Colloque Histoire de la Régulation

The Financialization of French Medical Biology: an RT Approach

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I am very honored to be with you today and I would first like to thank the organizers of this symposium for giving me the opportunity to speak about my research work which I started in 2019 as a master's student and which is now part of my current thesis topic. This work has sought to document, investigate, and understand the transformations of medical biology laboratories since the birth of the sector in the 1970s in France. Although during my research it was brutally highlighted by the current health crisis, this sector and its organization were and still remain relatively unknown, as shown by the frequent confusion with pharmaceutical laboratories in the public debate, but also and above all by the absence of any significant academic work dedicated to this sector in the economic and social sciences.

This lack of awareness contrasts with its centrality in the healthcare system: private laboratories contribute to more than 70% of medical diagnoses in France each year. The health crisis has largely confirmed their importance in the healthcare system, particularly in terms of epidemiological surveillance, with nearly 85% of PCR tests being carried out by them. Without going so far as to assert a "French idiosyncrasy", we can say that medical biology in France has a dual nature: on the one hand, it is specifically medical, insofar as unlike countries such as Germany, it is a discipline of physicians or pharmacist-biologists, responsible for the pre-analytical phase (taking the sample with relevant clinical information), the analytical and the post-analytical phase (validation and interpretation of the result, communication with the patient and with the clinical or general practitioner); on the other hand, unlike the United Kingdom where medical biology is entirely public, in France historically it has been organized around a predominantly private sector, which performs more than two thirds of the volume of medical biology procedures each year.

After a year of research work, during a session of the seminar on the theory of regulation directed by Agnès Labrousse, I had the opportunity to discover one of the historical research programs of the Theory of Regulation, of which I knew almost nothing at the time: the sectoral approach, the meso-economic analysis, of a long period. It was from this research program of Regulation Theory, initiated by Pierre Bartoli, Daniel Boulet and Robert Boyer in the early 1990s and considerably enriched by others since then (Lamarche, 2011, 2021; Montalban, 2007; Bastien, 2017, etc.), that I drew the concepts and methodology that have structured my entire approach. As such, I wish to place this paper and the associated work alongside a very fine article emphasizing the current mesoeconomic concerns of RT, published in 2016 in the Journal entitled: “La Régulation contre-attaque : quatre doctorants face aux héritages de la théorie de la regulation”.

The regulationist method first led me to take an interest in what Bartoli and Boulet have called "the process of sectorisation", i.e. the analysis of all the historical conditions that specify the ways in which a sector is constituted. The process of historical differentiation of medical biology, which led to its birth as a coherent and, to a certain extent, autonomous sector, began in the early 1920s with the emergence of demands from the professional unions of doctors and pharmacists, regarding the lack of a legislative framework for biological examinations, which were then expanding rapidly. At that time, the diplomas for carrying out biological

examinations were not defined, and laboratories existed in very different forms: they were mainly located in hospitals, faculties and dispensaries, as well as in pharmacies.

At the end of this historical process, during which progress in biological diagnosis had increased and union demands had intensified, a first institutional codification of the sector's boundaries was established by law in March 1946, but was above all completed by another law dated July 11, 1975 which constituted the real starting date when the sector's boundaries as we know them today were defined. This was done by creating the biology branch for medical and pharmaceutical internship, and by establishing the monopoly for duly qualified biologists regarding laboratory management and the performance of medical biology procedures.

From this point on, it is possible to specify the characteristics of the sectoral regulation that were set up by analyzing the institutional arrangements and the economic system of operation. The institutional arrangements for the sector were structured from the 1970s onwards around three fundamental principles: firstly, a principle of financial independence. Given the medical nature of the activity, the legislator established financial and professional independence as a fundamental principle and, to this end, made it a requirement that that the capital invested in laboratories could only be held by the biologists who practised in the laboratory. The second principle was the regulation of competitive practices: the 1975 law prohibits, in particular, advertising and the outright purchase of a competitor. Finally, the third principle is the principle of socialization for the financing of medical biology laboratories, organized by agreement between the representative unions and the National Health Insurance Fund, with fees set according to a classification. From the 1970s and 1980s, these measures were combined with several macroeconomic, demographic and technological variables that shaped the economic functioning of the sector and its economic fabric, which is made up of small, single-site structures with a small workforce (about ten employees, mainly technicians and secretaries), where biologists played a central role by being the owner, director and medical manager responsible for diagnosis, sampling and explanation of results to patients and prescribing physicians.

Profit strategies (Boyer, Freyssenet, 2000) were therefore very limited: a laboratory could not buy out a competitor, create a second site, advertise, or play on prices given by the classification. A laboratory could distinguish itself from another in a very localized area, by the quality of its reception, by the quality of the contact with the biologist who performed the sampling, by the diversity of the biological analyses offered compared to its local competitors, as well as by the speed of the results. The salary relationship characteristic of this mode of regulation was then based on a model of paternalism between, on the one hand, the biologists in the laboratories who were at the center of all medical and economic decisions (the vast majority of whom are men) and, on the other hand, the female employees in an exclusively technical and assistance role: 95% of the technicians are women.

During this period, the substantial increase in the demand for medical biology procedures (i.e. medical prescriptions) and in the supply of procedures offered, as well as the automation revolution (at a time when practices were very much based on traditional methods), created a virtuous economic circle enabling laboratories to achieve considerable economies of scale and productivity gains. Thanks to strong union organization and in the face of relatively disorganized supervision, during the 1980s biologists managed to maintain a very favorable tariff classification: the profits made during this period made them the best paid medical profession. This is what biologists themselves call the golden age of medical biology. In this

context, unlike certain countries such as Germany, in France medical biology did not industrialize during the 1980s: the institutional arrangements thwarted the industrialization logics of the Fordist accumulation regime. The meso dynamics diverged from the macro dynamics.

However, despite protective institutional arrangements, a sectoral mode of regulation is not a fixed state but a process that is constructed and transformed, and it can be eroded and broken up. In this respect, I would like to return to the factors of erosion of the mode of regulation that led to the onset of a structural crisis.

From the 1990s onwards, the growing cost of medical biology led the public authorities to start a movement to reform the sector: they increased the incentives for the concentration of laboratories with a view to reducing health expenditure: in this sense, a law in 1990 allowed non-biologist investors (a first) to own shares in the capital of laboratories up to a limit of 25% and to create a maximum of 5 ex nihilo laboratory sites, as well as to make association between biologists easier. This law thus allows "a diversification of profit strategies" for laboratories, but fails partly because the effect of hysteresis is powerful: in a sector of primarily medical professionals, accustomed to the paternalistic management of their laboratory and where local competition is strong, practices do not change easily. The desire to preserve the existing situation - i.e. a comfortable income - is often stronger than the desire to bring in new investors.

In 2001, the logic of concentration in the sector was greatly accelerated by a law: the MURCEF law, which made it possible to set up chains of laboratories by means of a "cascade" legal arrangement, which must be owned by biologists. Some biologists seized the opportunity, but overall, professionals were not the main actors in this concentration movement. In fact, by going through subsidiaries abroad and using a principle that is a component of European law - the principle of mutual recognition of qualifications - it has been commercial companies, declaring themselves to be companies of biologists (and which France was obliged to recognize as such, given this legal principle) that have managed to circumvent French legislation and penetrate the sector. These companies, owned by financial actors (investment funds, companies listed on the stock exchange) and industrialists, have turned the movement of concentration between liberal professionals desired by the public authorities into a movement of financialization of the sector. In addition to the entry of financial actors, other elements are adding to the observation of a structural crisis: the trade unions of the profession successively lost the lawsuits where they opposed the financial groups; three successive public reports (an IGAS report, a ministerial report and a report from the Court of Auditors), as well as an opinion from the European Commission, were published advocating further consolidation of the sector and a total opening up of the capital of the laboratories, which considerably fueled the climate of uncertainty. Divisions within the profession were emerging, with a majority of biologists opposed to the financialization of the sector, and a growing minority of biologists selling their laboratories to interested groups.

From this structural crisis, a new mode of sector regulation emerged in the early 2010s, very different from the historical model: a model that I have called industrial-financialized, based on two major institutional arrangements. First, the Ballereau ordinance of 2010, which favors the industrialization of the sector through two provisions: it authorizes the organization of multi-site laboratories (previously prohibited) with a central technical platform that concentrates chains of automatons, a platform supplied by peripheral sites that are only responsible for taking samples. This ordinance also imposes an accreditation that corresponds to a "quality" process, which obliges all laboratories to have 100% of their analyses approved

by an independent organization. The idea of the reformers is to impose an international standard that benefits large structures in order to encourage small laboratories, for whom accreditation quickly becomes time-consuming and financially costly, to sell out.

The 2013 law, the last major law on medical biology, finally settled the issue and legalized the position of the financial groups that had entered the sector since 2001, thus guaranteeing the continuation of the financialization phenomenon. At the same time, the State has been pursuing a policy of slow and continuous reduction in the price of biological procedures since 2010. This choice is gradually eroding the margins of small laboratories, where larger structures and/or those in the process of consolidation are compensated through volume.

The result is clear: in less than a decade, the six financial groups that owned 16% of laboratory sites in 2010 owned approximately 78% of sites in 2020; the number of biologists' companies has fallen from 3,400 in 2010 to fewer than 400. As a result of this competition, the price of laboratory shares has soared, sometimes reaching more than 300% of the turnover and making it impossible for young biologists to enter the capital of laboratories.

The economic system of operation is characterized by a concentration and an industrialization of structures and their organization; by a financialization which is manifested in the successive repurchases of laboratories by investment funds, by means of successive LBOs; by the formation of an oligopoly which dominates the sector and which is clearly dominated by the actors themselves: The Association for the Progress of Medical Biology (APBM) brings together the seven financial groups in the sector (Synlab, Unilabs, Biogroup, Cerba, Eurofins Biomnis, Inovie). These groups now negotiate directly with the public authorities, thus supplanting the traditional unions of the profession.

While the sectoral approach to RT is based on a rejection of institutional isomorphism at the sectoral level, showing precisely the differentiation of mesoeconomic spaces, as well as the diversity of productive models (Boyer, Freyssenet 2000), it seems to us that Montalban's work on the pharmaceutical industries (2007, 2014), which falls within the framework of RT, has made a particularly rich contribution, since it has led to the cohabitation of several production models, while at the same time showing very well the actors in the pharmaceutical industry sector converging towards a blockbuster model. While I have also observed a diversity of undeniable production models among the main groups that dominate the sector, I have been struck by the convergence of these, which, despite their respective histories and idiosyncrasies, are moving notoriously towards an industrial-financialized model, which is based on a strategy of volume, on an internationalization of the policy of external growth (including among the groups that were exclusively French at the outset), and on recourse to LBOs.

The industrial-financial model is also characterized by the disappearance of the biologist as the central figure of the laboratory, given the development of technical platforms and the ever-increasing automation of analyses, and it is also distinguished by the development within the laboratories, of managers of quality controllers, etc. Within these groups, the pre-analytical phase, sampling, which was the preserve of the biologist, is now performed by technicians. The post-analytical phase, of interpretation and explanation of results, which was the medical character of French biology (in contrast to Germany, where biology is only analytical), is automated and digitized, which makes it difficult to have a dialogue with the clinical doctor and the patient.

Finally, this model is characterized by an inversion of the balance of power between the players in the sector and the State. The negotiation of a very advantageous price for PCR tests during the health crisis, and the progressive number of hospitals outsourcing their biological examinations to private laboratories, show the ability of biology groups to assert their interests in this new sectoral configuration.