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Book Reviews

La Gouvernance des Innovations Médicales"

Virginie Tournay

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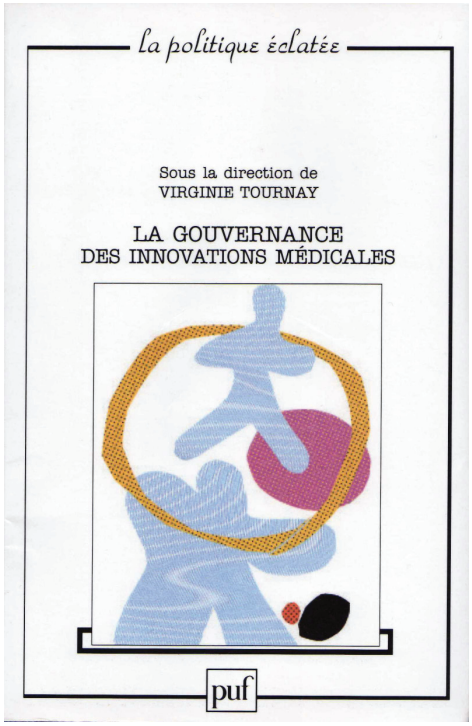
The book *"The governance of biomedical innovations"*, collection of articles organized by Virginie Tournay and edited by the French University Press under the direction of Lucien Sfez, introduces innovating aspects in the field of sociological literature about the current advances of biomedicine related to experimental procedures and clinical innovations (and their standardization process). The organizer of the book, also author of the introduction and of several chapters, adopts as a disciplinary approach the fields of political and historical sociology, clearly assuming the contribution of philosophers like Michel Foucault, Maurice Hauriou and (above all) Gabriel Tarde. From the starting point of this double theoretical approach, the author proposes a perspective of pragmatic sociology for interpreting the standardization, legitimation and sustainability over time of contemporaneous scientific innovations applied to the biomedical field. Based on this perspective, instead of considering – according to the dominating sociological interpretations of scientific research - the social legitimation of new concepts or the advances in biomedical techniques as fruit of the "wish of the State" or of macro-social interests (economic and political), in which the articulation of science with economical and political powers would turn the discovery of innovating technologies and procedures into "cognitive matrices of public policies" (Introduction, p. 33-35), the author proposes a theoretically innovating



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way of conceiving the social processes of construction and sustainable legitimation of scientific discourse and practice with respect to biomedicine; a view followed by the other authors of the book and applicable to the entire knowledge about life.

The "pragmatic" sociological proposal of the author invites the reader to see the production, standardization and social legitimation process of discoveries arising from clinical or basic research as historical result – and proposition – of the action of a variety of actors whose range of interests and capacity of political movement reaches far beyond the known dual relation State (through policies) *vs*. society, or science *vs*. society, or professionals vs. users. This wide range of interests and divergent, may times conflicting logics join together in a constant process whose result, not always foreseeable, will lead to acceptance of one or another procedure and its standardization. Thus, the category governance was launched for indicating that the production of knowledge as such in the biomedical field cannot anymore be understood (or analyzed) only from a classic epistemological viewpoint, as something exclusively resulting from the activity of scientists and experts. Understand the production of knowledge implies in reconstructing the arrangements in the baseline of these regimes of knowledge, which include at the same time the user, the patient, the citizen, the consumer, the associations, among other actors (for example: hormonal reposition therapy and the women's collective).

In the course of the changes in the governance of innovation in the biomedical field, Vinck and Weiss (presentation) point to three dynamics in the standardization of research practices. The first one refers to the "regulation of medical competence" as such, represented by diplomas and authorization to exercise the profession from the beginning of the XIX century onward. This regulation focuses on the physician as an individual and is aimed at excluding those qualified as quacks, a dynamic that proliferated over the first half of the XX century in qualification systems, continuing education and periodical certification of specialists. In Brazil, for example, a variety of specialist societies confer diplomas and maintain continuing education activities, sometimes with the participation of the Federal Council of Medicine (the highest normative organism of the medical profession in the country). This dynamic of standardizing the specialist (or the individual professional practice) seems not to have limits and culminated since the 1970s in the establishment of consensus guidelines aimed at implementing a standardized approach to cases remaining controversial (genetic testing for disease susceptibility, very complex treatments such as AIDS treatment, etc.)

This first standardization dynamic of the medical practice is complemented by a second one focused on the regulation of the scientific practice. Clinical research will require an ample regulation process involving not only measurement instruments and equipment but also standardized criteria. This strong homogenization will motivate the development of international studies, the so-called multi-centric studies. With the return of clinical research to the medical practice, some sectors like cancerology become hybrids of research/experimentation and clinical treatment, the latter many times oriented by standardized protocols dictated by the results of research (or trials) that are still in course. From the scientific viewpoint, the so-called randomized clinical trials turned into the golden standard in the research for new therapeutic substances, diagnostic and therapeutic methods, imposing themselves as a criterion of proof for the medical practice.

The colonization of therapeutics by ongoing scientific research and technology products still under test poses important risks and therefore the medical practice became also a locus of dilemmas and concerns called bioethical, which sometimes, when excessively acute, require regulation even on legal level.

The third and last standardization of the biomedical field is related to what the presenters of the book call the *logic of the great institutions* (Winck e Weisz), including i) medical professional associations (like the *American Medical Association*, *American College of Surgeons*); ii) the health managers; iii) the politicians in charge of the public healthcare service. For facing the difficulty of administrating conflicts and fundamental differences between a liberal medical practice, an economicist health management and the logic of the public system (demand for access to the healthcare services), p*rotocols* and standardization, above all in hospital medicine, constitute fundamental instruments for the management (or governance) of the health systems.

Together, the articles of this book discuss the new configurations of actors (forms of participation, articulation between different actors) in the production of the "governance" of technological innovations and in the incorporation processes of new goods or services by the medical (or biomedical) practice. Industry representatives, researchers, clinicians, managers and sometimes patient associations and social movements present themselves in the production process of new knowledge and in the regulation of the use of new technologies in the health practices, participating in the political and technical decisions. Going beyond a co-administration of health questions and power differentials in this management, the category *governance* indicates the possibility of *redefining* the problem itself based on the action of a heterogeneous network of actors holding different knowledge (and power). They discuss the process of objectifying what is and what is not to be considered a disease in face of the biomedical innovations. The questions posed by the category redefine for example the following problems: which governance mechanisms are involved in the definition of genetic predisposition? Why, and to what extent, medicalize the aging process? How to redefine surgically the sexual identity?

Thus, the book of Virginie Tournay and colleagues redefines in a substantial way not only the questions regarding the legitimation of the field of biomedicine but the very way they are put into question.