Ways of Regulating Drugs in the 19th and 20th Centuries. Edited by Jean-Paul Gaudillière and Volker Hess. London, Palgrave Macmillan, 2013. 344 p. £ 60.–. ISBN 978-0-2303-0196-2

Historians of science and medicine, historians of economics and business and historians of the professions have contributed, with different approaches and questions to the emergence of the history of pharmaceutical drugs. Several of them – and the most part of the authors of *Ways of Regulating* – were the members of the European network *Standard drugs and drug standards* that has publicised researches about drug trajectories and standardisation of drugs during the last decade. Looking at the drug trajectories through the regulation tools, the contributions of *Ways of regulating* offer stimulating analysis and new points of view. The regulation is described as a negotiation between different actors (state, industrials, physicians, patients, consumers, lawyers, etc.) referring to different orders of norms and rules. But the analysis of regulation isn't another way of telling the story of drug trajectories: it opens to new questions in the field of the history of pharmaceutical drugs. The role of patients as consumers, the influence of courts, the balance of power between state administration and professionals are some of the unusual topics discussed here. The studies cover the 19th and 20th centuries, the industrialised and the developing economies.

Volker Hess defines the regulation as a “performative action” from the case study of “secret remedies” in 19th century Prussia. The marketing of these drugs is regulated first by manufacturers and traders and, broadly, by the public sphere. Late in the 1830's, the scientific expertise was mobilized to justify state concessions. The regulation mixed public reason and state interest.

At the beginning of the 20th century, the story of Salvarsan exposed by Axel C. Hüntelmann is exemplary of the “making of a drug”. Following the framework of the regulation enforced for the sera, clinical testing helped to evaluate public health risk. The “making of” is the process of negotiating the therapeutic effects as well as the unintended effects, it becomes later a model for the following drugs.

Regulation isn't a unique process but a series of “dispositifs” that define production standards and norms for medical uses. This plurality is produced by tensions between laboratory, physicians, industrials, public officers and all people involved in the regulation of plant extracts production and marketing in the interwar period in France and Germany, as analysed by Jean-Paul Gaudillière. In such a view, regulation isn't an issue to avoid competition but the assertion of professional autonomy.

The challenge of autonomy, and precisely the clinical autonomy, appears at the core of the US regulating system, according to the case study of “adverse drug reactions” presented by Harry M. Marks. The clinical autonomy remains crucial in an era of rapid technological innovation.

The regulation of therapeutic innovation is mainly a premarket regulation. But the drug trajectory goes on after the marketing authorization: the drugs may change the definition of diseases and reciprocally. Jeremy A. Greene shows how contested is the postmarket regulation of drugs in practice. It reveals that drugs are both goods and commodities and the regulation will balance between effectiveness and efficacy, medical authority and health information.

Does drug safety regulation strongly influence the organisation of research and development within the pharmaceutical firms? Vivian Quirke describes the practices

of Imperial Chemical Industries (ICI) and underlines that the concern for safety has preexisted many regulations. The firm has set a “therapeutic culture” since the 1950’s and self-regulation.

The case of anticancer drugs offers a different framework for the analysis. Alberto Cambrosio, Peter Keating and Andrei Mogoutov suggest that drugs are research objects rather than unproblematic tools for the management of the disease. In such a perspective, it is worth to describe the practices that produce new drugs and to pay attention to clinical trials that compare regimens and protocols. In the course of clinical trials, the relation between biology and clinic changes and also transforms the identity of the drugs. This is a challenge for regulation.

Users may influence the way of regulating drug. In the case study of breast cancer prevention, Ilana Löwy underlines the major part of the users in the process of evaluation and regulation of drugs that intend to keep healthy people from becoming ill.

Users and more, patient activism, shape new issues of regulation. The access to new treatment for AIDS like AZT was helped by expedited approval delivered by the FDA. Donna A. Messner explains that the requirement of a new kind of regulation shapes the activism movement, who demands access to experimental drugs and modifications to the traditional approach to clinical trials. Activists made and broke the rules.

The regulation of drugs isn’t only an issue to protect citizens and public health. The Stalinon affair studied by Christian Bonah tells us much about the practices of regulation. The role of courts, law and jurisdiction in the work of regulation is also crucial. Last, regulation appears as a permanent and focused control.

The story of psychoactive drugs like Halcion helps to understand how regulation balances between market and public acceptance. Toine Pieters and Stephen Snelders describe contrasted reactions towards psychoactive drugs. Regulation may help to define equilibrium between safety management and drug innovation.

Patents, as analysed by Maurice Cassier, are another way of regulating. The conflict between patents rights and patient rights has reached new dimensions with the AIDS epidemic: it’s illustrative of the rivalry between the laboratories monopolies, the owners of therapeutic inventions and the actors of public health.

These different contributions help to suggest a typology of regulation following four categories. The first one is the state or administrative intervention, the second is the laboratory tests and human and animal experiments, the third one is the professional way of regulating and the last one is the public judgement. The different cases illustrate the emergence of a regulatory science: the production of knowledge for administrative, political or judicial action, with feedbacks to medical science. Last the analysis of different ways of regulating provides a heuristic model, a focus on the dynamic of change in pharmaceutical industry. Five ways of regulating may be described: a professional way; an industrial way; an administrative way; a public way and a juridical way. These distinctions reflect the multiplicity of actors and dispositifs that constitute the regulatory system.

Ways of Regulating offers a stimulating history of the pharmaceutical products and industry during the 19th and 20th century. The choice of the authors is to assume different ways of analysing drug trajectories: the history of the products, the economical aspects, the political dimension, the influence of social actors, and so on. The

demonstration is really convincing: it shows that if drugs aren't like other goods and if public health refers to a specific market, their history might not remain at the frontiers of the history of sciences, economic history or political history. Or in other words, the question of drug trajectories and of their regulations has become crucial enough to be liable to resolutely and fruitful multidisciplinary approaches, of which this book is a major issue.

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