

Rival Institutional Dependencies within Pharmaceutical Policy  
A Bayesian Process-Tracing Analysis

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# 1 Introduction

For decades, the initial and evolving impacts of regulatory bodies upon business activities are important, if not the main, concerns of scholars working on the very rationale of regulating industries. Most of them see regulation as the corrector of the market failures which jeopardize the spontaneous mechanics of the coordination of economic agents (see for example Viscusi, Vernon and Harrington 2005). Aware that in many situations, regulatory policies are set up outside this common framework, other Economists as well as Political Scientists have also tried to explain the changes and enforcement challenges which have led to the development of these "unnecessary" institutional mechanisms. Though perceptible since the first criticisms of traditional Public Interest Theories of Regulation (Coase 1959, Huntington 1952), these reflexions gained significant renewed impetus following George Stigler's famous essay on Regulatory Capture (1971). In this influential contribution, the Chicago Economist developed the idea that, in most cases, regulation is in fact a product of the political work of the regulated industry, and a way for a group of dominant firms to secure acquired positions from competition of potential challengers. According to him, it is more advantageous for dominant firms within an industry to support the development of favorable regulation rather than obtaining direct subsidies: in the first instance, a group of firms will gain sustainable benefits whereas in the second financial support will at best be only be a temporary solution against the threat of new competitors. That is why regulation remains the main target of industry representatives when pressuring elected officials, civil servants or even bureaucrats themselves. Correlatively, the mandate of regulation to serve the public is most of the time a smokescreen that hides its primary function: protecting the dominant interests that led to its development.

Since Stigler's article, both theoretical and empirical contributions have considerably refined these initial insights. Moving from a firm-centered approach, Laffont and Tirole (1993) introduced for example a complete model of government decision-making wherein the behaviors of firms to frame or to design regulatory bodies are directly placed within the policy-process. But despite the advances offered by a diversification of approaches, Stigler's ideas that the rationale for regulation had to be searched for in the interests actually served by a regulatory body acted as a powerful, cognitive frame shaping – sometimes implicitly – the way scholars addressed the issue of the regulation of economic activities or studied the way bureaucrats interact with special interests (Moe 1985, Noll 1989). Within this literature, a traditional correlational framework is used for the diagnosis of the capture of a public organization. Actor preferences are postulated anteriorly to any analysis. Then, inferences are made on the basis of the satisfaction of wishes from the regulated group by the regulator, or by elected officials if the study is focused on the creation of a new bureaucratic entity. If a positive association/correlation is found, authors will generally conclude that the regulator has been deliberately *captured* by private interests.

In a recent book edited by Carpenter and Moss (2013), some scholars expressed their opposition to this established conception, considering it as excessively binary. Noting that the "Capture Theory" travelled well beyond academic circles, influencing media coverage of business activities or affecting the perception of the regulation by the public, these authors questioned its foundations and found in it a great deal of shortcomings<sup>1</sup>. First, these editors argue in their introduction that this approach lacks a clear conceptual architecture. Despite the large number of publications aiming at demonstrate the corruption of public bodies by private actors, none of these define precisely what is considered as being "Regulatory Capture" or "the Public Interest". More essentially, according to Carpenter and Moss none

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<sup>1</sup>As mentioned by Lodge (2014), and perhaps surprisingly, Regulatory Capture Theory has received somewhat less attention from European Political Scientists than from their American counterparts. This situation contrasts with the worldwide interest of Economists for such a conception, and by media coverage of the "corruption" of public bodies, relatively similar on each side of the Atlantic.

of the concepts used are mobilized as the counterfactual of others, just as the intentions of each actor are empirically understudied in these analyses. Methodologically, they identify a contrast between the subtlety and the refinement of existing mathematical models of regulatory capture and the relatively simple conception of causality seeming to guide applied researches in the field, where a convergence between the frequency distribution of (presumed) interests between several actors is considered enough to demonstrate a failure, as well as concluding by calling for the *deregulation* of the sector considered. Consequently, and despite this approach being given the dignity of a theorem by many scholars and commentators, these authors believe "that far more evidence is needed to make an accurate diagnosis of capture". Considering the issue of the relation between business and political spheres as critical, they advocate a strengthening of these approaches through a much richer conceptualization of regulatory capture, and by exploring this "economics of influence" by embracing its multiple forms and complexity. To do so, they insist on the need to take a more careful look at what actually happens in the course of regulatory practice, underlying the crucial importance of historical, long-term trends and in-depth studies. The debate between classic Regulatory Capture Theorists and the alternative view developed by scholars gathered around Carpenter and Moss raises many theoretical issues. However, it also raises (and perhaps more fundamentally) a methodological one around the right way to "detect and measure" regulatory capture, in Carpenter's words. In this respect, the oppositions between the two different approaches may be easily expressed through a distinction between a classic statistical "correlational" conception of inference, and another more focused on the complex combinations of different patterns, attached to a rigorous conception of causality, mainly asserted in probabilistic terms. Within these two frameworks, various methodological tools can be used and mixed. More suited for econometric and regression analysis, the first is easier to apply to large samples, or to many decisions if a single bureaucracy/industry is examined. More data-hungry as regards detailed empirical material or complex sets of historical evidence, the second is typically driven by within-cases analysis<sup>2</sup>.

Literature on Regulatory Capture, however, remains largely dominated by the first paradigm. Consequently, and in many policy areas, researchers wishing to test the approach developed by Carpenter et al. will often face existing results that show that a regulatory body is actually captured by industrial or special interests. Difficulties arise where numerous cases are analyzed, and when causal links are searched on just a small part of this sample. Three main problems emerge:

1. **Positioning existing data within one's analysis:** If large- $n$  data are based on robust statistical findings, how can we exploit it in the small- $n$ , case-study analysis? Do we need to separate each of the two approaches or can we use the first to help us to make better inferences for the second?
2. **Case Selection:** How should one select specific cases using existing statistical observations? What are the implications of each of the potential selection processes for research design?
3. **Generalization of "within-case" results to "cross-case" sample:** If causal links proving regulatory capture are not found (and consequently, contradict statistical results), how far can we expand some of our findings from a limited number of cases to some of those of the large- $n$  study?

The main goal of this paper is to demonstrate that recent advances in the field of Bayesian Integration of Qualitative and Quantitative Data (hereinafter BIQQ, see Humphreys and Jacobs 2015, Bennett 2008, 2015) can provide an elegant framework to meet some of these challenges. To do so, the paper extends previous quantitative research undertaken on the relations between the institutionalization of

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<sup>2</sup>Notable exceptions to this rule can be found. See for example Carpenter (2004).

drug reimbursement agencies and the weight of the pharmaceutical industry in 17 countries. These structures were set up in order to evaluate new medicines entering the market on the basis of clinical and economic inputs. A successful passing of this "gold standard" (Maor 2007, Benoît 2015) is a precondition for the reimbursement of these products - i.e, their effective consumption. Positioned at the crossroad of rival interests (pharmaceutical industry, patient groups, public or private reimbursement organizations), these bodies can thus influence the career of a treatment in a given country. Our initial empirical results revealed an inverse relation between the development of this type of public organization and the prosperity of pharmaceutical groups operating on their soil, suggesting a plausible pernicious relation between firms and regulators (Benoît and Gorry 2013, 2014). In order to go beyond this correlation, additional data analysis was undertaken in two comparable countries, selected after a comparison of statistical observations through a Gaussian Mixture Model (GMM). Using quantitative results to establish our *prior* confidence on the capture hypothesis, qualitative materials (documentary analysis and semi-structured interviews) were then collected under a research framework following a Process-Tracing approach, consistent with the theoretical frame built by Carpenter and Moss. The results obtained in this way demonstrate that the causal role played by drug companies to limit the scope of HTA agencies was less important than the influence of diverse *institutional dependencies* (Roger 2014). In all *likelihood*, and despite the large- $n$  data, we find a very weak *probability* that drug reimbursement agencies have been the victims of the capture of the policy-process by manufacturers. However, and as already demonstrated by Humphreys and Jacobs, we also suggest that these findings can only have a modest contribution given our sample, and as such are insufficient to infer findings regarding all large- $n$  data. In the light of this conclusion, some indications for further research are presented and discussed.

The paper is divided as follows: first, we briefly introduce the approach of regulatory capture as developed by Carpenter et al., and, largely inspired by Humphreys and Jacob (2015), we develop a simple mathematical framework for Bayesian qualitative causal inference that is consistent with Bennett (2006, 2008, 2015), Collier, Brady and Seawright (2006), and, in some respects, Zaks (2011). Then, we present our quantitative data and analyze our statistical observation through a Gaussian Mixture Model, before explaining and justifying our strategy for case selection. In part 3, the Bayesian Process Tracing approach is applied to the French and British cases, mainly on the basis of 87 semi-structured interviews led in the two countries. The last part of this working paper is also the most provisional: in line with the recommendations of Humphreys and Jacobs, we attempt to generalize our case-study results as regards the large- $n$  sample. Central for BIQQ, this point is complicated here by the important volume of qualitative data and by the proportion of our sample, quite small, given the number of cases examined via Process-Tracing.

## 2 Theory

The development of one or several regulatory bodies within a policy area is a classic case of *institutionalization*<sup>3</sup>. It is also a frequently used way to examine whether a bureaucratic entity is the result of direct pressures from industrial or special interests. Indeed, many authors argue that the capture of regulatory agency is deeply rooted in its main *function* within a sector, that must consequently be found in the rationale for its setting up (see for example Hazlett 1990, 1998). Conceptually, it raises the issue of statutory capture, i.e. the capacity of particular interests distinct from public or general interest to significantly impact the legislature responsible for the institutionalization process in order to protect,

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<sup>3</sup>Defined as the structuration of "sets of norms, rules and conventions" (Hall and Taylor 2009).

maintain or reinforce its position within a given sector (Carpenter and Moss 2014, Ch. 3). Public Interest, Industry Interests and Special Interests are partly autonomous from the main actors that are likely to support them, respectively Legislature, Industry, and (possibly) a third group (distinct both from the Legislature and Industry, can be for example a patient organization). Public Interest and Industry or Special Interest conflict when their proper interests do not coincide. This situation may lead to a potential opposition between the different actors - but not necessarily. Through *political work* (Jullien and Smith 2008) private actors can however try to have an impact on legislature. In this context, a capture mechanism is an "undue or disproportionate influence whereby the Industry wishes the legislature to choose its preferences over the Public Interest". Capture occurs when legislature, when implementing a regulatory regime, deliberately and repeatedly choose industrial or special interest over public interest ("deterministic capture"), or, in probabilistic terms, "when the legislature's choice of [Industry]/[Special] comes with a higher probability with capture than without". Thus:

$$P[L = I|C] > P[L = I] \sim C \tag{1}$$

and/or

$$P[L = W|C] < P[L = W] \sim C \tag{2}$$

Where [W] denotes the Public Interest and [I] the Industry. Obviously, [I] can be replaced by special interest [S] (Carpenter and Moss, Ch. 3). The nature of [W] must be empirically established or specified before the analysis, and can be hardly different across time and space. It may coincide with the rhetoric of the legislature under study even if in practice, elected officials may use these principles to legitimize a choice different from that of the public - strategically or not. If we agree with Carpenter to adopt a Republican conception of Public Interest, where the interest of the people is considered as being superior to that of any other actor, we think also that our conception of [W] must not be too prescriptive. In other terms, we have to integrate a certain degree of plasticity in our understanding of [W]. A more flexible strategy, privileged in this contribution, consists in abandoning the purpose of a full conceptualization of [W] in focusing on actors' interaction through a historical perspective. In this context, [W] is seen in negative terms, and we focus on circumstantial evidences of capture that will make sense with long-term trajectories within a given regulatory area. Thus, jeopardizing or preservation of [W] is deduced from interactions between conflicting interests. As counterfactual, *intents* of [I] or [S] to take control over [W], the legislature or to impact the decision-making process have to be specified. Indeed, and in many contributions, scholars interpret the intents of the different actors without any clear investigations, and make inference on the basis of the coincidence of their presumed interest. However, comparative analysis of firms' political preference and behaviors reveal a great diversity of institutional relationships between Industry and Legislature amongst sectors (Itçaina, Roger and Smith forth., Jullien and Smith 2014, Smith 2009). On this basis, capture mechanisms need to be observed and explicitly demonstrated. Again, a positive association/correlation is not sufficient to diagnose a formal, deliberate preference for [I] or [S] by the legislature rather than for Public Interest. Inference has to be express through rigorous causal proofs. Thus, the intent of particular interests, or an empirically observable capture mechanism, are not enough to affirm regulatory capture under this framework. To draw such a conclusion, a clear impact on the policy process has to be determined (for example, the design of an agency with statutory features or a decision-making approach explicitly in favor of regulated interest). We shall return on this

crucial methodological aspect on the next section. Finally, and contrary to standard Regulatory Capture Theory approaches, Carpenter and Moss consider that a binary conception (captured/uncaptured) of such a phenomenon contradicts many empirical examinations of what happens actually in regulatory practice. Whether apparent or not, regulatory capture occurs by degree: never completely absent, it can also have solely a minor impact, and does not prevent bureaucrats or regulator to serve the Public. Although a rare outcome, *strong capture* "violates the public interest to such an extent that the public would be better served by either (a) no regulation of the activity in question – because the benefits of regulation are outweighed by the costs of capture, or (b) comprehensive replacement of the policy and agency in question" (Carpenter and Moss 2014 Introduction). In this respect, and when studying the influence of particular interest on a legislature, scholars need also to define *how* and to *what extent* regulatory capture prevails in a sector.

Put simply, this theoretical framework lends great importance to the dynamic of *interests*. However, and according to the work of many Political Economists (see for example Hay 2004) this term is here used in a very different way than it is by rational choice institutionalists or by standard approaches to Regulatory Capture. We think that interests composition, structured by ideas (Gofas and Hay 2010), values (Smith 2015), and on the way each individual or collective actors perceive his/her or its proper interests constitute the major part of the explanation of such a phenomenon. Investigations on the content of the shaping of the different interests are thus a key-point of this pluralistic, far more rich conception of Regulatory Capture. In sum, this approach implies "1) to posit a defensible model of public interest, (2) to show action and intent by the regulated industry, (3) to demonstrate that ultimate policy is shifted away from the public interest and towards industry interest".

In practice, empirical research on Regulatory Capture are dominated by the standard, classic methodologies developed as an extension of Stigler's writings. Scholars seeking to determine whether a regulatory regime is dominated by the interest of [I] or [S] over [W] will quite often face existing quantitative results, based most of the time on large- $n$  samples. If, as described previously, this empirical material is not sufficient to diagnose a formal capture (even less to identify its type), we think that such data should not be rejected for the research design of further, small- $n$  studies. In the context of an existing statistical relation between  $X$  and  $Y$ , where  $X$  denotes [I] or [S] and  $Y$  a reform of a regulatory regime by a legislature, the application of our theoretical framework consists in an investigation on whether  $X$  caused  $Y$ , i.e., on whether Industry succeeded in pressuring the legislature to choose [I] over [W]. Such formulation clearly echoes theoretical as well as more empirical reflexions around qualitative methodology, and on the way in-depth studies should be used to generate causal inferences beyond statistical associations (Hall 2003). Despite the diversity of research practices under this label (Kay and Baker 2015), Process-Tracing, as a technique "of looking for the observable implications of hypothesized causal processes [...] [at] a lower level of analysis than that of the proposed theoretical explanations" (Bennett 2008) constitutes a valuable tool to address this type of issue. Based on the search for clues to test causal hypothesis, keen to provide multiple, competing historical explanations to valid them, Process-Tracing appears as particularly well suited to examine regulatory capture phenomenon in all of its complexity. More recently, some scholars (Bennett 2008, Beach and Pedersen 2013, Rohlfing 2013) noted its proximity with the Bayesian approach to causal inference. In our view, equating Process-Tracing in Bayesian terms can help researchers working on small- $n$  case study data dealing with large- $n$  results on at least two main aspects, for which we provide a mathematical framework in the next section:

1. **Large- $n$  observations as Prior:** existing statistical observations showing an  $X$ - $Y$  relationship and experts' opinion act as our *prior* degree of confidence on the causal hypothesis ;
2. **Causal Process observations as clues:** to determine whether a regulatory regime has been

captured by [I] or [S], within-case evidences are *clues* allowing us to form our *posterior belief* about the *probability* of the hypothesis, conditionally to our *prior*.

### 3 Model

The baseline model developed in this section is an application of that developed by Humphreys and Jacobs (2015) for Bayesian Causal Inference in the context of Process-Tracing. As these scholars already provided numerous examples of such an approach in earlier versions of their theoretical paper, we directly express their framework in the terms of our case-study. This operation can be considered as the first-step to Bayesian Integration of Quantitative and Qualitative data (hereinafter BIQQ) for which this working paper provides elements in its last section. Issues related to Case-Selection are treated in the next one.

#### 3.1 The Problem of Type Ambiguity

Let ( $X$ ) denotes a situation in which some countries in a population are observed to have *strong* pharmaceutical groups operating on their soil while others have not. Assume that, subsequently, we observe which countries develop a *strong* Health Technology Assessment (HTA) Agency and which do not ( $Y$ ). In this paper, the development of a HTA Agency with limited prerogatives (by the pharmaceutical industry or not) is considered as being the positive result ( $Y = 1$ ). Let us further assume that each individual case belongs to one of four unobserved "types", defined by the potential effect of pharmaceutical groups on the design of a HTA Agency in a given country:

1. **adverse**: Those who developed a strong HTA Agency because of successful pressure by the pharmaceutical industry ;
2. **beneficial**: Those who developed a HTA Agency whose prerogatives were successfully limited by the pharmaceutical industry ;
3. **chronic**: Those who did not develop a strong HTA Agency, irrespective of the attempts at pressure from the pharmaceutical industry ;
4. **destined**: Those who developed a strong HTA Agency, irrespective of pressure from the pharmaceutical industry.

Thereafter, we will use the letters,  $a$ ,  $b$ ,  $c$ ,  $d$ , to denote these causal types and  $\lambda_a$ ,  $\lambda_b$ ,  $\lambda_c$ ,  $\lambda_d$ , to denote the relative share of these types in the population. In line with our theoretical framework, we consider the types  $a$  and  $b$  as *regulatory capture* ones, where the pharmaceutical industry, for several reasons, successfully impacted upon the policy process to such an extent that the statutory features of a new bureaucratic entity are in line with its interests. Consequently, we do not consider *a priori* that the development of a strong HTA Agency automatically implies that a legislature has privileged [W] over [I] (causal type  $a$ ). However, and symmetrically, this lens also takes into account cases where a legislature develops a weak, or limited HTA agency without deliberately favored [I] over [W] (causal type  $c$ ). The main difficulty arising when comparing different countries and/or institutional situations is that the meaning of [W] may considerably vary across cases - a point that need to be integrated and contextualized within the analysis. As drawn from Rubin (1974) by Humphreys and Jacobs, these types differ in their "potential outcomes"  $Y$ , they would have depending on  $X$ . Thus,  $Y(x)$  denote a case or type's potential outcome when  $X = x$ . In this context, the potential outcomes...

1.  $Y(0) = 1, Y(1) = 0$  for type  $a$  ;
2.  $Y(0) = 0, Y(1) = 1$  for type  $b$  ;
3.  $Y(0) = 0, Y(1) = 0$  for type  $c$  ;
4.  $Y(0) = 1, Y(1) = 1$  for type  $d$ .

... are illustrated in Table 1, where [L] denotes the legislature, that can either act consistently with the public interest or the industry interest (respectively, and as previously, [W] or [I]).

	adverse Effect	beneficial Effect	chronic Effect	destined Effect
L = I	HTA Agency +	HTA Agency -	HTA Agency +	HTA Agency -
L = W	HTA Agency -	HTA Agency +	HTA Agency -	HTA Agency +

Table 1: Potential Outcomes

As summarized by Humphreys and Jacobs, the effect for a case, here of the pharmaceutical industry, is defined as "the difference in potential outcomes for that case between the treatment and control conditions"  $Y(1) - Y(0)$ . This common way of modeling the problem raises the "*the fundamental problem of causal inference*" meaning in practice that we can only observe  $Y(1)$  or  $Y(0)$  for any given case - not the differences between each of these quantities, i.e., the effect of the political work of the pharmaceutical industry on the design of the different HTA Agencies, defined previously as the *type* of each individual cases. Reproduced from Humphreys and Jacobs (2015), Table 2 displays the ambiguity that we face about the type of a case given an observation of  $X$  and  $Y$  for that case.

	$Y = 0$	$Y = 1$
$X = 0$	$b$ or $d$	$a$ or $c$
$X = 1$	$a$ or $d$	$b$ or $c$

Table 2: The fundamental problem of type ambiguity

It should be noted that a case can only involve one element of  $a, b$  and one element of  $c, d$ . For example, if we observe a country with a strong pharmaceutical industry that has developed a HTA agency with very little capacities to regulate the market for health products, we do not know whether this weak HTA agency has been set up because of the capture of the legislature by the manufacturers ( $b$  type) or if it would have been weak in any case ( $c$  type). In the next section, we apply this conceptualization to Process-Tracing, expressed in Bayesian terms.

### 3.2 Bayesian Process-Tracing

When we try to find causal-process observations on the basis of correlational data, a Bayesian approach to Process-Tracing can be a valuable tool to maintain an equilibrium between the formalization required to produce strong inferences and the need to preserve the flexibility of interpretations offered by the use of qualitative material. As already stated by Kreuzer (2015), Bayesian Process-Tracing makes two



basic claims, 1) that "not all hypothesis are created equal", and 2) that "hypothesis' quality affects the confidence we can have in the inferences drawn from evidence". Inference, in this context, is based on the collection of *clues* (Collier, Brady, and Seawright's 2004) "that will be observed with some probability if the case is of a given type and that will not be observed with some probability if the case is not of that type" (Humphreys and Jacobs 2015). Put differently, and under this paradigm, we begin with a *prior* expressing our confidence about the probability that a hypothesis is true. Additional data collected allow us to form our confidence *a posteriori* on the probability that this hypothesis is true. In fact, Bayes' rule is deduced from the rule of composition of probabilities, a fundamental axiom of probability theory: if  $A$  and  $B$  are two events, this rule implies that the probability  $P(A, B)$  to observe both  $A$  and  $B$  can be written as:

$$P(A, B) = P(A/B).P(B) = P(B/A).P(A) \quad (3)$$

Where  $P(A/B)$  is the probability to observe  $A$  knowing  $B$  has been observed and  $P(B/A)$  is the probability to observe  $B$  knowing  $A$  has been observed. As noted by Amossé, Andrieux and Muller (2001), Bayes' rule is simply a particular form of writing this twofold equality:

$$P(A | B) = \frac{P(B | A) P(A)}{P(B)} \quad (4)$$

Where  $A$  denotes our hypothesis, problematized here as our belief on one or several parameters of interest and  $B$  denotes a particular realization of new data. Our posterior belief derives from three considerations. The *likelihood* ("how likely are we to...")  $P(B | A)$ , in other terms, the probability to observe this data if our hypothesis is true; our probability  $P(B)$  to have observed these data regardless of whether the hypothesis is true or false. Finally, our posterior belief is conditioned by our level of prior confidence  $P(A)$  in the hypothesis. Bayesian Process-Tracing can be easily formalized under this framework. To use an example similar to that developed by Humphreys and Jacobs, suppose that we already have  $X, Y$  data on one country that set up a HTA agency. We know that this country possesses a pharmaceutical industry which strongly contributes, say to the national income ( $X = 1$ ) and that the HTA agency has been developed with very limited capacities to control this market ( $Y = 1$ ). How can we determine whether  $X$  caused  $Y$ ? By applying the modeling proposed by Humphreys and Jacobs, answering this question implies to follow five steps: defining our parameters, specifying our prior beliefs about the parameters, defining the likelihood function, assessing the probability of the data and deducing inferences.

**Parameters.** When we only have correlational data on a case and as stated above, only two of the four potential causal types have been rejected. The central task of Process-Tracing in this context is to determine, by collecting additional information, what is the causal type of a case amongst remaining possibilities. Clues are then searched on a within-case basis, leading us to refine our prior confidence on the probability that rival hypothesis are true or, more formally, likely. The variable  $K$  is used to denote the outcomes of the search for one or several clues, with  $K = 1$  indicating "that a specific clue (or collection of clues) is searched for and found, and  $K = 0$  indicating that the clue is searched for and not found" (Humphreys and Jacobs 2015).  $j \in [a, b, c, d]$  refer to the type of an individual case and our

hypothesis, a belief about  $j$  for the case examined or, more precisely, whether the case is a  $[a, b, c, d]$  or a  $[a, b, c, d]$  (alternative hypothesis). Here, the parameter of interest is thus the causal type.

**Prior.** We assign a prior degree of confidence to the hypothesis  $P(A)$ , for example, in the hypothesis that a country with a strong pharmaceutical industry ( $X = 1$ ) and that has set up a weak HTA Agency ( $Y = 1$ ) is a  $b$ .

**Likelihood.** Let  $(P(K = 1 | A))$  denote the likelihood, i.e the probability to find a clue if the hypothesis is true. The probability is a function of the case examined causal type. We note  $\phi$  the probability to find a clue for a causal type  $[a, b, c, d]$ . For example,  $\phi_b$  express the probability of observing the clue for a case of  $b$  type ( $P(K = 1 | j = b)$ ) and  $\phi_c$  the probability of observing the clue for a case of  $c$  type ( $P(K = 1 | j = c)$ ). Differences between these probabilities offer to provide clues with "probative values" (Humphreys and Jacobs, 2015), in other terms, improving our learning concerning the causal type of the case examined. In the context of Process-Tracing, the belief to find clues from different process potentially linking  $X$  to  $Y$  come from existing theories or proofs collected by other researchers. For example, some scholars established that the development of regulatory agencies with certain statutory features could have been a way for governments to set up an "implicit" industrial policy in favoring national firms through these mechanisms (Thomas 1994). If we believe this hypothesis is true, we would consider identification of clues related to it, or confirming it as highly probative for  $a$  or  $b$  types (industry who successfully pressured a legislature) but weakly probative for  $c$  or  $d$  types (where an agency, regardless of its design, is created whatever the attempts from the manufacturers are). In the context of a qualitative research led from known quantitative data (the statistical correlation/association  $X, Y$ ) the likelihood must also reflect the modalities of case-selection (we shall return on this point in the next section).

**Probability.** Considered as the probability  $P(K = 1)$  of observing a clue if we look for it in case, regardless of its type. More formally, "it is the probability of the clue in a treated case with a positive outcome". In our example, where the case examined can solely be a  $b$  or a  $c$  type, we calculate the probability from  $\phi_b$  or  $\phi_c$ , jointly with our prior beliefs "about how likely an  $X = 1, Y = 1$  case is to be a  $b$  or a  $c$  type" (Humphrey and Jacobs 2015).

**Inference.** Bayes' rule is now applied to describe our learning resulting from Process-Tracing observation. If we find a clue that we are looking for for our case, our posterior belief in the hypothesis under which our case is a  $\phi_b$  increases in function. Thus:

$$P(j = b) | K = 1) = \frac{P(K = 1) | j = b)P(j = b)}{P(K = 1)} = \frac{\phi_b P(j = b)}{\phi_b P(j = b) + \phi_c P(j = c)} \quad (5)$$

Under a Bayesian framework, Process-Tracing is conceptualized as a criteria offering to estimate the probability to find  $K$ , thus  $(K = 1)$  or  $(K = 0)$  for different causal types. Then, this approach will allow us to better hierarchize Van Evera's causal tests (Van Evera 1997) - knowing the probabilities associated with  $\phi_a, \phi_b, \phi_c$  and/or  $\phi_d$ . Each of these tests (smoking gun, hoop, straw in the wind, doubly decisive) will have thus a different probative value, depending on our prior belief. This baseline model constitutes a first, simple expression of Process-Tracing in Bayesian terms. It helps scholars to determine the causal type of a case on the basis of probative clues. As stated by Humphreys and Jacobs, a perfect Bayesian approach would consist in a formal integration of our degree of confidence in the clues and our questioning on a case's causal type when estimating the likelihood, in defining the hypothesis as a vector  $\theta$  that would include both the case causal type and the corresponding values  $\phi$ . In this context, our

prior belief is defined as a probability distribution  $p(\theta)$  over  $\theta$ . Mathematically more demanding, this approach is also more rigorous, and would allow for a better positioning of qualitative causal inferences regarding quantitative analysis led on a larger scale. Within this framework, cross-case and within-case are conceptualized as steps of a same continuum. If this working paper mainly focuses on the transition between quantitative to qualitative data, such "mix-method" approach is crucial in Bayesian Integration of Qualitative and Quantitative data and has been developed and tested by Humphreys and Jacobs. We provide theoretical as well as empirical, further elements on these points in Appendix.

From this perspective of generalizing within-case data to cross-case observations, the next critical stage before beginning qualitative study is to define a methodology to select cases to be examined from a larger sample. Qualitative research literature is rich in different approaches to meet the challenge of building comparative frameworks (see for example Roger 2013). However, we argue in the next section that, if we consider that Process-Tracing has to contribute to refine our findings from statistical observations, we need to depart from these quantitative results when building our research design.

## 4 Case Selection and Research Design

The empirical cases developed here are based on a Ph.D. dissertation on the evolution of the regulation of the pharmaceutical market in France and England (1994-2014)<sup>4</sup>. Part of this research tries to determine the conditions for the emergence of Health Technology Assessment Agencies in both countries. The main objective of these bodies is to study the effectiveness of a wide set of health products. Due to their weight in health spending, most of these activities are nevertheless dedicated to the measurement of the therapeutic and/or economic efficiency of new medicines after their marketing approval by the competent authorities, but before the definitive fixing of their prices (Linden et al 2007). Consisting of doctors, health services managers and health economists, their staffs mobilize various evaluation tools including mostly cost-effectiveness, relative-effectiveness and/or cost-minimisation analysis (Kobelt 2013). Their role is to provide an aid to payers (welfare state authorities, national insurers) to facilitate the decisions by identifying technologies to be paid for by the community. For the Beveridgian and Bismarckian healthcare systems in Western Europe, where the demand of these products is socialized by reimbursement mechanisms, a decision from a HTA agency may have a considerable impact on their consumption. For this reason, and even this opinion may be controversial, these bodies can reasonably be considered as the actual Regulators of several European pharmaceutical markets (Benoît 2015, Thatcher 2007, see also Maor 2007). HTA Agencies have an indirect influence on the price of the drugs paid for by the public purse. Moreover, such decisions can influence the price paid in other countries – and this because several European markets serves as a "reference" for price negotiations in Europe and in some overseas countries. In addition, they set up guidelines that prescribers are required to follow when prescribing subsidized drugs for their patients (Richards, 2010). Through these mechanisms, HTA agencies directly socialize the consumption of medicines within their jurisdiction. In case of a "no" decision, a new drug may not be prescribed in a given country and the manufacturer will be in a weaker position to achieve their desired price or reimbursement rate in other countries. Nevertheless, not all of these bodies have similar power from one country to another. How can these variations be explained?

As a first step, and regarding their potential influence on pharmaceutical industry's profits, we tried to address this question by comparing the positioning of 17 HTA agencies (mainly, but not exclusively

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<sup>4</sup>See Benoît, C. 2016. *Parallel Convergences. A Political Economy of the transformations of the French and British Governments of Pharmaceuticals (1994-2014)*, Ph.D. Dissertation (Political Science), Sciences Po Bordeaux.

within the European Union)<sup>5</sup> to several indicators related to the weight of the pharmaceutical industry in these respective countries. The ‘positioning’ indicator (HTA) was built on the basis of the date of creation of the agency, the influence of its publications and those of its experts, from various qualitative data (documentary analysis, exploratory interviews) and previous work done by others (especially Maor 2007, Thatcher 2007 and Boothe 2013). The indicator related to the weight of the pharmaceutical industry (Pharma) rests on the share of GDP dedicated to pharmaceutical spending (before and after the agency was set up), the production of medicines, Research and Development (R&D) expenditures, added value of the pharmaceutical sector and its share of trade balance, in each country. Indeed, the arbitrations between health, industrial and innovation issues inherent to the regulation of this market frequently leads to volatile political compromises and provokes variable institutional designs across nations (Gorry 2012, Permanand 2006, Carpenter 2014). Well suited for this type of questioning, a Principal Component Analysis (PCA, see Vyas 2009) was led at the scale of our sample. It appeared that an *inverse* relation could be established between the Pharma Indicator and the HTA indicator - i.e, more a country possesses a strong pharmaceutical industry, and less the HTA agency that has been set up will have an impact on the regulation of the pharmaceutical market. Consistent with many previous publications (Abraham and Lewis 2001, Gagnon 2012, Stigler 1971), this result suggests a pernicious influence of firms over regulator, or in other terms, of [I] over [W]. Promoting an efficient use of healthcare budgets, these agencies appear to be less developed where industrial considerations could have potentially had an effect on regulatory policies (Benoit and Gorry 2013, 2014).

Albeit significant, this analysis remains however limited and includes bias difficult to adjust on a purely statistical plan. Despite the weighting of each indicators for each observation, the comparability of the cases remains questionable, because of the size of the different countries and their respective historical trajectories in the regulation of this sector. Reliable data results thus in the building of variables with a highly heterogeneous composition. More fundamentally, and in line with our theoretical framework, such outcome from an explanatory analysis is anything but sufficient to diagnose a statutory capture of these HTA agencies. To determine whether  $X$  caused  $Y$  more in-depth, we will consequently apply the Bayesian Process-Tracing approach described above. In this contexte, the quantitative results will help us to form our prior belief about the capture hypothesis. During this step, we move from our large- $n$  sample to a small- $n$  within case analysis, more appropriate to explore the ramifications of this  $X - Y$  relationship. Different sets of strategies may be adopted to select specific cases from our sample. For more ‘classic’ Process-Tracing approaches, this change in scale of analysis is not necessarily a big issue: previous research or explanatory documentary analysis are used to identify several cases for which a comparison of trajectories would be relevant. A comparative grid is then built on this basis (see for example Bezes and Parrado 2013). However, in the perspective of the BIQQ, findings from qualitative research will contribute to making inferences as regards quantitative ones. In this respect, two main criteria (that are not necessarily incompatible) can be applied:

1. **Similarity/Dissimilarity between cases:** This strategy consists in selecting cases without considering their statistical properties, and solely on the basis on their potential types. As Ross (2004) did on his analysis of the causal mechanisms linking Natural Resources and Conflict (from quantitative results obtained by Collier and Hoeffler 2004), we can for example only retain cases with  $X = Y = 1$  (Similarity) or, at the opposite, cases with different profile (Dissimilarity, for example  $X = 1, Y = 0$ ). Such a configuration, especially within the "dissimilarity" strategy, can facilitate our identification of several causal mechanisms and to mobilize a slightly more robust

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<sup>5</sup>We provide a complete list of countries examined in Appendix.

comparative grid. However, and because of the weaker attention paid to the statistical positioning of these cases on the large- $n$  sample, this approach can increase the difficulty of BIQQ;

2. **Statistical Weight of cases:** An alternative strategy consists in selecting cases on the basis of their contribution to the statistical results. Here, the focus is less on their potential types than on their contribution to the results drawn from the sample. The objective is twofold: improving the consistency of Process-Tracing causal observations with existing results, and increasing our capacity, through BIQQ, to make a significant contribution to these. However, this approach may be impossible to operationalize when appropriate case are difficult to compare on the basis of a similar grid.

In order to choose one of these two options, or eventually to find a mix between them, statistical observations need first to be *classified*. For this clustering purpose, we use a Gaussian Mixture Model, a parametric probability density function represented as a weighted sum of Gaussian component densities<sup>6</sup>. To realize this GMM, we departed from our statistical observations ( $n = 17$ ) and we tried to cluster them according to the variables  $X$  (Pharma indicator) and  $Y$  (HTA indicator). Then, we selected an Inference Algorithm (SEM) to estimate the number of classes, regarding the structure of the sample. We used a Stochastic version of Expectation-Maximization (EM) algorithm. Results are presented in Figure 1.

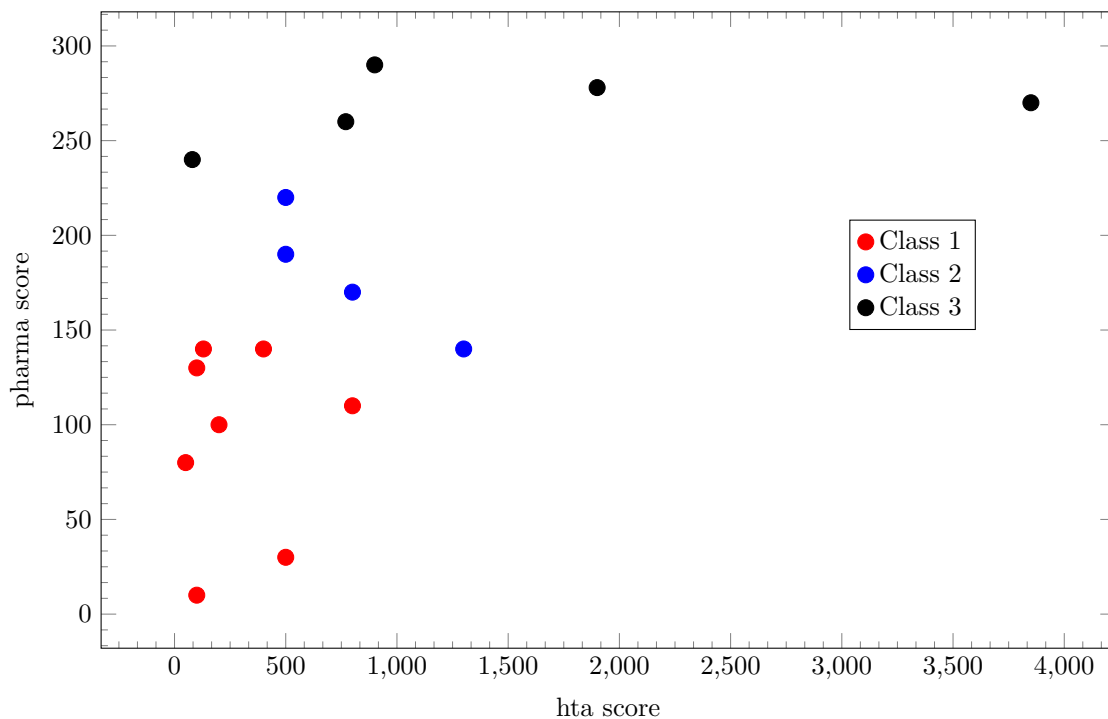


Figure 1: Results for the Gaussian Mixture Model

<sup>6</sup>See Douglas (2009) for an introduction.

Entropy Estimation of Eigenvalues (EEE) with 3 clusters was estimated as the best model, according to Schwarz's Bayesian Criterion (SBC). Each point displays an observation (country), according to its "Pharma Score" (vertical axis  $X$ ) and "HTA Score" (horizontal axis  $Y$ ). This approach helps us to estimate the parameters of a distribution in modeling them as a sum of several Gaussians. Algorithms allow us to cluster statistical observations in different classes revealing the partition of their structure. We see that it can be represented in three classes, corresponding respectively to:

1.  $X > 0, Y > 0$ . Countries with a weak to a moderately weak HTA Score, and a weak to moderately weak Pharma Score;
2.  $X = 1, Y = 1$ . Countries with a weak to a moderately weak HTA Score, and a high Pharma Score;
3.  $X = 1, Y = 0$ . Countries with a moderate to high HTA Score, and moderate to high Pharma Score.

The main "contributors" to our first result (inverse relation between HTA and Pharma) are in fact countries in black (France, Germany, Italy, South Korea). The only country with both a high HTA and high Pharma scores is England (black, far right), while those in red have in some respects a similar profile to countries positioned in one of these two classes. To develop the Bayesian Process-Tracing approach beyond these statistical relations, we have to select two or more cases according to their similarities/dissimilarities if we follow the first approach described above, or on the basis of their statistical weight if we decide to follow the second one. At this stage, we compared France (black) and England (black), that allowed us to combine cases with different properties (first option, dissimilarity) and with a strong statistical contribution to our sample. However, more investigations on at least one other case will be required for BIQQ, if we follow the example developed by Humphreys and Jacobs on their work on Ross (2004).

France and England have both strong pharmaceutical companies operating on their soil ( $X = 1$ ). However, whereas France developed a HTA agency with very few regulatory power on the market ( $Y = 1$ ), England has set up an agency with a great capacity to assess and to appraise new drugs as precondition for their effective access to patients ( $Y = 0$ ). Consequently, we have to determine whether France is a  $b$  or a  $c$  case, i.e., if the pharmaceutical industry successfully limited the development of a HTA agency with strong prerogatives, or if the prerogatives of the French HTA agency would have remained weak regardless of manufacturers' attempt. For England, we have to determine whether the case is a  $a$  or a  $d$ , i.e., if the pharmaceutical industry successfully favored the development of a HTA agency with strong prerogatives, or if the prerogatives of the English HTA agency would have remained strong regardless of manufacturers' attempt. Thus:

[France]

$$P(j = b) | K = 1) = \frac{P(K = 1) | j = b)P(j = b)}{P(K = 1)} = \frac{\phi_b P(j = b)}{\phi_b P(j = b) + \phi_c P(j = c)} \quad (6)$$

[England]

$$P(j = a) | K = 1) = \frac{P(K = 1) | j = a)P(j = a)}{P(K = 1)} = \frac{\phi_b P(j = a)}{\phi_a P(j = a) + \phi_d P(j = d)} \quad (7)$$

In line with our model, we have to determine whether the pharmaceutical industry (or industrial interest) had an influence on the statutory features of both of these agencies. Put differently, we use Process-Tracing to challenge this *capture hypothesis* under which the French and British cases are respectively  $b$  and  $a$  causal-types. We start with a prior belief on this hypothesis as a basic premise, that will both condition our search for *clues* ( $K = 1$ ) and our *posterior belief*. Defining a *prior belief* is a major issue of any research designed within a Bayesian framework, and gave rise to many debates in the field of Statistics (see for example Salomond 2014). When their research is only based on quantitative data, scholars generally define it by assuming that their sample follows a particular probability distribution. When causal inferences have to be made on the basis of qualitative data, the subjective dimension inherent to this operation may however appears more directly. Again, BIQQ provides a slightly more robust framework for setting a *prior*, to which we will return in Appendix. At this stage, we simply set it consistently with our quantitative data and, to a lesser extent and as Kreuzer (Forthcoming) suggested, with existing literature. The main objective of this step is to assess the quality of the causal hypothesis. In this respect, we know from our statistical analysis that the importance of HTA agencies is negatively associated with that of the pharmaceutical industry for the largest share of our sample. Regardless of the quality of this finding, a brief look at previous work in the research field of Pharmaceutical Policy and Regulation shown similar results, with an explicit conflict between health (usually assimilated to [W]) and industrial issues (see for example Abraham and Lewis 1990, Gagnon 2008, Thomas 1990). Moreover, this result is also consistent with a lot of research showing that regulatory agencies are designed to favor larger and older firms rather than smaller or newer competitors (Viscusi 1992, see Carpenter 2004 for a literature review). Such results should *a priori* lead us to attribute a high probability for the capture hypothesis is true. However, and following our theoretical framework, we know that these research lack of a clear conceptual definition of [I] and [W]. We also know that proof for regulatory capture requires far more evidence: in most cases, what scholars define as regulatory capture can simply resulting from other trends or causal mechanisms in the policy-process, that are not entirely covered by the theory (institutional inertia, path-dependency effects, learning from both elected officials/bureaucrats and firms, long-term trends such as previous relationships between a given Industry and the State...).

To reflect simultaneously the consistency of our results with existing literature and the shortcomings they share with most of this work, we set up a 0.5 prior degree of confidence in the hypothesis for both of our cases. Symmetrically, it means that our prior degree of confidence that our hypothesis is false is 0.5. In the next section, we present our Causal Process Observations resulting from Process-Tracing for the French and British cases. Then, on the basis of the clues collected and our quantitative results (hereinafter our prior belief in the hypothesis  $\phi_b$  and  $\phi_a$ ), we estimate the learning resulting from Process-Tracing. This result only describe the causal type of these two cases. Nevertheless, we develop a research agenda in Appendix to complete the analysis through BIQQ.

## 5 Causal Process Observations

We present here the causal process observations resulting from the application of our research framework to the trajectory of the French and British cases. According to it, we have to determine if a "Statutory Capture" by the pharmaceutical industry prevailed when their respective legislature developed a HTA Agency, so if [I] was deliberately privileged over [W]. Because of the framing of our research question,

aiming at extending the exploration of our quantitative data, we did not focus on what happened after these agencies were set up in terms of regulatory capture and political control or interference<sup>7</sup>. [I] refers to the interests, ideas and values effectively promoted by the pharmaceutical industry representatives in the political field. Of course, these may be quite diverse within the sector, for example, between older, largely internationalized firms and smaller groups. However, and without denying these contradictions, we decided to focus on [I] as effectively perceived by the legislatures, and on the direct confrontations and oppositions between these two generic actors. Beyond strictly focusing on the influence of [I], we also looked at pressures from [S] (special interest(s)) on the policy-process. Despite the fact that it was not the point of our examination of causal process observations that linked  $X$  to  $Y$ , such elements are crucial to test the alternative hypothesis (respectively  $\phi_c$  and  $\phi_d$ ). When the *capture* of the legislature by [I] or [S] was not obvious, we simply consider that it followed [W].

Regarding our formulation of this questioning, searching here for the modalities of a potential capture of the legislature by the Industry obeys the same rules as determining if  $X$  caused  $Y$  and if so, what are the ramifications, implications and conditions for this causal effect and if not, what led to  $Y$ . In other terms, we consider that in many respects, demonstrating regulatory capture means here find what linked (or do not)  $X$  to  $Y$ . A same analytical grid was applied to both of our cases. Nevertheless, we present them separately for convenience. This is also related to distincts potential outcomes, the French one can only be a  $b$  or a  $c$  type, and the English one only a  $a$  or a  $d$  type.

The two HTA agencies, the French *Haute Autorité de Santé* (HAS, established in 2005) and the English and Welsh *National Institute for Health and Clinical Excellence* (NICE, established in 1999) were compared in their genesis, setting up and development. However, we also looked at the different trends and trajectories of the "government" of pharmaceuticals in the two countries in order to analyze the complementary or disjunctions between the temporalities influencing actors' positioning and behaviors. A mid-term perspective (approximately 30 years for each case) on these evolutions was adopted. We based our data collection on semi-structured interviews with Civil Servants/Bureaucrats, Elected Officials, Experts and Pharmaceutical Industry members and Representatives ( $n = 87$ ). This non-representative sample was built and exploited through the methodology of Elite Interviewing in the context of Process-Tracing developed by Tansey (2007). According to this approach, key-actors were identified, mainly on the basis of documentary analysis. With this large quantity of data, we had to deal with multiple clues and to take into account several interaction effects between them. Some of the methodological implications induced by such a configuration are discussed and addressed throughout the text.

## 5.1 An institutional change initiated upstream, leading to a weak contribution by the manufacturers to the situation observed (France)

Over the last 30 years, the regulation of market access for pharmaceutical products in France known numerous changes for which the development of the HAS was only an element. A first "critical juncture" (Collier and Collier 1991) can be identified during the course of the year 1993, when the French Agency for Drugs (ASM) is set up to regulate the delivery of the Marketing Authorization. Previously centralized, this procedure is thus delegated to an independent agency, with a personnel composed by experts under contract. This transformation reflects the willingness of French authorities to separate the scientific approval regulation from other interests, especially budgetary, in their access to patients (Bergeron and Nathanson 2012). An other ambition is promoted through this reform: at the scale of the

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<sup>7</sup>More information on that point can be found in Benoît 2015.



European Union, the first years of the decade 1990 see the progressive building of a common market for drugs, based on similar approval procedures in every member-States. A dual mechanism underlie such evolutions: on one hand, a growing penetration of principles inspired by the new public management, through the deployment of an autonomous (from the political tutelage) and decentralized governance and, on the other, a convergence between European countries, following a dynamic of harmonization (Holzinger et Knill, 2005). Reluctant to these evolutions, a small group of senior civil-servants, keen to maintain the regulation of the market within the bosom of the national State, succeed in avoiding that the drug pricing be given to this new, experts-lead authority. To this end, they use their networks in the Bérégovoy (leftwing French Prime Minister) legislature. This operation was a success: the French Ministry for Health and Social Affairs give them its support by stonewalling the delegation of pricing to the ASM. Building a coalition around Jean Marmot, these members of the "Welfare Elite" (Genieys 2010) propose to create a new bureaucracy with Weberian features, partially autonomous from the influences from the Ministry and from the experts from the ASM. For this purpose, they positioned this new bureaucratic entity in a direct relationship with the pharmaceutical industry: the Economic Committee for Drugs (CEPS). Each five years, an agreement is set up by both of these parts. Then, the price of a new drug is negotiated between the CEPS and the firm concerned. Over the next years, this Committee will be led by senior civil servants whose influence will strongly increase within the French Government of Pharmaceuticals (see Benoît and Nouguez forthcoming). The transmission belt between the independent evaluation of the scientific, therapeutic properties of a new product by the experts and the price negotiation according to budgetary and/or industrial approaches partly but non exclusively on the basis of this data is operated by a technical section - the Transparency Commission. Composed of a majority of clinicians, this unit is in charge of re-examining new drugs with the aim of fixing their reimbursement rate, and to facilitate the negotiation of their price.

Since the 80's, and simultaneously to these evolutions, a network of hospital consultants and University Professors tries to promote a decision-making approach in health more informed by Evidence-Based Medicine, who experiences at the same time an important boom in most countries in the anglo-saxon world.

Members of this network promoted, in its initial form, a more efficient use of health resources et directed to the supply of products that have been proved to be cost-effective. Lashed to a de-bureaucratization of the healthcare systems, their narratives found a favorable echo within several Ministries and administrative organizations. Positioned at the crossroad of diverse international circles mixing researchers and practitioners, they put forward successful policy experiments of this kind in Scandinavian countries (Lothgren and Ratcliffe 2004). A private non-profit organization, the National Agency for the Development of Medical Evaluation (ANDEM) is then set up in 1989. This body aiming at centralize, collect and diffuse information relatives to medical evaluation see its prerogatives extended in 1996, when it became a public establishment of an administrative character: the National Agency for Accreditation and Evaluation in Health (ANAES). Its competencies evolve do not involve yet drugs, whose examination after the approval decision (AMM) remains own by members of the Transparency Commission (CT) until the mid-2000's, when the HAS was set up. The CT and ANAES were then merged to create a single independent public authority (an *independent administrative agency*), equally positioned between the Agency for Drugs and the CEPS. Agents from the Direction for Social Security (DSS) have taken the initiative for this rapprochement. Linked both within the Ministry of Health and within the Ministry of Economy and Finances, those members try then to increase their legitimacy vis-à-vis other members of competing Ministries organizations (Pierru 2011). To do so, they built a narrative on the basis of several public reports criticizing the share of health expenses dedicated to drugs in the country, and developed the idea of the setting up a new agency (the HAS) that would centralized the

different components of medical evaluation - with a primary focus on drugs. Placement of the CT at the core of the new organization would allow to, in the field of pharmaceuticals, to canalize the flow of products with a marketing authorization coming to the market while framing the price negotiation within the CEPS - considered as being inflationary cause more in favor of the industry. A first draft proposing a new agency with clear budgetary orientations is submitted to the *Assemblée* (Parliament) for its approval. Supported by the French Ministry of Health Philippe Douste-Blazy, a coalition of MPs coming both from the majority and from the opposition obtain a withdrawal of the delegation of budgetary competencies to the HAS - afraid of losing their freedom to prescribe. The setting up of a hybrid organization is finally approved. Although independent, this new agency is remained close to the DSS, and externalizes some of its attributions. In the regulation of the French pharmaceutical market, this "second-line" bureaucracy (Benamouzig and Besançon 2007) does not have the positioning wished by its promoters: strongly limited by the conditions of the AMM decision and representing only an input amongst many others for the pricing negotiation within the CEPS, the decision-making procedure developed by its experts only constitutes a small incremental change of the market-access of drugs in France.

**X.** During this period, the pharmaceutical industry is involved in the evolution of the regulatory framework, although we can observe different kind of behaviors according to the size of the firm and the nationality of its parent company (French, European or Oversea). If firms better positioned in terms of products portfolio or direct incomes are best placed to influence the lobbying agenda of their representatives within the National Union of Health Industries (SNIP, subsequently became LEEM, for *Les Entreprises du Médicament*), smaller French groups can count on their relation in the Parliament or Ministries to influence the policy-process - especially in using their strong local implantation on the national ground to claim for more protection. However, and despite clear attempts to influence the policy-process, we cannot identify an explicit movement of politicization (Jullien and Smith 2008) of the evolutions described above within the sector. The development of the CEPS was favorably welcomed. Criticizing prices too low for a decade, industry representatives anticipate thus a better retribution of their "research effort" promised by the development of an organization more "comprehensive" regarding their respective constraints (Chauveau, 1999). In line with the agreement between the Committee and the Industry, high prices will be proposed for the more innovative products. Jean Marmot, its first President, is also favorable to the promotion of the French Pharmaceutical Industry through certain incentives<sup>8</sup>. In this new environment, the French market is thus characterized by a marketing approval decision placed within a network of european agencies and by pricing mechanisms based on a negotiation led by different actors in an inter-administration. The position of the Transparency Commission, set up in 1980, is modified by its integration within the HAS, independent agency. Following the logic of Process-Tracing, these first clues are enough to validate a Straw in the Wind Test (Collier 2011): if we consider established relationships between industry representatives and the CEPS, it remains *likely* that the development of a new organization changing - even incrementally - these institutional relationships could be thwarted by the industry. Some of its members or representatives could for example try to use these link to build an alliance with senior civil servants to preserve existing positions and to limit institutional change. However, these evolutions do not constitute a change that would call into question

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<sup>8</sup>Several scholars, the media as well as elected officials regularly expressed concerns about the potential capture of the CEPS by Industry interests. Our qualitative research suggest however that most of these critics result from a misinterpretation of the actual positioning of this bureaucracy within the French government of pharmaceuticals. In fact, it is explicitly designed to reduce both experts, political and industrial interferences to protect the autonomy of its decision making process. In many respects, CEPS is closest to [W] than a lot of French regulatory bodies in the field of medicines. See Benoit and Noguez (forthcoming).

the institutional order of the sector. Already structured to produce expertise required by the HAS, due to their familiarity with the procedures used by the CT, market-access departments of French firms or filial of foreign groups face here a rearrangement of the regulation, rather than an necessity to adapt to a transformation with broader amplitude. Within the Industry, the organizational change we note are largely incremental, and are progressive adjustment to these recompositions. If we look at firms' intents (Carpenter and Moss 2014) as well as their behaviors (Martin 1995), there is no evidence to support that the deployment of the HAS would come to compromise their interests or representation of what they consider as an "appropriate" or "acceptable" regulation. Consequently, we cannot affirm that we have enough, or more precisely, appropriate clues to support the *statutory capture hypothesis*, that is, that the positioning of the HAS had been limited due to the influence of the manufacturers. Conversely, our confidence in the alternative hypothesis  $\phi_d$  increases. Regarding collected clues, we can validate a Smoking-Gun Test, insufficient to definitively banning the capture hypothesis  $\phi_b$  (additional clues supporting  $\phi_b$  can still be collected) but suggesting that there is a high probability to support hypothesis  $\phi_d$ .

**Interpretation.** For this case, and as observed on areas hardly different of it, the issue of the temporalities of institutional change and of its sequences appear as critical (Pierson 2004), as well as the content of the different evolutions examined (Abbott 1990). The two main transformations of the French pharmaceutical market appear as interdependent. The "Europeanization" of the marketing approval decision at the beginning of the 90s provides to a group of senior civil servants an opportunity offering them to redefine the modalities of the pricing of medicines in France. The segmentation between therapeutic considerations and budgetary, even industrial issues becomes a clear institutional feature of the sector at that time. Promoted by an internationalized academic community, medical evaluation remains outside this change, less due to the incapacity of its members to take part of it than to their slightest interest for this object. The development of a new agency to regulate the pharmaceutical market becomes however an issue at the beginning of the 2000s, when agents from a ministerial direction, recently set up, try to reinforce their position within the bureaucratic field. Partially reconnected from the evolutions described above, these manoeuvre face a politicization of the reform proposed. Albeit approved, this opposition provokes the deployment of an organization juxtaposing activities pervasively distinct, without managing to contest existing boundaries. Largely outside the finalities of these struggles, industry members and representatives do not seek to position themselves vis-à-vis the setting up of a new bureaucratic entity which, in its final design, does not introduce a change of the regulatory framework. For the evolutions described, their positioning attempts, and intents to influence it have to be searched upstream, during the placing of the marketing approval decision at the scale of the European Union and when the CEPS was set up. The clues collected did not show a causal role played by the manufacturers or its representatives in the positioning of the HAS in the French market. The case is more presumably a *d* type rather than a *b* type.

## 5.2 Learning by manufacturers but their influence thwarted by pre-existing coalitions (England)

In England, the beginning of the 90s is marked by an important reform of the National Health Service (NHS) impulsed by the Conservative Government. During the years following their came to power in 1979, the Tories commit to not transform the NHS. This period is characterized nevertheless by intense exchanges on several difficulties of the system and highlighted by diverse reports published under the precedent majority (Labour). Mainly nourished by Think-Tanks whose ideas are close to that of the Conservatives and b Health Economists (Paton 1998) this debate extends progressively from

these initial circles to numerous forums. Relaying these initiatives, some agents from the Department of Health (DoH) publish in turn experts reports linking the difficulties of a sustainable funding of the system and the issues related to the effectiveness and efficiency of this expense. Representatives from the Adam Smith Institute call Patrick Jenkin, Secretary of State for Health and Social Services, a privatization of the NHS through its change in a Private-Insurance based system. Doubts are however expressed about the political cost of such a reform - promptly considered too high. An audit of several countries is then realized (France, USA, Germany) and this initiative is definitively excluded. Norman Fowler, successor of Jenkin (1986) reacts more favorably to convergent offers from some economists, who recommend to introduce market mechanisms within the system without changing its current financing scheme. Supported in the academic field, the idea of the « Internal Markets » promoted by Alain Enthoven marks the beginning of a consensus between bureaucrats from the Department of Health, scholars and Conservative politicians (Enthoven 1991). A durable « reform configuration » (Bezes 2009) is then established between actors up to this time in interaction, but unable to establish a consistent policy narrative. In order to get more easily a consensus, some economists keen to depoliticize the debate present their project as a « Market Socialism » (Paton 1998). Slowly naturalized, the necessity for a reform is used by the majority to neutralize the mistrust expressed by the Labour opposition in Parliament disqualified on the ground of its incapacity to propose alternative solutions to the problems previously identified. A reform is finally enacted in 1991. The principle of internal markets induced then a new funding allocation scheme. At the local level, the Primary Care Trusts (PCT) should identify the needs of their populations for whom they will be accountable. Then, they will have to compose a healthcare provision proportionally to available resources. A competitive bidding approach to providers will allow these organizations to optimize their choices regarding their priorities. They will provide annual reports on their purchasing policy (Klein, Day and Redmayne 1998).

Organized as a professional group since the mid-1970s, Health Economists criticizing the Keynesian paradigm, nearly hegemonic at that time, tried in their own words to « colonize the medical spirits » to increase NHS efficiency and their positioning within the system (Croxson 1998). Poorly integrated in the mainstream of their discipline and suffering from little consideration by the « medics », these scholars obtain a progressive recognition of their work within the Department of Health, reinforced by the Conservative accession to power. First requisitioned to realize pieces of expertise work on healthcare supply, they criticize the conceptions defended by the agents working for the DoH, regarded as too bureaucratic. Positioned at the core of a multifaceted network, they succeed in modifying to their benefit existing structures. On their own behalf, annual conferences mixing diverse actors (think-tanks, academics, MPs) allow them to promote a wide set of quantitative tools offering to rationalize NHS management. The 1991 reform is considered as the first expression of their legitimacy (Hurst 1998). Its implementation will then see a progressive extension of this new social authority. Diagnosing a lack of expertise from PCTs to complete successfully their new prerogatives (their purchasing policy), the economists that worked for the project pleaded thus for the creation of local organizations to help them making these arbitrations. Four Committees (« DEC's ») are thus deployed in four NHS administrative areas. Covering at that time a small part of the NHS, their influence will increase rapidly throughout the decade. However, any formal coordination of their respective decisions will be developed. However, and within these organizations, relationships are established between health economists and Medical Doctors, or Professor in Health and Social Policy. Some Universities (York, Southampton, Sheffield and Birmingham) offer their support and strengthen the personnel in place. Based on diverse use of economic calculation, the methodological assistance provided aims at favoring an optimization of budgets. Covering a wide field of expenses, the provision of drugs will however be erected as a specific issue as a consequence of several divergent decisions between different regions of the country. Acquired

*de jure*, the reimbursement of a pharmaceutical product with a marketing authorization for the British market will thus be submitted to the budgetary decisions of the PCTs. Consequently, a treatment could be available in an area of the country, and not in a other. Known as « pesticide lottery », this phenomenon constitutes an old chestnut of the debates over the NHS. Regularly reactivated, this infringe to the egalitarian principles of the system was extensively mobilized by the « New » Labour during the 1997 electoral campaign and associated with a narrative built around the fight against inequalities (Wood 2014). A political alternation in *trompe l'oeil* (Campbell and Rockman, 2001, Hay, 1999) benefits to health economists working with the Department of Health. To meet the post code lottery, they propose an extension of the prerogatives delegated to the DECs, accused of reinforcing inequalities between NHS regions. Taking advantage of a re-centralization movement engaged in other policy sectors, they offer their expertise for the creation of a new evaluation body unifying existing local initiatives. This single bureaucracy will be in charge of the reimbursement decision for any product coming to Great Britain. Thus, the shift from a Conservative to a Labour legislature does not challenge equilibriums within the reform configuration previously established. Permitted by existing institutional arrangements, the strengthening of the legitimacy of health economists expertise within the Department of Health consolidates then an approach with depoliticized features. However, the project defended here is lashed to a discourse handled by Tony Blair's Government: the final purpose of exiting tools is re-qualified in order to meet a new rhetoric, fluidizing in this way the change. This new bureaucratic organization, NICE, will then condition the access to reimbursement of new products to the recommendation of its experts. A cost-effectiveness analysis based on clinical and economic inputs will allow to compare the therapeutic added value of a new product for each monetary unit spent. In many respects, the agency soon becomes a watchdog on the British market. Through its positioning, the agency acts a Regulator with large prerogatives. Extending progressively its sphere of influence, its members succeed in influencing indirectly pricing and reimbursement decisions took in other countries.

**X.** Pharmaceutical Industry in England is characterized by an important group of dominant firms well positioned at the global level. We cannot observe, as it was the case for France, a multitude of small manufacturers. During the period examined, and due to the internal market reform in 1991, firms have to review their strategies because of the modification of resources allocation at the local scale. However, the institutional change occurring at this stage does not transform existing institutional relationships. Some local arbitrations prevailed before this reform, traditionally compensated by the manufacturers through volume agreements with ambulatory pharmacists and in hospitals. Nevertheless, it must be noted that the economic expertise so deployed provokes a restructuring of market access departments within British companies, especially for Glaxo, Smith and Zeneca. We see an increase in the recruitment of health economists to meet the new efficiency criteria developed by the DECs. Facing the constraints imposed by a PCT to motivate a "no" decision for a specific product, the manufacturer could for example justify its reimbursement on the basis of a second expertise. Though rarely different from that of the PCT, the later could for example lead to show the local payers the benefit gained otherwise induced by the product appraised - an opportunity cost. This localized market access scheme preexisting to the reform is thus reinforced by organizational and technical devices. By structuring an expertise upstream and by familiarizing with this new regulatory tool, firms appear as more inclined to adapt the change initiated by NICE: a Straw in the Wind clue type reinforcing our prior belief in  $\phi_a$ . The growing politicization of DECs decisions and the resurgence of the issues related to the so-called Post code Lottery are also echoed within the pharmaceutical industry. When the debate was diffused in the media (Wood 2014), the main representative organization of the sector, the Association for the British Pharmaceutical Industry (APBI) mobilized the members of its Governmental Affairs Department to criticize the heterogeneity of the decisions from one NHS region to another. Several meetings took

place between these representatives and agents from the Department of Health. The purpose of the manufacturer was to promote a centralization of local procedures. This Smoking-Gun clue reinforces our belief for  $\phi_a$ : an agency, NICE, unifying the separate local entities (the DEC's) with extended competencies is effectively set up. However, we observe at the moment of its creation a great suspicion from the manufacturers vis-à-vis its deployment. A structure considered as too constraining would jeopardize the "reward for innovation" by forcing the manufacturers to lower their prices, or by limiting the access of certain treatments to patients. If we look at the content of the negotiations between the agents of the Department of Health and those of the APBI, and in the light of our qualitative material, it appears that the industry expressed its hostility to the creation of a "hammer" bureaucratic organization, with a decision-making process based on the application of a rigid, "gold-standard" criteria. Such claim is not contradictory with the development of a common regulation to all regions of the NHS. However, it appears that, while calling for a centralization of the procedures, industry representatives also tried to shape the design of this new device - without succeeding however in obtaining a scheme in their benefit. This interpretation is consistent with NICE development. Consequently, and despite some clues to support this opinion, it is unlikely that the British case is a *a* type: the industry did not favor the setting up of NICE with the statutory features observed, although its implication in the debates suggests that the manufacturers were in favor of a centralization of the market-access schemes in England. If we cannot consider that the industry favored the development of NICE with an important capacity to regulate the pharmaceutical market ( $\phi_a$ ) we cannot however definitely sustain the alternative hypothesis  $\phi_d$ , not because of our lack of clues to validate Van Evera's causal test - but because the causal role effectively played by the manufacturers or their representatives to design NICE was not as residual as it was for French case.

**Interpretation.** The development of appraisal mechanisms within DEC's appear as a consequence of 1991, internal markets reform. Promoted by a group in favor of their setting up, these tools were assimilated by local organizations and gave a strong legitimacy to health economists working with the Department of Health. The institutional change induced by the creation of NICE rests on a combination of several factors. A politicization of technical decisions is first considered by the new majority at Westminster. Better represented within the Ministry than they were during the previous period, health economists exploit this opportunity window to propose a reshaping of the regulation consistent with their perception of appropriate solutions. Their perspective is associated with the political principles promoted by the New Labour. Contrary to what we have observed for the French case, the manufacturers mobilize their representatives to influence this change. The probability to confirm  $\phi_a$  for that case results from their learning of tools that will be centralized through NICE. By deduction, they can appear more spontaneously favorable to a regulatory instrument they have already experimented. However, and in spite of that situation, there is little evidence to support this proposition. Rather than considering that the manufacturers played a causal role on NICE design, it is more appropriate to consider that they tried to do so without resulting in the expected target.

### 5.3 Inference

For neither of the two cases, we have been able to determine a causal influence of the pharmaceutical industry on the statutory features the agencies. In line with our theoretical framework, it appears clear that the legislatures examined did not privilege [I] over [W]. The capacity of medical doctors to influence the policy-process in France suggests an alternative explanation that we have not fully explored, under which the HTA agency had been limited in its prerogatives by their Special Interest, i.e. [W] < [S]. Our explanation of the British case rests upon the observation of the resilience of existing

coalitions within the Department of Health to the pressures from the manufacturers, and the capacity of health economists to face the "Post code Lottery" crisis by an alignment of their ideas to that of the new majority. Table 3 presents a summary of our evidence.

Evidence for [W] < [I] (France)	Capture Mechanism	Evidence for [W] > [I]
Direct relationships between companies and the States within the CEPS Existing Incentives for French Companies	No Evidence Found Design of HTA agency as the reflect of struggles within bureaucratic/political fields	Institutional change earlier MD as veto players Opposition from the Ministry (suggest [W] < [S])
Evidence for [W] < [I] (England)	Capture Mechanism	Evidence for [W] > [I]
Intent from the manufacturers to change existing rules Support for centralization of HTA	Pressures on DoH officials Politicization of Post code Lottery	Design of HTA agency clearly different from that expected by [I] Strength of coalitions within DoH

Table 3: Evidence

To make our inferences on the basis of our causal process observations, we have to associate each clues to our initial propositions ( $b$  and  $a$ ). To do so, we assigned probabilities to each corresponding results of Van Evera's Tests (1997), for which Table 4 displays our results.

	Straw in the Wind	Hoop Test	Probability for $\phi_b$	Probability for $\phi_c$
France	1	0	0.2	0.7
	Straw in the Wind	Smok.Gun	Probability for $\phi_a$	Probability for $\phi_d$
England	1	0	0.6	0.8

Table 4: Results for Van Evera's Tests

According to Bayes' rule, the probability so obtained are then computed with our prior belief and the probability attributed to the alternative hypothesis:

[France] (for  $\phi_b$ )

$$P(j = b \mid X = Y = K = 0) = \frac{0,2 \times 0,5}{0,2 \times 0,5 + 0,7 \times 0,5} = 0,2 \quad (8)$$

[England] (for  $\phi_a$ )

$$P(j = a \mid (X = Y = K = 1)) = \frac{0,6 \times 0,5}{0,6 \times 0,5 + 0,8 \times 0,5} = 0,4 \quad (9)$$

Our posterior belief in the probability that the first case (France) is a  $b$ -type is 0,2. It appears more favorably to be a  $d$ -type. The second case (England) is more challenging. If the clues collected led us to

conclude that despite its mobilization, the pharmaceutical industry did not play any direct role in the design of the statutory features of the agency, we have also noted that it called for a centralization of an expertise previously led by local organizations. Consequently, we can consider that we have Smoking Gun clues for both of our hypotheses. However, and in the long term, a comparison of different sequences suggests that the influence of the industry, albeit strong, is less important than that of resilient coalitions within the Department of Health and amongst other actors who promoted the reform. Thus, we have here concluded that there was a very high probability for the case is a *d* type, and a high probability for the case is an *a*-type. Our posterior belief (0.4) suggests thus a weakening in our prior belief that our case is an *a*-type, although this hypothesis cannot be definitively excluded. This observation poses the issue of a better definition of our prior beliefs for which BIQQ provides some responses: for a case where the clues collected do not allow us to decide formally between two competing explanations, the information that we have before causal process observation may be far more revealing.

## 6 Where to from here?

Regarding the statistical contribution of French and English cases to our sample, our qualitative results are clearly insufficient to directly make an inference to the large-*n* data and to change our results. As already shown by Humphreys and Jacobs when they studied the links between Natural Resources and Conflict, "even strongly probative within-case evidence collected for a small number of cases may make only a small contribution to inference when combined with a substantial amount of correlational data". Thus, more case-studies are required to explore the ramifications and modalities of statutory capture in this policy field. To do so, we have planned supplementary analysis and clue collections on the German and Italian cases, mainly using work carried out by others (notably Hassenteufel 2015 for Germany, and Capri et al. 2001, Garattini et al. for Italy). The two countries appear in black on the Gaussian Mixture Model results, meaning that they share the common feature of being  $X = 1$ ,  $Y = 1$  cases (as France) and being strong contributors to our statistical result (inverse relation between HTA and Pharma). Once this additional data collection will be achieved, we will build another model to integrate quantitative and qualitative results in a fully Bayesian setting. Such an approach is slightly different from that proposed in this provisional paper, in the sense that our prior is not a way to condition the causal process observations, but instead is directly formed on the basis of "mixed" data (Humphreys and Jacobs 2015).



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## 8 Appendix

Country	[hta score] $X \approx$	[pharma score] $Y \approx$
Austria	0	0
Belgium	0	0
Canada	1	0
Czech Republic	0	0
Denmark	1	0
Finland	0	0
France	0	1
Germany	0	1
Hungary	0	0
Ireland	0	0
Italy	0	1
Netherlands	1	0
New Zealand	1	0
Norway	1	0
South Korea	0	1
Spain	1	0
Sweden	1	0
Switzerland	0	1
United Kingdom	1	1
United States	0	1

Table 5: List of countries examined (provisory results)

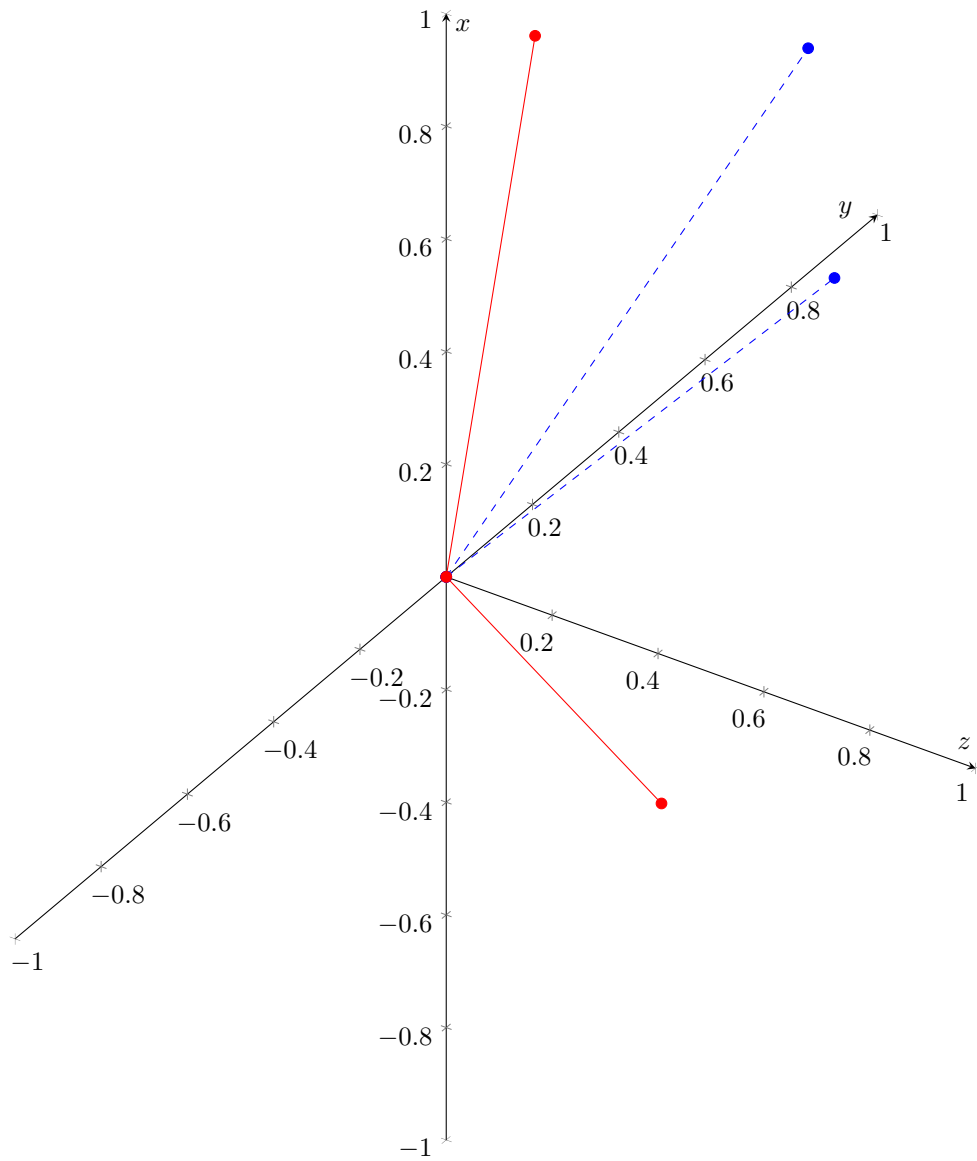


Figure 2: Correlation circle in the factor space of (F1 and F2)  
 $[x, y = 78, 21\%]$  ;  $[y = 27\%]$   
 Source: Benoît et Gorry (2014), Benoît et Gorry (forthcoming)