chronic and acute illnesses and, at least in the United States, an unprecedented expansion of drug advertising, we have entered the pharmaceutical age. Although the expansion in the quantity and quality of pharmaceuticals has increased both the length and quality of life for many, the complicated politics of pharmaceuticals have received surprisingly little attention from historians.[1] In a timely injection of historical insight into the ongoing debate over the politics and practice of pharmaceutical regulation, Daemmrich provides us with a useful and informative comparative examination of the divergence in pharmaceutical research and regulation in Germany and the United States since the 1950s.

Eschewing economism and functionalism as adequate explanations of differing traditions of regulation, Daemmrich embraces a broadly constructivist approach, examining the development of regulatory regimes as the product of the complex creation of scientific knowledge by a broad array of institutions, governments, interests groups, and industries. He argues persuasively that the divergent trends in testing and regulation in Germany and the United States stem from quite different "therapeutic cultures." This notion of "therapeutic cultures" Daemmrich defines as "the historical evolution of a distinctive set of institutionalized relationships among the state, industry,

physicians, and disease-based organizations" (p. 4). While in the United States drug regulation in the postwar period shifted frequently in response to perceived crises or external pressures, in Germany, the continuity of professional self-regulation and corporatist cooperation contributed to a relatively stable regulatory regime that placed physicians firmly in the center of decisions about both pre-market testing and post-market oversight of adverse drug reactions.

Daemmrich focuses on three areas of the drug regulation process: drug laws, clinical trials and post-marketing surveillance. After a chapter on the evolution of drug laws in the two states, Daemmrich, in order to draw the contrasts between "therapeutic cultures," examines a number of significant case studies: the antibiotic Terramycin in the 1950s, the tragic case of Thalidomide in the 1950s and 60s, the beta blocker Propranolol in the 1960s, the cancer drug Interleukin-2 in the 1980s and 90s and the protease inhibitor Indinavir in the 1990s. These case studies highlight the various ways in which the two countries have dealt with the competing demands of the pharmaceutical industry, physicians and patient groups.

The broad outlines of Daemmrich's conclusions about the emergence of separate regulation regimes focus on the growing divide between a centralized American bureaucracy, embodied in the Food and Drug Administration, that increasingly enforced a system based on statistical modeling and quantitative decision-making, and a German system that remained decentralized, qualitative and firmly in the hands of physicians. This divide, he sees, has created a U.S. system where the "the primary nexus of power is between the state and citizens," while in Germany, the power to decide on the availability, regulation and surveillance of drugs has remained in the hands of a "formal network of actors" (p. 153). In practice, the United States has seen an increasing antagonism between "disease-based" citizens' groups and the federal government. In Germany, on the other hand, the regulation system has been less politicized, "because the medical profession has maintained certain forms of guild authority and 'pre-modern' relationships of trust" (p. 159).

In an intriguing conclusion, Daemmrich speculates on the future of drug regulation in a rapidly globalizing world. Since 1990, the regulators and pharmaceutical manufacturers in the United States, the European Union and Japan have worked together on the "International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use" (ICH). Although regulators and producers share a desire to ease the regulatory burden across borders and to ensure an ethical international regime of drug testing, Daemmrich believes that the differing "therapeutic cultures" of the member states pose important challenges to the growth of a global drug regulation regime. He foresees criticism coming from two sides. On the one hand, citizens' groups and patient advocates will battle against a "technocratic system that excludes their concerns." On the other, physicians will resist attempts to create a standardized regime that reduces their influence over decisions about patient treatment and their own professional latitude. Daemmrich closes by championing a pluralist solution. "The challenge ahead is to design working institutions for a polity of unprecedented size and diversity," he claims. "Only if we rise to that challenge by incorporating multiple voices and designing transparent decision-making procedures--ones that grant visibility and participation to patients--will globalization become something more than the reduction of trade barriers that benefits a minority of the population in advanced industrialized countries" (p. 163).

Pharmacopolitics is an important book. It takes up a matter that is current and urgent and offers not only an explanation of the historical roots of the current controversy, but also humane recommendations for a policy area badly in need

of a sense of history. Yet the book is also an important example of detailed comparative work. As the field of German history becomes less national and more international, Daemmrich provides an example of how to go about the difficult task of close comparison. For this reason, the book deserves a wide audience.

Note

[1]. This lack of research is particularly pronounced in comparative work. For examples of recent comparative work, see John Abraham and Julie Sheppard, "Complacent and Conflicting Scientific Expertise in British and American Drug Regulation: Clinical Risk Assessment of Triazolam," *Social Studies of Science* 29 (1999): pp. 803-843; John Abraham, *Science, Politics and the Pharmaceutical Industry: Controversy and Bias in Drug Regulation* (New York: St. Martin's Press, 1995); and Stephen Ceccoli, "Divergent Paths to Drug Regulation in the United States and the United Kingdom, *Journal of Policy History* 14 (2002): pp. 135-169.