

Prikazi / Reviews

Daniel Carpenter

**Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA
(Princeton, NJ/Oxford, UK: Princeton University Press, 2010)**

xx + 804 pp, including lists of illustrations (28), tables (26), and abbreviations and acronyms; Index

One must admit that a short title extremely rarely can reflect the content of a huge book in a satisfactory way. In the case of the latest book by Daniel Carpenter, however, that exception has occurred: there is no better manner to describe the role, destiny, and reality of the U.S. Food and Drug Administration, but by the two key words: reputation and power.

Where does that particular interest to study the history of a regulatory agency come from? The author Daniel P. Carpenter, the Allie S. Freed Professor of Government at Harvard University, offers an explanation himself: he has been influenced by his grandfather, a city health commissioner of Milwaukee, and by his mother, a radiologist, who both taught him about the entwinement of public health, science, and politics. Their stories have revealed to Daniel Carpenter also that public health must combine benevolence and weighedness with resoluteness and a certain degree of coercion, in order to obtain the best results for a community. Carpenter's previous book, *The Forging of Bureaucratic Autonomy: Reputations, Networks, and Policy Innovation in Executive Agencies, 1862-1928* (also published by Princeton University Press, in 2001), was a milestone in the field: the present work, devoted to the FDA, has been a logical continuation of the same specific and thorough pursue.

In his study, Carpenter first considers theory of regulation, analysing the notions and practice of „reputation“ and „public interest“, as well as the risks of based-upon public decisions. He justly stresses the „paradox“ of the American society, being at the same time „anti-bureaucratic“ and obedient to federal regulatory agency. Carpenter's fascination with the regulatory power executed by the FDA lengthens out to all its aspects – directive, gatekeeping, and conceptual – as well as to its features eventually adopted in other nations. A particularly inspiring sub-chapter is devoted to „organizational reputation“, that is, to the reputation an organization reaches thanks to its specific capacities and roles.

In the first part of the book, entitled *Organizational empowerment and challenge*, Carpenter departs from the very beginning of the regulatory statutes in the USA – the Federal Food, Drug and Cosmetic Act of 1938, resulting from the New Deal policy, but also from tragic experiences with elixir sulfanilamide (1937). In the following post-war period (1944-1961), the focus was the establishment of protocol and procedure in devising new drugs. The end of that period was marked by the thalidomide affair with an epidemic of congenital defects in Europe and Australia: in the US, launched was the name of Frances Kelsey, the FDA medical officer who had refused to approve thalidomide (Kevadon) for the USA market. Subsequently, in 1962 and 1963, new standards for FDA drug review and new rules for clinical trials were introduced. The range of reputation the agency reached at that point might be illustrated by the fact that, since 1964 until 1967, 25 new FDA public advisory committees were authorized. Congressional hearings and judicial affirmation furtherly extended the agency authority. The late twentieth century brought new regulatory challenges related to dietary supplements, cancer and AIDS therapy.

In the second part of the book – *Pharmaceutical regulation and its audiences* – stressed and analysed has basically been the particular position the FDA created on the crossroad of scientific research and political regulation, as well as the ways the FDA has faught to preserve its own autonomy in front of the stratagems of powerful pharmaceutic industry and approval pressures.

What can one learn from the Carpenter account? Probably the most important message is that regulatory administration is not something that can be developed easily and rapidly: decades of experience and protocolizing, lessons from domestic- and foreign-market tragedies, but, before all, a highly standardized scrutiny, result in an immense pool of reputation that becomes entitled to exercise power over community and in the community interest. Carpenter's story is a story of continuity and a proof that quantity, if correctly guided and honestly monitored, must evolve into quality.

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