Governing (through) Prices: The State and Pharmaceutical Pricing in France[1]

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Accepted Author Version of: Nouguez, É., Benoît, C. & Jacobs-Colas, A. (2017). Governing (through) prices: The State and pharmaceutical pricing in France. *Revue française de sociologie*, 58, 399-424.
DOI : 10.3917/rfs.583.0399

Abstract. This article examines the pricing of reimbursed prescription drugs in France from shortly after World War II to the mid-2010s. We analyze the consecutive forms this policy has taken, from unilateral pricing by the state (1948-1980s) to price negotiations between an inter-ministerial committee and pharmaceutical companies, which went into effect in the mid-1990s. On this basis, we show that state price control in France implies two ways of governing markets: government of values, where the idea is to assess medications on criteria of social justice ("la justice sociale")—that is, public health, keeping the national health insurance budget balanced, promoting research and development and supporting industrial employment—and government of behaviors, where the idea is to assess medications in accordance with market accuracy ("la justesse marchande")—that is, ensuring that prices will incline pharmaceutical companies and market actors to behave in ways that will serve state pharmaceutical policy. The aim of determining a just and accurate price through negotiation has regularly given rise to confrontation both within France's inter-ministerial negotiating committee, called the Economic Committee on Pharmaceuticals (*Comité Économique des Produits de Santé* or CEPS), and between that committee and pharmaceutical companies—in sum, between actors concerned to promote the distinct and antagonistic notions of social justice and market accuracy.

Key words. Regulation — Prices — Market — Pharmaceuticals — Values – Pharmaceutical Industry—Behaviors

[1] Preliminary versions of this article were presented at the French Political Science Association annual meeting in 2013 (in a panel organized by Benjamin Lemoine, Vincent Gayon and Michel Freyssenet) and in seminars run by Pascale Trompette and Gilles Bastin, Maurice Cassier, Anne Revillard, Léa Toulemon, and Lise Rochaix between 2013 and 2016. Our thanks to the seminar organizers and participants, the editors of this special issue (Matthieu Ansaloni, Pascale Trompette and Pierre-Paul Zalio), and the anonymous reading committee of the *Revue* for their useful comments on earlier versions.

The price of drugs in France is often a matter of public controversy as well as conflict between the main actors implicated in the sector.2 Recently, two NGOs, the *Ligue contre le Cancer* (League Against Cancer) and *Médecins du Monde*, campaigned to denounce a "disconnect" between the high prices the French state had granted companies for a number of therapeutic innovations and the real costs of producing those drugs.3 The claim was that high prices revealed the increasing power of private interests, understood to conflict with the priorities of public health and access to treatment. Drug company representatives, too, regularly complain about drug prices in France, which they say are too low. They argue that they should be better remunerated given how their companies provide high-skilled jobs, contribute positively to the country's trade balance, and invest considerable amounts of money in research and development (R&D). In this understanding, company activity should not be undermined by "budgetary" considerations, assuming that low prices could also threaten the entire treatment discovery process.4

This sharply polarized situation is hardly specific to France. It is found in most countries where pharmaceuticals are funded by the public purse in one way or another.5 However, it is singularly acute in the French case due to the state's pivotal role in regulating drug prices, a role it has played since the end of World War II. The fact is that from 1948 through the 1980s, the French government set drug prices unilaterally. At that time, the aim was to establish public health as an exclusive state prerogative, especially early on, in the period of economic reconstruction, as the country was developing its national health insurance system, the *Assurance Maladie*. It also seemed extremely urgent at that time to regulate the drug market, perceived as monopolistic and highly inflationary.

In the mid-1990s the state partially abandoned this decision-making power, shifting to agreement-regulated price negotiations between a committee whose members come from a number of ministerial directorates (the *Comité Économique des Produits de Santé* or CEPS; hereafter, the Committee) and pharmaceutical companies. The state's main concern at that time was to "better assess" therapeutic innovations, a critical aspect of a

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[2] See, for example, "Prix des médicaments: racket," an editorial in *Prescrire* 36, no. 389 (2016): 217, and B. Rocfort-Giovanni, G. Arnaud, "Ces pilules hors de prix qui ruinent la Sécu," *Le Nouvel Observateur*, September 29-October 5, 2016.

[3] One of the main targets of these associations was Glivec®, a drug for blood and bone marrow cancer: the "annual price" of treatment with this drug was estimated at 40,000€ whereas its "real production cost" was estimated at 200€; another was Sovaldi®, a drug for combating Hepatitis C: three months of treatment for one person was said to cost 41,680€ whereas production cost was estimated at 75€. See *Ligue contre le Cancer* [https://www.ligue-cancer.net/article/35294_pourrons-nous-tous-etre-soignes-en-2016-sauvons-notre-systeme-de-sante] and *Médecins du monde* [https://leprixdelavie.medecinsdumonde.org].

[4] LEEM [*Les Entreprises du Médicament*, the industry's professional association], "Des prix parmi les plus bas d'Europe," September 2011 press communiqué; and LEEM, "Prix des médicaments innovants en cancérologie: le LEEM s'indigne des 'manipulations' de la Ligue contre le Cancer," March 2015 press communiqué.

[5] See, for example, Sarah Boseley, "Patients Suffer When NHS Buys Expensive New Drugs, Says Report," *The Guardian*, February 19, 2015.

drug's value that had not been given much weight under the previous system, while keeping the national health insurance system (hereafter NHI) financially sound.

In this overall context, some observers argue that the "injustice" of current drug prices is an outcome of "ill-adjusted" power relations between the Committee and the drug industry. As they see it, the "fortune" that drug companies have made—thanks to "exorbitant" prices—is directly due to a failure of public regulation and the state's overall inability to establish the "right" price for pharmaceuticals.6 Responding to these criticisms, Committee members have cited the complexity of regulation that purports, simultaneously, to integrate healthcare imperatives (i.e., ensuring all patients access to quality drugs), business imperatives (facilitating innovation, research, and employment in France and Europe), and financial imperatives (controlling public healthcare spending), their task of pricing no fewer than 15,000 drugs of diverse legal status (patented or generic), therapeutic value (ranging from very high to very low) and commercial status ("niche" drugs, mass consumption drugs, orphan drugs). The Committee also has to take into account prices in other European countries as well as medical prescription volume, two variables over which it has little control, as we shall see in greater detail below.

The pharmaceutical market in France thus exhibits fairly complex price structure (Chauvin 2011). What we wish to stress here is that in a number of respects, that complexity is an outcome of the role played by the Committee itself. When it comes to setting the prices of new drugs as they arrive on the market, this powerful regulator simultaneously draws on principles of social justice and market accuracy (see below). This in turn gives rise to multiform negotiations that combine the distinctive features of a regulated market on one hand and an administered system on the other. Prices controlled on this basis then give the market its shape, stabilizing a certain relationship between those who govern (the Committee) and the governed (pharmaceutical companies, healthcare professionals, other experts, and patients).

The present text is primarily concerned to discover how regulators operate in such settings. It therefore contributes to the literature on price control, especially in contemporary contexts, while offering an overview of the effects that price control activity has had on the structure of the French pharmaceutical market. As the article progresses, we introduce and develop a set of theoretical and empirical perspectives for understanding how the "social justice" and "market accuracy" implicated in price control can be made to fit together in the course of the price regulation process. We then describe this process as both government of values and government of behaviors (Dumez and Jeunemaître 1989; Boltanski and Thévenot 2006; Dubuisson-Quellier 2016).

The rest of the paper is organized as follows. We first show the heuristic value of this set of concepts in enhancing academic debates on state price control. We then draw on historical materials to characterize the main changes in pharmaceutical price control in France, arguing that it grew more complex over time as it worked simultaneously to integrate a number of social values and attain more thorough control of market

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6 Assemblée Nationale, Commission des Affaires Sociales, "Compte rendu de l'audition de Dominique Giorgi, président du CEPS," Paris, December 4, 2013.

behaviors. From 1948 through the mid-1980s, the state aimed to balance the imperatives of public health, public financial health, and industrial development primarily by pricing drugs at production cost. During that period, the pricing process could not effectively control drug company or medical prescriber behaviors or rising government spending on prescription drug reimbursement. When the state created the Committee in the mid-1990s, it was establishing a framework that would enable it to set prices jointly with pharmaceutical companies. In this new context, both government of values—that is, making medications' therapeutic added value the basis for price negotiations—and government of behaviors changed. This ultimately entailed a schizophrenic situation in which the Committee left the task of reducing prescription volume to the NHI system while its own price-setting worked to cancel out the financial effects of that system's action.

BOX 1. — ***Sources and methods***

This study is based on qualitative material from a variety of sources, including documents on the history of drug pricing in France and historical works and academic research studies published from the 1970s to the 1990s; also a considerable body of administrative reports on regulating the prescription drug market in France from 1948 to 2014. Information on the Committee is from a range of specialized journals and documents from the *Comité d'Histoire de la Sécurité Sociale*.
For reasons of business confidentiality, we could not attend Committee meetings or exchanges between the Committee and drug company representatives. We therefore sought to reconstruct the Committee's activity through systematic analysis of its reports (1999-2014) and agreements with the pharmaceutical industry association; a total of 20 interviews, including 7 with Committee members from 2010 to 2012 and 5 with drug policy actors; and analysis of an NHI database listing all reimbursed drug prices.

Social justice and market accuracy (*justice sociale et justesse marchande*) in price control: price as an instrument for governing values and market behaviors

During the twentieth century, a number of different states (France from 1936 to 1986, the United States during the two world wars and during the Nixon presidency, the USSR) controlled or administered different economic sectors and in some cases their entire national economy. Drug prices are still directly controlled in France, Belgium, Spain, and Italy, and indirectly controlled in most other Western countries, either through regulation of pharmaceutical company profits, as in the United Kingdom; fixed levels of reimbursement, as in Germany; or reference price lists established through insurance company-organized tenders, as in the Netherlands and the U.S. (Sermet 2007). The legitimacy of state intervention on price, considered the "market variable," has elicited a considerable amount of debate among economists and, to a lesser degree, sociologists and political scientists.

That debate is structured around the following two questions: What principles of legitimacy justify intervention of this kind? And what, in a given sector and in practical terms, makes state control preferable to free market operation? One response to these two intimately related questions is that price control is a means of governing values; that is, of "incorporating" principles of social justice or notions of the general interest

into pricing and thereby controlling the (re)distribution of economic value. Another response defines price control as a means of governing behavior; that is, using prices to get market actors to move in directions preferred by the state.

Price control and social justice: a way of governing values

State price control can be thought of first as a means of governing values. This notion involves an idea found in economic sociology on the valuation processes used to attribute value to objects and persons (evaluation) and to redistribute added (or subtracted) value among them (valorization) (Vatin 2013; Aspers and Beckert, 2011). While the first studies to use this approach focused on processes of "qualification" (Musselin and Paradeise 2002; Beckert and Musselin, 2013), more recent studies have investigated types of price formation (Muniesa 2000; Chauvin 2011; Reverdy 2015) and how companies themselves set prices (Barrey 2006; Finez 2014; Yon 2014). These studies, which developed in the wake of economics research, have brought to light two unique functions of price in valuation processes: a price represents by way of a single sign or signal the entire range of different values attributed to a given commodity or person; and prices organize the (re)distribution of value between trading partners. Prices, therefore, involve a wide range of value judgments aimed at qualifying them as "just" or "unjust" in light of competing principles of justice (Boltanski and Esquerre 2016).

Historically, state control was a means of intervening directly in valuation processes by incorporating notions of the general interest into prices and "imposing" them on a market whose "natural or spontaneous operation" was perceived as "unjust." If we follow Hervé Dumez and Alain Jeunemaître (1989), the state intended first and foremost to control the prices of commodities it deemed "vital for the population" or that touched on "state prerogatives"; another major concern was to keep those commodities under its control. Examples are wheat or bread, pharmaceuticals, housing, energy, and transportation. Price control has also enabled the state to protect "vulnerable" groups against what are seen as the market's deleterious valuation effects, as in the case of organ transplants (Steiner 2010) or adoption (Roux 2015). In public monopolies, meanwhile, state intervention in prices has aimed to optimize social wellbeing by neutralizing the power relations inherent in markets and redistributing rents between producers and consumers (Finez 2014; Yon 2014). Similarly, the state has permitted supermarkets and department stores to sell at a loss to prevent them from taking unfair advantage of their monopsony (or oligopsony) position by setting low prices that would threaten producers' profits (Barrey 2006).

In this context, state price setting can be thought of as a genuine means of "testing" the many notions of social justice and the actors associated with them (Boltanski and Thévenot 2006) Importantly, it brings into play heterogeneous and potentially conflictual "ways of formulating the general interest" (Yon 2014; Vatin 2013; Stark 2009). In the case of France's national railroad company (SNCF) studied by Jean Finez (2014), prices based on distance travelled were replaced in the 1960s by prices based on marginal costs, an approach promoted by engineer-economists (influenced by Maurice Allais' work) as a way of optimizing "returns to labor" in the sector. This in turn was replaced in the 1990s by a new pricing system based on marginal utility, chosen because it would take into account service profitability while improving consumer access to rail travel. In the case of the French electricity company EDF, Guillaume Yon

(2014) has shown an opposition between the marginal cost pricing promoted by Allaisian economists and the regional development and consumer equality imperatives of local officials. This led to a political compromise: applying a single rate throughout France in exchange for differentiation by consumption period (and type of consumer).

Price controls, then, appear a means for the state to apply the notions of the general interest and social justice in attributing values to commodities and distributing those commodities among market actors. Meanwhile, liberal economists from Turgot to Hayek have criticized state price control as a threat to "market accuracy": is there not a danger that governing values through prices will in fact govern behaviors in ways that go against the general interest?

Price control and market accuracy: a way of governing behaviors

Sophie Dubuisson-Quellier (2016) has looked at the different approaches and instruments that states wield to govern market actor behaviors. Drawing on Foucault's concepts of "governmentality" and "security device" (dispositif de sécurité), she defines government of behaviors as a means of controlling the population without drawing on either law or discipline but rather on "mechanisms" that "tend to a nullification of phenomena … in the form of a progressive self-cancellation of phenomena by way of the phenomena themselves. In a way, they involve the delimitation of the phenomena within acceptable limits, rather than the imposition of a law that says no to them" (Foucault 2009: 71; quoted in Dubuisson-Quellier 2016: 23). In the eighteenth century, Foucault explains, political economy was key to changing how behaviors were governed: the market became a means of getting people to behave in the general interest, yet one that respected individual freedom of action. By acting on prices either directly (through control or framing) or indirectly (through taxation or subsidies), the state now sought to "guide the economy" (Dumez and Jeunemaître 1989) by inhibiting "speculative" behavior on commodities of crucial importance (grain or rents during periods of scarcity), orienting consumer and investor choices (Finez 2014; Yon 2014), and containing inflation and price volatility (Reverdy 2015).

Of all the economic instruments available to the state, price control has elicited the sharpest criticism from economists, most of who consider it absurd and indeed dangerous (Dumez and Jeunemaître 1989). In opposition to the state's emphasis on "social justice," economists have held up the principle of "market accuracy," in the sense ascribed to it by Fabian Muniesa in his study of the "accuracy effects" of the electronic stock quotation system at the Bourse de Paris, designed to overcome rate manipulation by traders, a cause of closing price volatility. Though accuracy and justice are empirically and theoretically connected in important ways, accuracy alone acknowledges that prices can represent and structure market actor behaviors. It is significant that to illustrate his "security device" concept Foucault cited the grains policy promoted by liberal economists and physiocrats throughout the eighteenth century. For Boisguilbert and Turgot, price control as a policy treated citizens like children (in that it assumed they were unable to negotiate), unjust (in that it undermined property rights), and counter-productive (in that it would encourage grain owners to keep their stocks off the market as long as prices were capped). Conversely, by letting foodstuff prices rise freely, the state would offer an incentive to grain owners not only to sell but to invest in increasing their production, which would in turn lead to lower prices through the "natural" rebalancing of supply and demand (Foucault 2004; Dubuisson-Quellier 2016).

Hayek later denounced price controls as the worst threat to the economy in that they distorted the information that agents communicate to each other through prices and led to non-optimal resource allocation (Arrous 1990). For the engineer-economists in charge of devising a pricing model for France's public monopolies (SNCF railroad company and EDF electricity company), state intervention in prices could only be justified if it worked to "imitate perfect market competition by calculating a virtual price that real prices would have to approach in order to optimize economic management of the company" (Finez 2014, p. 18). The marginal costs price system, this argument ran, would allow for setting a "just" value for the goods and services on offer and facilitate "accurate" allocation of production factors while influencing the monopoly's investment choices and consumer choice. This is why economists were so hostile to a later price modulation, which in their view distorted the model (Yon 2014: 100-105).

From governing values to governing behaviors? State pricing of pharmaceuticals in France, 1948-1994

The French policy of setting pharmaceutical drug prices has sparked precisely this debate about whether or not it can combine value government and behavior government in such a way as to determine the right prices. Virtually unique in Europe and the world (Lecomte and Prais 1998; Sermet 2007), this policy has undergone considerable changes, both in how pharmaceutical value is assessed and how market actor behaviors are regulated. Two main periods can be distinguished. From the postwar era to the 1980s, drug prices were set by the state alone. Since the 1990s, prices have been controlled through negotiations between a committee whose members come from different ministerial directorates and the pharmaceutical companies. During both periods, price control in this sector was considered a vehicle for promoting the state's understanding of the general interest in the areas of public health, public finances, and industrial policy.

Administrative state control of pharmaceutical prices: from "price frame" (1948-1968) to "price grid" (1968-1993).

The French state moved to control prescription drug prices immediately after World War II. This policy was part of a general economic plan (Dumez and Jeunemaître 1989) characterized by particular vigilance on medications—for three main reasons. First, in response to the epidemics that broke out directly after the war, the French public authorities were keen to make essential drugs accessible to the population, especially penicillin, which was then manufactured exclusively by American firms (Chauveau 1999). Second, with the development of the country's national health insurance system, lists of reimbursed prescription drugs were established; in this context, the state wanted to prevent inflationary public spending by precluding pharmaceutical companies from taking unfair advantage of their monopoly position. Third, as French industries were rebuilt, protectionist impulses surfaced. The debates in the French parliament around a law of August 18, 1948, known as the Solinhac Act reflect the tensions between these different imperatives (Chauveau 1999: 283-297). Whereas the Socialists and Communists claimed pharmaceutical companies should serve the interest of public

health by providing specialized medications at near-production cost, Radicals and representatives of the Gaullist Mouvement Républicain Populaire argued that in order for the French drug industry to develop and modernize, French drug makers had to be granted generous prices.

A compromise was reached in which the state would administer drug prices on the basis of a "price frame" (Cadre de Prix) that would cover not just industry production costs but also a flat-rate profit margin, the latter meant to compensate companies for their research efforts, financial and administrative costs, and advertising costs. That margin decreased with production cost and was indexed on inflation. Sophie Chauveau (1999) has presented the many drawbacks of this price control system. First, pharmaceutical companies could easily manipulate it, inflating their production costs by using expensive active ingredients or medical components, thereby generating production costs that ranged from 1 to 17 FF. Second, though the government was able to maintain quite low price tags, reimbursement spending rose continuously due to faster—and often non-substantive—drug renewal, as the state usually granted new products higher prices than existing ones. Moreover, the system could not impact prescription volume, which increased considerably in the middle of the period.

In the 1960s, the state's approach to medication policy began to change. Following the Stalinon®, Thalidomide® and later the Distelbene® scandals (1953, 1961-1962, and 1971 respectively) and as part of a program to harmonize situations within the European Economic Community, the French public authorities stepped up their demands for harmless medications with therapeutic value and for pharmaceutical company compliance, a position that led to the country's "visa" medication marketing authorization procedure (Bonah and Gaudillière 2007). But it also began taking greater account of pharmaceutical company interests; namely, by authorizing drug patenting, first through a specific process (the Special Medication Patent, established in 1959), then as part of the general patenting process (1968). This new approach was also at least partially applied to procedures for pricing drug and determining which ones would be eligible for reimbursement. A law of June 5, 1957, stipulated that only medications that were "effective … and could be presumed to provide therapeutic improvement or lower overall treatment costs" would be reimbursed, and that "at comparable levels of effectiveness or savings, preference will go to medications produced through the manufacturer's own research efforts." It was at this time that the "Coudurier Committee" (named after its first chair) was established, with the job of assessing both scientifically (in its Section I) and economically (in its Section II) the value of prescription drugs that makers wanted approved for NHI reimbursement.

On April 5, 1968, the 1948 price frame was abolished by administrative decision and replaced with a "price grid" (Grille de Prix) designed to take into account the specificities of individual pharmaceutical companies. One objective of the new calculation system was to raise prices for relatively cheap drugs and lower prices for relatively expensive ones. Pre-tax sales prices would now be calculated in terms of raw materials, direct labor, packaging, production, quality control, commercial, administrative and financial costs, licensing and research costs, dividends, and a profit margin, which it was up to manufacturers to request. In some respects, the price grid can be seen as an attempt to correct the flaws of the price frame, namely by integrating the entire range of company costs. But it also broke with the preceding arrangement in that it took account of

therapeutic contributions, company research efforts, and (from January 1976) treatment cost in determining the price of new pharmaceutical drugs.

Despite these important changes, the price grid was criticized for the same reasons as the price frame. First, in becoming more complex, price control now gave rise to questions of—and uncertainties about—the cost of active ingredients, daily treatment costs, what the potential market for a given medication was, the real therapeutic improvement it offered, and the value of pharmaceutical company research programs (Jeunemaître 1985). Second, controlling drug prices can only work to contain reimbursement expenses if prescription volume is controlled too. In 1994, France had the lowest prescription drug prices and the highest drug sales volumes in Europe (Dorion et al. 1994). Third, this system was accused of handing rents to French pharmaceutical companies, as it gave them no incentive to invest in research or take account of foreign competition (Chesnais 1985; Thomas 1994).

A move toward ending state control of drug prices? The creation of the Economic Committee on Pharmaceuticals (CEPS) and the instating of agreement-framed price negotiations

In the early 1980s the Coudurier Committee was dissolved. The technical Section I became the Commission for Transparency, in charge of appraising the therapeutic value of drugs, while pricing was devolved to a small inter-ministerial group made up of representatives from the NHI, the Social Affairs and National Solidarity Ministry's pharmacy and medications directorate, and the Industry Ministry's textiles and chemical industries directorate. Their decisions then had to be approved by the Finance Ministry's competition and consumption directorate (Jeunemaître 1985).

But it was not until the mid-1990s that today's regulation framework was developed, the main event being the creation of two institutions that would play a major role in drug market regulation: France's Medication Agency (Agence Française du Médicament or AFM) and the Economic Committee on Pharmaceuticals (CEPS). Though both were established directly after—and in response to—France's "blood contamination affair," which broke in 1991 (Bergeron and Nathanson 2017), the aim was also to prepare the French administration and the country's pharmaceutical industry for the emergence of a much more competitive European Union-wide pharmaceuticals market (Hauray 2005). There was no serious parliamentary opposition to the decision to grant a scientific agency the task of assessing therapeutic value. However, the Socialist government under Prime Minister Pierre Bérégovoy was opposed to creating an economic drug pricing commission within the AFM, arguing that pricing was a state prerogative (Bergeron and Nathanson 2017). The compromise solution later developed by the newly elected, center-right government of Edouard Balladur was to keep pricing policy a matter for the state while granting the pharmaceutical companies still greater say than they had already acquired. Created unofficially in 1993 and officially recognized in 1997, the CEPS followed the country's inter-ministerial model, first implemented in the early 1980s. Its members came from the main ministerial directorates and National Health Insurance organizations,[7] and its mission was to negotiate with drug makers the prices for drugs prescribed either in hospitals or by private physicians.

[7] Until 2004, the Committee was made up of representatives from the four government directorates implicated in drug pricing (the general directorate of health, the directorate

Under its first chairman, Jean Marmot, the Committee radically changed the way drugs were priced and how the market was regulated. First, it established itself as the sole authority for pricing pharmaceuticals and acted to free itself of influence from its members' ministries. Second, it no longer unilaterally set pharmaceutical prices but negotiated them in the framework of agreements reached with individual pharmaceutical companies and an overarching agreement with the National Pharmaceutical Industry Association (Syndicat National de l'Industrie Pharmaceutique or SNIP).8 The companies could not set their own prices, but they did acquire the right to scrutinize Committee pricing decisions, while the Committee now had a right to look into company accounting and development strategies. Third, the first framework agreement, signed in 1994 by the Committee and the SNIP, established a new approach to pricing altogether: new drugs deemed of considerable therapeutic value by the Commission for Transparency would be granted high prices, in exchange for limited sales volume or a company agreement to pay back part of its gains in the form of discounts. Meanwhile, the pharmaceutical companies were called upon to lower the prices of their existing brand-name drugs by transforming them into generics or removing them from the list of reimbursed drugs.

But though this new system "allowed for greater flexibility in pricing, it brought with it the risk that market administration shared [between the state and the private sector] might not achieve the optimum efficiency determined by competition criteria alone" (Pauriche and Rupprecht 1998: 9). And while Committee policy now took fuller account of pharmaceutical industry concerns and perspectives in setting prices, was it really more just and accurate?

Integrating market behaviors into government of social values: the two sides of Committee drug pricing

The policy of having the Committee conduct joint agreement-framed negotiations with pharmaceutical companies produced a confrontation between the negotiating partners, with the Committee understood to represent aggregate demand for pharmaceuticals while the companies represented aggregate supply. But first and foremost it changed the principles that structured pricing. The Committee developed a new way of governing value by linking drug prices to their therapeutic contribution, and a new way of governing behaviors wherein the NHI organization would mobilize doctors, pharmacists, and patients by playing on drug prices while the Committee would try to

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that oversees the NHI (*Direction de la Sécurité sociale*), the general directorate of industry, and the general directorate of consumption, competition, and fraud repression), as well as a representative from the NHI; the Committee chair and vice-chair, meanwhile, were handpicked by the government. The Law of August 13, 2004, instated "parity" between the four ministerial directorate representatives and four NHI representatives, two from the National Employees Health Insurance Fund (*Caisse Nationale d'Assurance Maladie des Travailleurs Salariés*), one representing all other compulsory health insurance programs, and one representing optional complementary health insurance organizations.

[8] The SNIP was renamed the LEEM (Entreprises du Médicament) in 2002.

anticipate those behaviors when setting prices. As we shall see, the attempt to get the antagonistic principles of social justice and market accuracy to work together gave rise to intense controversies within the Committee itself and between it and its market actor negotiating partners.

Assessing the utility of pharmaceutical drugs: from therapeutic valuation to market valuation

Committee drug pricing pursues a series of objectives that are all "formulations of the general interest" (Yon 2014) in that price is supposed to reflect and resolve—simultaneously—public health needs, state financial constraints, and issues of innovation, industry development, and equal treatment of drug companies. This range of different principles is reflected in both Committee composition and the jobs of its various members:

> The CEPS is complicated, you know, because there are people on it with different perspectives—and that's a very good thing. The NHI is more reluctant to pay, as is the ministerial directorate that oversees it. The general health directorate, meanwhile, is closer to the patients. The industry ministry is more concerned about employment and research in France and Europe, while the competition directorate is attentive to equal treatment [of companies]. And since it's also part of the Finance ministry, it's attentive to financial questions. So these people have slightly different perspectives. So if we want to avoid blockages it is particularly important to avoid institutional posturing, where one person says, "I'm obviously going to vote for the price the company has requested because it's a company that does research," and another one says, "Well, I'm obviously going to vote to accept the company's price because it will provide a drug that patients need and I don't want to run the risk of not having it," and yet another one says, "I'm obviously voting against [that price] because it's absurd to pay so much money for something that's hardly better [than an existing drug]"
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> (Former Committee chair, interviewed February 2012).

But as soon as Committee pricing became a matter of negotiating with pharmaceutical laboratories, it also had to integrate market accuracy principles; that is, to take into account the situation of the French market on European and world markets, and market supply structure (monopolistic, oligopolistic, or competitive).

From the late 1990s, price negotiations have centered on Commission for Transparency (CT) assessments of medicines' "therapeutic added value." The CT became part of the AFM in 1993; in 2004 it was integrated into the Haute autorité de Santé (High Authority for Health). The CT is made up of medical experts and pharmacists, and its job is the medical-technical assessment of drugs. It first rates the drug on "medical service rendered" (SMR) or the absolute value of the given drug (or therapeutic class); this rating is then used to determine a reimbursement rate9. It then determines a "medical service rendered improvement" level (ASMR), indicating the "therapeutic added value"

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[9] Drugs with a high SMR are reimbursed 65% by the NHI (the remaining 35% is covered by optional complementary health insurance organizations); drugs with a medium SMR are reimbursed 30%; those with a low SMR are reimbursed 15%; and those with an "insufficient" SMR are not reimbursed.

of the given drug compared to others in its therapeutic class; it is this rating that is used to determine price. There are five ASMR levels, ranging from I for major therapeutic advances to V for no real improvement or cases where "clinical effectiveness and product safety do not differ from those of existing drugs" (internal memo to the administrative board of the NHI fund).

In several respects the ASMR has functioned as a standard both within the Committee and between the Committee and the drug companies. In contrast to the system used in the United Kingdom, which takes the cardinal measure of Quality-Adjusted Life Years (QALYs) to assess medication utility and can therefore "mechanically" generate a price (the number of additional years of life is multiplied by the "price" ascribed to a year of life in good health; see McCabe et al. 2008), France's ASMR is an ordinal measure that ranks medicines according to what they contribute compared to their predecessors (Sorasith et al. 2012). The ASMR determines the relative desirability of the drug in terms of both public health and the given pharmaceutical company's market position (Table 1).

TABLE 1 – ***Effect of ASMR level on the theoretical negotiation structure***

ASMR level	Level of "public health need" met by the drug	Drug company's market position
I-III	High to moderate	Monopolistic to oligopolistic
IV	Minor	Oligopolistic to competitive
V	None	Competitive

The ASMR also operates as a frame for negotiations. The agreements between the Committee and pharmaceutical company representatives stipulate that drugs that have received an ASMR of I to III (major to moderate improvement) can demand prices consistent with those in four other EU countries (Germany, United Kingdom, Spain and Italy) while drugs that have received an ASMR of V (no improvement) can only be reimbursed if they save the NHI money. The situation of drugs with an ASMR IV rating (minor improvement) is harder to determine.

Though the ASMR rating system offers a strong frame for discussions between the Committee and drug company representatives, it does not mechanically determine the substance of those discussions. For ASMR I-III drugs, the Committee and drug companies are legally required to find a price within the range defined by prices in the four reference countries (prices in Germany and the UK are usually relatively high and in any case not controlled, whereas in Italy and Spain the state has a role in setting prices, which are usually lower):

> Discussion of the price of a highly innovative drug amounts to an open confrontation between company demands and a more or less urgent need, for health reasons, to add the drug to the reimbursed list. In that negotiation, the Committee realistically considers the so-called "European" price for the drug as a legitimate constraint on the company but one that it can only use to counter the administration if justified. In other words, the Committee usually understands that a company will not accept a price too different from those on other major European markets, but the risk is

> having the drug turned down for reimbursement altogether if the conclusion is that the innovation does not sufficiently respond to health needs or offer sufficient benefits
> ("Les méthodes de négociation des prix du médicament [Methods of negotiating drug prices], Appendix 1, Rapport du CEPS, 2002, p. 42).

Negotiating the price of innovative drugs therefore presupposes that both the Committee and the pharmaceutical companies assess their "balance of power," which is structured around two dimensions: the given drug's potential value for public health, which will determine the financial effort the Committee is willing to make to "get the drug" and that the laboratory is willing to make to "get the French market"; and how urgent it is to get the drug on the market, as measured by the levels of political and media pressure on the Committee and of investor or executive pressure on the drug company representatives. The degree of urgency in turns determines negotiation length.

While laboratory "demands" are considered legitimate for medications with high therapeutic added value, they become problematic for drugs rated ASMR IV; that is, of a therapeutic value too low to position the drug in the previously defined EU price range but not low enough for the company to accept a lower price than those found on other European markets:

> You can tell the parent company of a firm selling a drug at, say, 50€ a packet throughout the European Union that the drug has been rated IV, or even V [in France], you still won't get him to sell it for 10€ in France, because then everyone will come buy it in France and the market's dead. So you've got to live with that, if you see what I mean.
> (Former Committee chair, interviewed February 2012).

Establishing an equation between a therapeutic benefit and a price can therefore pit the general health directorate representatives, whose priority is the value of the drug for the therapeutic arsenal, against the NHI directorate and the NHI fund officials, who refuse to pay such a high price for such a minor innovation. In cases like this, internal Committee deliberations and Committee-pharmaceutical company negotiations can drag on, and it may be extremely difficult to reach a compromise on the hierarchy of valuation principles and the relative value of the given drug.

The fact is that from 2000 to 2006, medications offering no therapeutic improvement (rated V) represented 60% to 80% of Commission for Transparency assessments. For this type of drug and generic drugs, the Committee's approach is the opposite of the one used for value-added drugs. Article R.163-5-1-2 of the Code de la Sécurité Sociale stipulates that drugs that offer no therapeutic benefit can only be reimbursed if they save the Sécurité Sociale money. As Medications rated V are in no way needed (let alone urgent) for public health, financial imperatives come to the fore in Committee negotiations on this type of drug. Moreover, a drug rated V has been equated with its competitors on the market, meaning its manufacturer is in a situation of near-perfect competition. Logically in these cases, internal Committee deliberations and Committee-company negotiations focus on finding a price that falls between a competitive one based on drug company production costs and the estimated price of the "cheapest" comparable drug.

As mentioned, ASMR is only one feature that negotiators take into account. Other considerations, such as company R&D investment, prices found on other European markets, or the structure of the given therapeutic class (number of available drugs it already contains, whether or not generic versions exist) also influence negotiations. New medications rated IV or V fall into one of the following three Committee-established categories: 1) "anti-generics" sold by a company as a "de facto substitution for [the same company's original] drug at precisely the moment it loses—or will soon be losing—its patent protection"; 2) drugs sold by one company that "are the outcome of independent research [by it and another company], provided the risks taken by the companies are similar"; 3) "me too" drugs developed at fairly low risk because their predecessors were so successful. Category 1) drugs are priced at generic drug levels unless they can demonstrate improved therapeutic value over their predecessor. Category 2) drugs are understood to be competing with each other and to diversify the available drug supply; they can be granted the same price as drugs already on the market. For category 3) drugs, "the Committee seeks to obtain the greatest savings possible" (CEPS 2009: 54-55).

The Committee also revised its pricing modes for existing medications to more closely resemble those in effect on other European markets—namely, by developing generic drugs (Nouguez, 2017). Jean Marmot was instrumental in bringing generic drugs to France. He used the development of these copy drugs to stimulate price competition on the existing, brand-name medications market and thereby to compensate for the higher prices granted to innovative drugs. But while the Committee negotiates the price of brand-name medications with the companies, it has always set the price of generic drugs "unilaterally" and priced them at a specific percentage lower than the corresponding brand-name drugs. That gap gradually widened as the generic market grew, from -20% in 1996 to -60% in 2012. Moreover, the Committee tried to imitate the operation of a perfectly competitive market by "administratively" lowering brand-name drug prices by 15% in 2010 and by an additional 12.5% 18 months later; then by 20% in 2012. In late 2006, the government requested the Committee to cut the prices of still patented equivalents whose therapeutic contributions were minor (ASMRs of IV or V). The Committee's response was to work toward "price convergence" in a number of therapeutic classes by citing the equivalent ratings of the drugs in question—evidence that they were highly interchangeable—and estimates of the inroads made by corresponding generic drugs on these markets (see below).

However, in response to pressure from the government and Parliament to bring generic drug prices more into line with those found in other European countries, the Committee set out to distinguish the "fair price" from the "minimum price" by simultaneously taking into account the financial imperative of maximizing savings to the NHI, drug sector imperatives (maintaining a "viable" generics industry), and health needs (protecting the population against the risk of poor-quality generic drugs):

> I've always thought you've got to protect the generic makers. If all we had was the English generic market, there would be no more generic makers in the world—because they are losing money! So I've always thought it was important for generic drug makers to make money, and we can't keep pushing their head under water. We don't need tenders, we need a regulated market. … We've got to keep the generic

> makers at least a little happy or we're in big danger of getting bad generics, with people who'd take advantage of the situation by dumping mass quantities of paracetamol or something else on the market, and they'd be much more difficult to control than they are now
> (Former Committee chair, interviewed February 2012).

The Committee also established a set of exemptions from the price-cutting system it had developed, the aim being to take account of "the small size of a given market, the complexity of an original drug formula, or its [already] low price due to how long ago it was developed" (Rapport du CEPS 2010: 14).

Committee policy considerably changed the pricing process by making a drug's therapeutic contribution the basis for its price. The Committee replaced the former relatively flat price architecture (Chauvin 2011), in which all drugs, old and new and of either high or low therapeutic potential, were assessed in terms of production costs, with a highly polarized architecture in which the NHI still buys the vast majority of existing drugs deemed perfectly equivalent and therapeutically interchangeable at no more than production cost while paying premium prices to get a limited number of patented molecules with "high therapeutic added value." However, we cannot establish a mechanical tie between ASMR ratings and drug prices (Sorasith et al. 2012), precisely because internal Committee deliberations and Committee-company negotiations combine multiple, potentially antagonistic notions of social justice (concern for public health but also for industrial development and the NHI budget) and market accuracy (taking into account market structure and prices on other European markets). This in turn means that the Committee does not simply set prices that reflect drugs' therapeutic interest but is also in charge of planning how state drug spending will be distributed among the different market actors and how it will evolve.

Planning prescription drug reimbursement spending: (re)distribution of value and "schizophrenic" government of prescribing behaviors

One of the main criticisms of state price control in the early 1990s was that it was "schizophrenic": while the state managed to keep drug prices low, it was unable to control prescription volume, which was among the highest in Europe, or the fact that, for structural reasons, doctors systematically prescribed the most expensive medications, causing drug reimbursement spending to soar. After 1996 and the Plan Juppé [named after the prime minister of the time], governments shifted from accounting-focused control of health spending, which had dominated in the 1970s and 1980s, to a dual system of medical control. First, Parliament was given the task of planning healthcare spending: lawmakers would henceforth be required to set a maximum spending figure (Objectif National des Dépenses d'Assurance Maladie or ONDAM) each year, to be integrated into the annual law on how much the NHI would be allowed to spend on drug reimbursement. Second, healthcare providers—drug companies, hospitals, private physicians, pharmacists and others—would now be pressured to behave more responsibly; the approach here was to link their income to keeping within the ONDAM limit (Hassenteufel 2003).

In 1999, the Committee was given a role to play in this policy: it would ensure that drug reimbursement spending remained within the Parliament's annual spending limit, and plan the allocation and development of reimbursement spending to that end. In sum, the

ONDAM became a reimbursement expenditures "growth rate" beyond which the Committee now had the right to impose financial sanctions on drug companies. Meanwhile, the Committee was working with drug industry representatives to help pharmaceutical companies plan how their own profits would evolve. The first framework agreement called for signing a five-year price contract to protect pharmaceutical companies from the volatility caused by government decisions. These two contradictory dynamics thus turned the Committee into a planning authority called upon to manage distribution among the various market actors of both spending on and income from reimbursed drugs. But when it came to setting and attaining its planned objective, the Committee ran up against a major obstacle: while agreement-framed price negotiations gave it considerable control over industrial behaviors, it had little control over prescribers (physicians and pharmacists), whose behaviors were regulated by agreements between them and the NHI. Thus, the Committee only really controlled one of the two health cost levers: drug price. It had little control over prescription volume or structure.

To "determine its plan," the Committee sought to project how prescription volume and supply structure would evolve in the framework of its macro-economic price negotiations with companies. To do this, it set out to determine how drug spending should evolve. In the period from 1999 to 2003, it began by converting Parliament's overall annual spending growth rate 'K' into a spending growth rate for each of the 147 therapeutic classes: after 2003, it converted Parliament's set rate into a rate for each of 65 pharmaceutical-therapeutic aggregate categories, each covering drugs deemed therapeutically equivalent. The second phase was to "assess the prospects for normal sales development" of each therapeutic class in terms of "disease prevalence trends," "public health priorities," "innovation reliability," and "the development of generic drugs" (CEPS 2002). The Committee then sought to "identify the classes whose prices were too high given currently observed sales volume" (ibid., 47). Drawing on these "normal" and "desirable" development rates by pharmaceutical-therapeutic category, the Committee then worked to balance out the table of therapeutic classes to line up with Parliament's overall rate K. Beneath the technical complexity of these procedures we can glimpse the different justice and accuracy principles structuring the Committee's missions. Clearly, their assessments aim to fit together public health objectives (gravity and prevalence of the disease in question) and market architecture (pharmaceutical innovations, generic drugs).

To do this, the Committee had two instruments at its disposal. The first was of course the prices it granted companies for their medications. It had the power to lower prices for ASMR V-rated drugs and generics. It could also include "price revision clauses" in price contracts for innovative drugs (ASMR I-III and possibly IV); these stipulated that prices would be lowered as a function of sales volumes or the arrival of new drugs. But though it was theoretically possible to lower drug price tags, doing so proved politically costly, eliciting strong hostility from drug makers:

> [The question that came up around some drugs was] is it too expensive or isn't it, compared to what it should be? So you'll tell me that if it's too expensive, all I have to do is lower the price. But it's not that simple to lower prices [he laughs]. So there were medications that we still thought were too expensive, though today, at the required dose, we wouldn't be able to bring them back down to a reasonable price

(Former Committee chair, interviewed February 2012).

The Committee's second instrument was to require drug companies who exceeded agreed limits to make end-of-year payments to the Central Agency of Social Security Institutions (Agence Centrale des Organismes de Sécurité Sociale or ACOSS). This move could be used to dissociate prices from spending regulations. The Committee identified three distinct types of drug company payments. The first was "by individual drug," for innovative drugs: here, Committee contracts tied the approved price for the drug to clauses on dose or daily treatment cost in order to "ensure that real cost per patient … lastingly complies with what was agreed with the company when the drug was first put on the reimbursement list," or to volume clauses to "ensure that overall spending on a given drug remains aligned with its medically justified 'target'" (CEPS 2002). This meant the companies had to make those payments even if, collectively, they had not overshot Parliament's rate K for NHI funding. The second type was "payments by pharmaceutical-therapeutic class," applied when reimbursements at year's end for one of those classes exceeded by over 28% the threshold set by the Committee at the start of the year. The third type was "profit-related payments," aimed to sanction companies for overshooting rate K by skimming off a percentage of all pharmaceutical company profits and turning them over to ACOSS.

This system of drug company paybacks is what enables the national healthcare system to recoup part of drug reimbursement expenses and thereby to "achieve [the Committee's] plan" without changing officially granted prices:

> If a company forces us [to pay a high price] because it's really nasty and because it's selling for a hundred in Leichtenstein, we say, "Go ahead! You want to see a hundred-euro price tag on a box [of your drug] in France? Fine, be my guest. But let's be reasonable. If volume is greater than thus-and-such, you're going to give me something back, right? And if the dose increases, you're going to give me something back, right? And if a competitor shows up, you're going to give me a lot back, right? In that case I'll accept your price tag"
> (Former Committee member, interviewed February 2014).

Clearly, the company payback system creates a distinction between the official price for a box of the given drug (a fact that allows companies to show they are getting a price consistent with those on other European markets) and the real price paid by France's NHI. This enables the Committee to keep reimbursement expenses within a certain limit. And quantitative paybacks of this sort enable it to compensate to some degree for the financial effects of prescriber behaviors by financially balancing expenses planned at the start of the year, which are based on an optimistic estimate of how prescription volumes will evolve, and real expenses observed at the end of the year, based on real change in prescription volume.

This means that the real difficulty the Committee has planning healthcare expenses is its weak control over doctors and pharmacists, whose prescription and substitution behaviors (the latter refers to replacing brand-name with generic drugs) greatly impact those expenses. This situation is not neutral for Committee-company negotiations, as some fluctuation in prescription volume can be imputed to the drug companies' strategy of promoting their products to doctors (through office visits and/or papers at

professional conferences or seminars). A Committee effort to regulate those practices by way of a charter on drug company visits to physicians cosigned with company representatives had little impact. In reality, a division of labor gradually took over during the 2000s wherein the Committee negotiated drug prices with the companies while the NHI organizations worked to change health professionals' prescription and substitution practices through agreements signed with their associations. Whereas, from 1996 to 2002, the Juppé and Jospin governments tried in vain to establish a system of financial sanctions against private physicians who exceeded the ONDAM (including requiring them to pay back anything pocketed over that limit and cutting the fixed price they could charge per patient visit), the UNCAM, headed by Fréderic van Roekeghem from 2004 to 2012, chose positive incentive instead in the form of bonuses for doctors who either stayed within healthcare spending limits or actually saved the system money. The Improved Individual Practices Contract, (Contrat d'Amélioration des Pratiques Individuelles or CAPI) offered to private physicians from 2009 to 2011, followed by the system known as Remuneration for Attaining Public Healthcare Spending Goals (Rémunération sur Objectifs de Santé Publique or ROSP), available to physicians from 2011 and pharmacists from 2012, covered a series of NHI savings objectives, including, for physicians, a fixed prescription rate for drugs in particularly expensive therapeutic classes for which generic versions existed (examples are proton-pump inhibitors or PPIs, statins, angiotensin II receptor blockers or ARBs) and, for pharmacists, a fixed generic drug substitution rate.

While the macro-economic policy of regulating healthcare expenses through Committee-company price agreements and the NHI's micro-economic policy of orienting prescription and drug substitution behaviors in connection with those prices may seem complementary, they actually worked against each other, while opening the door to protests by health professionals. To begin with, the considerable price cuts the Committee started making in 2006 and the plan to extend reference prices (Tarifs forfaitaires de responsabilité or TFR)10 to all generic drug groups in existence for over 18 months angered the professional association of pharmacists, whose profits depend directly on those prices (Nouguez 2017). In retaliation against the price cuts, the pharmacists' association threatened several times to stop substituting generic drugs for brand-name originals, even though it was generics that had accounted for rising pharmacist income since substitution was authorized in 1999. While the Committee's price-cutting policy had saved the universal healthcare fund nearly a billion euros a year since 2006 thanks to the generic drug market, it now looked as if it was turning pharmacists sour on substituting generics for brand-name drugs and thereby threatening the future development of that very market. What's more, the pharmacists' association decided to appeal to the NHI to undercut the Committee's price-cutting policy; specifically, to show the NHI that pharmacists could obtain the same savings through agreements on generic substitution goals and therefore that they, too, could become valued actors in a healthcare savings policy:

It's much simpler for the Committee to deal with the drug companies in connection with innovation: I bring out a drug, I set the innovation price, and, in exchange, a number of existing drugs come into the balance, meaning price cuts, getting them on the "generic"

10 The TFR sets the reimbursement rate for a brand-name drug and its generic at the same level as for the cheapest generic drug in that group.

lists, taking them off the reimbursement lists, etc. But me, I've got nothing to negotiate with the Committee, I've got no real quantitative data. … Well, we found a few points we could negotiate on with the NHI, and one of them was generic drugs. The TFR [reference price] [was developed] as a source of savings and in exchange for the development of generic drugs. But [the] healthcare [system] didn't want to see it implemented because they knew that [generics] would ultimately stop being a source of savings and become a source of additional expenses, and because what they really wanted was to get pharmacists and physicians involved in a long-term rather than a short-term policy like the one the Committee wanted to set up
(Excerpt from a speech delivered by the president of the French National Union of Pharmacies at the Pharmagora Salon, April 2006).

Similar tensions can be seen between the Committee's and the NHI's respective strategies for dealing with drug prescribing. In the case of proton-pump inhibitors, the NHI wanted to encourage physicians who had signed CAPIs to prescribe "generic" PPIs, rather than new brand-name ones; it was particularly against prescribing Inexium® (esomeprazole), which had been developed by AstraZeneca to undercut sales of generics of its Mopral® (omeprazole). To this end, the NHI disseminated tables to prescribers comparing the costs of what were considered therapeutically equivalent PPIs, and it conditioned bonuses for relatively low prescription rates on the prescription of generic PPIs. Meanwhile, the Committee was adopting a PPI pricing strategy aimed to neutralize the financial impact of physicians' choice of PPI:

> In our opinion, Inexium® [esomeprazole] 20mg was the equivalent of Mopral® [omeprazole] 10mg. … The Inexium® contract was a little complicated because it was based on a market forecast for proton-pump inhibitors for the next seven or eight years. So we calculated generic omeprazole-for-Mopral® substitution rates, and I think we came up with 60% generics for the first year, 70% for the second, and 80% for the third. … In sum, we would offer Inexium® 20mg the price of a mix of 20% Mopral® 10mg and 80% generic omeprazole 10mg. To the exact centime. And on the basis of this initial price, we lowered the prices originally defined in the contract, since they were having a neutral effect on the healthcare fund; that is, the fund was basically indifferent to Inexium's® arrival on the market because, overall, it came to the same amount
> (Former Committee chair, Paris, interviewed in February 2012).

Clearly, then, as physicians' association representatives pointed out to us, it did not much matter whether doctors prescribed the latest brand-name PPI on the market or the oldest, since PPI prices were set accordingly by the Committee:

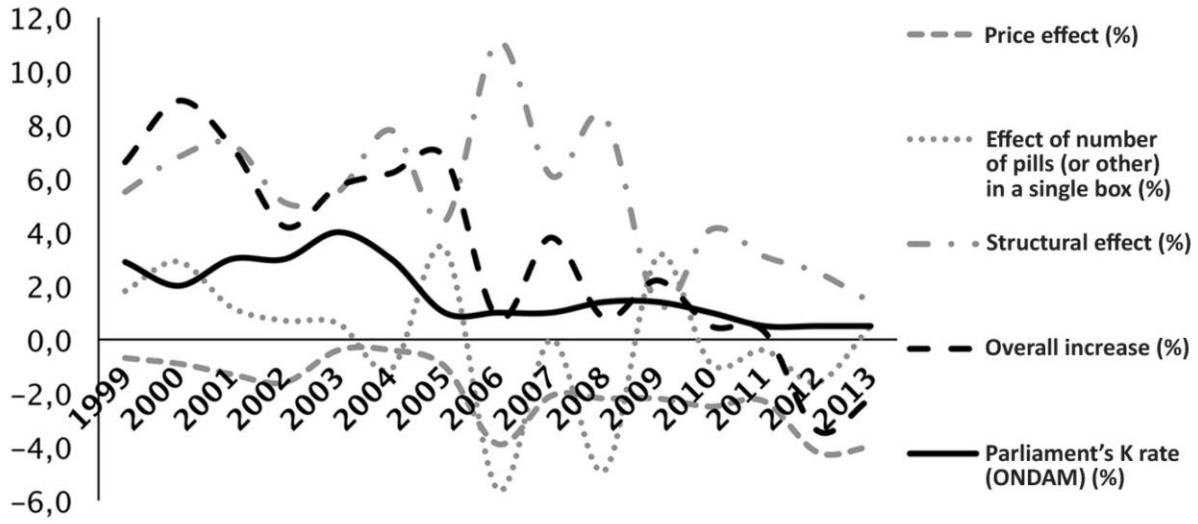
> Do you want to get critical? Then let's get really critical. Why, at the same time that Mopral® is going to be genericized, do they bring out a slight chemical variation of the molecule—I can't remember now whether it's levogyre or dextrogyre—at a much higher price that therapeutically contributes nothing? Who is it who sets the price? It's not general practitioners; it's the government. And once that price is set, there'll be an advertising campaign for generalists and gastroenterologists to get them to prescribe this new molecule that offers nothing [new]. … They ask doctors to make an effort, but it's the politicians who need to make an effort. The pharmaceutical industry lobby is what's behind it, with the problem of jobs. I can accept that. I

> understand that the government will compromise if they're being threatened with delocalization. But if they compromise, why should we be the ones blamed for the increase in prescription costs? Inexium® gets a price that's double Mopral® or generic omeprazole. It exists. What's my responsibility here? Am I supposed to automatically prescribe the generic? There's an inconsistency in all this! We're all doing drug policy, but the macro-economic dimensions escape us. I get that. But then don't tell me I can't prescribe as I see fit!
> (Head of MG France [French General Practitioners' Association], interviewed October 2006).

Despite these tensions, analysis of Committee-collected data (Figure 1) shows that it did succeed in obtaining increasing control over prescription drug spending. Three periods can be identified in this process: 1999-2005, when overall prescription drug expenses increased on average by 6%—far above the Parliament's average K rate of 2.7 for those years; 2006-2011 (with the exception of 2007), when the two rates converged, with an average real increase of 1.4% for a K rate of 1%; and 2012-2014, when real prescription drug expenditures fell by an average of 2.8% and so were far below Parliament's rate K of +0.5%.

As Figure 1 shows, pricing is the Committee's main lever for achieving its plan. With the help of low prices and the continued development of generic drugs, the average cost of medications in France fell continuously from 1999 to 2013. But prior to 2009, those price drops could not compensate for the shift to prescribing recent and more expensive drugs. Since that date, the reduced structural effect (and lower overall spending rates) have been due to the facts that fewer innovative drugs and a very high number of generic drugs have arrived on the market—a situation that has deprived physicians of prescribing alternatives to existing drugs—and, to a much lesser degree, UNCAM's CAPI contracts for improved individual healthcare professional practices.

FIGURE 1. — ***Breakdown of rising prescription drug expenditures, 1999-2013***



Source: Rapport du CEPS, 2000-2014; authors' graph.

We see that far from enabling a single entity to reconcile value governing and behavior governing, the Committee's policy actually worked to organize a schizophrenic form of government in which UNCAM sought to use Committee-set prices to govern prescriber behaviors while the Committee itself tried to use price-setting to offset the financial effects of those behaviors.

* * *

In the end, prescription drug pricing in France appears both a way of governing values through prices and a system whose use has been marked by ambivalent attitudes toward governing behaviors. During the first pricing period (1948-1993), government of values became deeper and more complex. Whereas the prices granted for drugs depended primarily at first on estimating the costs needed to develop, produce, and sell them, drug prices gradually came to be determined through negotiation between the Economic Committee on Pharmaceuticals and pharmaceutical companies. The early, relatively undifferentiated price architecture, in which drug prices were relatively homogeneous—and low—was superseded by a strongly polarized system in which new drugs with high therapeutic added value that cost several thousand and even several tens of thousands of euros, "rubbed shoulders" with generic drugs that sell for a few euros. Nonetheless, as we have shown, the more recent price architecture is not merely a reflection of relative therapeutic value (as estimated by the ASMR); it is much more complex, integrating principles of social justice (facilitating drug industry investment in France and Europe, keeping the healthcare budget balanced) and market accuracy (taking into account prices on other European markets, prices of comparable medications, and prices of other drugs in the given laboratory's portfolio).

At yet another level, the changes in pricing practices amount to so many new ways of organizing an original type of behavior governing. We have stressed how, from the 1950s to the 1990s, prescription drug pricing was purely a matter of monetary logic: to ensure access to all patients, keep healthcare costs within limits, and regulate the development of the drug industry, the French public authorities chose to handle prescription drug pricing in place of the market, turning the matter over to expert committees and bureaucrats whose job was to estimate a "fair price" on the basis of drug company production and R&D costs. But that policy gave rise to a contradictory situation in which the state governed prices but had no real control of drug sale volumes and structure, which were dependent instead on drug companies' influence over private physicians. Given that context, the creation of the Committee and the practice of agreement-framed pricing negotiations with drug companies could well be understood as the nth stage in a general process of price liberalization and market deregulation—precisely what Jean Marmot had in mind. However, our analysis of how the Committee operated has led us to the opposite conclusion: the doctrine applied from the late 1990s aimed not so much to govern behaviors through prices as to integrate a representation of market actor behaviors into the pricing process. While the framework of Committee-company agreements put an end to unilateral state pricing, granting drug companies the right to examine decisions and negotiate prices, it symmetrically ended those companies' virtually unilateral control over prescribing by giving the Committee the right to inspect and negotiate prescription volumes and structure, and therefore to exert considerable control over prescription drug spending. Despite several attempts, the

Committee ultimately failed to obtain greater control by governing market actors more deeply or fully through prices. For while prescription volume and structure have become key components in price setting, the Committee has not tried to use this as a means of regulating and orienting prescriber behaviors; on the contrary, it has sought to offset the effects of prescription volume and structure on overall spending. Last, while Committee-drug company price negotiations have "adjusted" to prices on other European markets and the degree of competition within the various therapeutic classes, the Committee has not aimed in return to use prices to "adjust" drug maker behaviors. It is as if the Committee governed prices at a distance from the market, working to internalize and offset market price organization without intervening in market operation itself.

This analysis clarifies the difficulties that Committee members have had answering criticism against the "unjust" nature of some drug prices and the "opaque," "complex" character of drug pricing altogether. Indeed, the issue is not so much to determine the "fair price" for each drug as to determine the "fair" price architecture: one that would divide up Parliament's budget allocations for prescription drugs among pharmaceutical companies while establishing a "just and accurate" compromise between two divergent approaches: one focused on the general interest and the other on market organization.

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REFERENCES

Arrous, Jean. 1990. "Socialisme et planification: O. Lange et F. A. von Hayek." *Revue française d'économie* 5 (2): 61-84.

Aspers, Patrick and Jens Beckert, eds.2011. *The Worth of Goods: Valuation and Pricing in the Economy.* Oxford: Oxford University Press.

Barrey, Sandrine. 2006. "Formation et calcul des prix: le travail de tarification dans la grande distribution." *Sociologie du travail* 48 (2): 142-58.

Beckert, Jens, and Christine Musselin, eds. 2013. *Constructing Quality: the Classification of Goods in Markets*. Oxford: Oxford University Press.

Bergeron, Henri, and Constance A. Nathanson. 2017. "Crisis and Change: the Making of a French FDA." *The Milbank Quarterly* 95 (3): 634-75.

Boltanski, Luc, and Arnaud Esquerre. 2016. "L'énigmatique réalité des prix." *Sociologie* (1): 41-58.

Boltanski, Luc, and Laurent Thévenot. 1991. *De la justification: Les economies de la grandeur.* Paris: Gallimard. Published in English as *On Justification: Economies of Worth*, translated by Catherine Porter (Princeton: Princeton University Press, 2006).

Bonah, Christian, and Jean-Paul Gaudillère. 2007. "Faute, accident ou risque iatrogène? La régulation des événements indésirables du médicament à l'aune des affaires Stalinon et Distilbène." *Revue française des affaires sociales* 3: 123-51.

Carpenter, Daniel P. 2004. "Protection without Capture: Dynamic Product Approval by a Politically Responsive, Learning Regulator." *American Political Science Review* 98 (4): 613-31.

Chauveau, Sophie. 1999. *L'invention pharmaceutique. La pharmacie française entre l'État et la société au XXè siècle.* Paris: Institut d'édition Sanofi-Synthélabo.

Chauvin, Pierre-Marie. 2011. "Architecture des prix et morphologie sociale du marché. Le cas des Grands crus de Bordeaux." *Revue française de sociologie* 52 (2): 277-309.

Chesnais, François. 1985. "L'industrie pharmaceutique dans la crise." *Revue d'économie industrielle* 31: 79-99.

Comité Économique des Produits de Santé. 2000-2014. *Rapports d'activité.* Paris: CEPS.

Comité Économique des Produits de Santé. 2015. *Données statistiques et questions-réponses.* Paris: CEPS.

Dorion, Mireille, Didier Lacaze, and Paul Gaüzere. 1994. *Rapport sur le médicament générique et le remboursement forfaitaire.* Paris: Inspection générale des Affaires sociales.

Dubuisson-Quellier, Sophie, ed. 2016. *Gouverner les conduites.* Paris: Presses de Sciences Po.

Dumez, Hervé, and Alain Jeunemaître. 1989. *Diriger l'économie. L'État et les prix en France, 1936-1986*. Paris: L'Harmattan.

Dupuy, Jean-Pierre, and Serge Karsenty. 1974. *L'invasion pharmaceutique*. Paris: Le Seuil.

Finez, Jean. 2014. “La construction des prix à la SNCF, une sociohistoire de la tarification. De la péréquation au *yield management* (1938-2012).” *Revue française de sociologie* 55 (1): 5-39.

Foucault, Michel. 2004. *Sécurité, territoire, population. Cours au Collège de France (1977-1978).* Paris: Gallimard-Le Seuil. Published in English as *Security, Territory, Population: Lectures at the Collège de France, 1977-78*, translated by Graham Burchell (Palgrave Macmillan, 2009).

Hassenteufel, Patrick. 2003. “Le premier septennat du plan Juppé: un non-changement décisif.” In *Carnet de santé de la France 2003*,” edited by Jean de Kervasdoué, 121-47 (Paris: Dunod).

Hauray, Boris. 2005. *L’Europe du medicament. Politiques, expertise, intérêts privés.* Paris: Presses de Sciences Po.

McCabe, Chris, Karl Claxton and Anthony J. Culyer. 2008. “The NICE Cost-Effectiveness Threshold: What it is and What that Means.” *Pharmacoeconomics* 26 (9): 733-44.

Muniesa, Fabian. 2000. “Un robot walrasien. Cotation électronique et justesse de la découverte des prix.” *Politix* 52 (4): 121-54.

Musselin, Christine, and Catherine Paradeise. 2002. “Le concept de qualité: où en sommes-nous?” *Sociologie du travail* 42 (2): 255-80.

Nouguez, Étienne. 2016. “Gouverner la concurrence par les prix: la politique française des médicaments génériques.” In *Gouverner les conduites*, edited by Sophie Dubuisson-Quellier, 229-62. Paris: Presses de Sciences Po.

Nouguez, Étienne. 2017. *Des médicaments à tout prix. Sociologie du marché français des médicaments génériques*. Paris: Presses de Sciences Po.

Pauriche, Patrick, and Frédéric Rupprecht. 1998. “Le secteur pharmaceutique, un secteur aux multiples enjeux.” *Économie et statistique* 312-313: 7-20.

Posner, Richard. 1971. “Theories of Economic Regulation.” *The Bell Journal of Economics and Management Science* 5 (2): 335-58.

Roux, Sébastien. “La circulation internationale des enfants.” In *Marchés contestés. Quand le marché rencontre la morale,* edited by Philippe Steiner and Marie Trespeuch, 29-61. Toulouse: Presses universitaires du Mirail.

Sermet, Catherine. 2007. “La prise en compte de l’innovation thérapeutique dans les politiques de prix et de remboursement des médicaments.” *Revue française des affaires sociales* 3: 319-41.

Sorasith, Christine, Sylvain Pichetti, Thomas Cartier, Nicolas Célant, Laure Bergua, and Catherine Sermet. “Déterminants de l’écart de prix entre médicaments similaires et le premier entrant dans une classe thérapeutique.” IRDES, *Document de travail* 43.

Stark, David. 2009. *The Sense of Dissonance: Accounts of Worth in Economic Life.* Princeton: Princeton University Press.

Steiner, Philippe. 2010. *La transplantation d'organes: un nouveau commerce entre êtres humains?* Paris: Gallimard.

Thomas, Lacy Glenn. 1994. "Implicit Industrial Policy: the Triumph of Britain and the Failure of France in Global Pharmaceuticals." *Industrial Corporate Change* 3 (2): 451-89.

Vatin, François. 2013. "Valuation as evaluating and valorizing." *Valuation Studies* 1 (1) : 31-50.