Original Investigation

Crisis and Change: The Making of a French FDA

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Policy Points:

- Introducing a recent special issue of *The Lancet* on the health system in France, Horton and Ceschia observe that “the dominance of English as the language of science and, increasingly, global health too often closes the door on the history and experiences of others.”¹
- In that spirit, this manuscript presents a detailed case study of public health policy transformation in France in the early 1990s. It casts light on processes of policy change in a political and cultural environment very different from that of the United States, showing how the public health policy process is shaped by multiple contingencies of history, ideology, and politics.
- More specifically, we describe the transformation of a disease catastrophe into a political crisis and the deployment of that crisis to precipitate reform of the French public health system.

Context: Until the last decade of the 20th century, France had no equivalent to the US Food and Drug Administration. In this paper we describe and interpret the complex series of events that led to the passage by the French Parliament in December 1992 of a law incorporating such an agency, the Agence du Médicament (literally, “medicines agency”). The broad aim of this project was to learn how public health policy change comes about by detailed analysis of a specific instance. More specifically, we aimed to better understand the circumstances under which public health crisis leads to significant public health policy reform.

Methods: This paper is based on detailed analysis of primary documents (eg, archived French health ministry papers, recorded parliamentary debates,

government reports, newspaper articles) and oral history interviews covering a period from 1988 to 1993. Thematic analysis of these materials was initially grounded in theories of organizational change, moving to constructs that emerged from the data themselves.

Findings: Policy entrepreneurs positioned to frame adverse events and seize opportunities are key to public health policy reform. However, whether these entrepreneurs will have the requisite institutional power is contingent both on political structure and on the power of competing institutional actors. Health crises *may* catalyze institutional reform, but our analysis suggests that whether reform occurs, or even whether adverse episodes are labeled as crises, is highly contingent on circumstances of history, political structure, and political ideology and is extremely difficult to predict or control.

Conclusions: Actors positioned to shape public health policy need to have a detailed understanding of the circumstances that facilitate or impede policy reform. Health crises are now more often global than not. Comparative, theoretically grounded, cross-national research that looks in detail at how different countries respond to similar health crises would be extremely valuable in informing both policymakers and researchers.

Keywords: France, drug and narcotic control, public health, health care reform.

UNTIL THE LAST DECADE OF THE 20TH CENTURY, FRANCE had no equivalent to the US Food and Drug Administration (FDA), the powerful agency that regulates Americans' access to prescription drugs. In this paper we describe and interpret the complex series of events that led to the passage by the French Parliament in December 1992 of a law incorporating such an agency, the Agence du Médicament (literally, "medicines agency"). The institutional changes that this action represented both in itself and in its sequelae went far beyond the mere passage of a single law or the creation of a single new agency. The 2 independent agencies created by this law—the Agence du Médicament (AM) and the Agence Française du Sang ("blood agency")—were constructed and framed as France's response to a national political crisis (the "*affaire du sang*," or "affair of the contaminated blood") and as the first pillars of a new state-sponsored ideology of "*sécurité sanitaire*." As in other industrialized countries with established systems for blood collection and distribution, HIV contamination of the French blood supply occurred in the early 1980s. By the mid-1980s, the threat to the

blood supply had been largely contained with little or no public notice. The “crisis” and its attendant political threat (the *affaire du sang*) erupted in 1991 when the fact of contamination was rediscovered, heavily dramatized, and laid at the door of government officials. (“Government” in this article refers to the executive branch: the president, prime minister, ministerial cabinets, and administrative services. The legislative branch, or parliament, is identified separately.) In this paper we tell a story of entrepreneurial slight-of-hand: how a handful of officials collaborated to link blood and drugs, creating not only the French FDA but also a new and prestigious terrain for the conduct of public health in France.

Curative medicine—the management of health care systems and the cost of medical care—is central to the political agenda of virtually every industrialized democracy. Public health, on the other hand—“community action to *avoid* disease”²—has seldom been of comparable interest to public authorities. This disinterest has been particularly marked in France for reasons both ideological—the potential of public health interventions to interfere with personal and property rights (the latter as well as the former enshrined in the 1793 Declaration of the Rights of Man and the Citizen)—and institutional: French physicians have historically used their power, both professional and political, to oppose any public health measures perceived as a threat to their professional prerogatives.^{3,4} Contemporary public health campaigns—tobacco control, for example—were often publicly construed as deprivation by an overprotective state of individuals’ right to enjoy dangerous pleasures.^{5,6}

During the period of which we write, responsibility for public health was located in a relatively small subdivision of the ministry of health, poorly staffed, with minimal financial resources, and buried in a much larger ministry that was responsible for hospitals, pharmacies, and the country’s systems of health and social insurance. Public health programs (eg, breast and cervical cancer screening; vaccination; information campaigns on tobacco, alcohol, nutrition, and other public health issues) were carried out, but “public health” was administratively and politically outranked not only by curative medicine but also by other, more prestigious activities of the French state.^{7,8} The blood crisis presented a unique opportunity—perceived as such and seized by politically well-placed health officials—to accord public health its rightful place (as they saw it) concretely in the form of new public health institutions and ideologically as “*sécurité sanitaire*.” (Literally translated as “health security,”

there is no good English translation of this phrase. With its implicit historical [*cordon sanitaire*] and contemporary [*sécurité social*] references, it has a far more muscular meaning in French than in English, invoking the sovereign power and responsibility of the state to protect the French population from health risks.)

Over the past 2 decades *sécurité sanitaire* has become the centerpiece of a new and substantial public health policy arena.^{7,8} Some indicators of this field's importance include the (now) 10 independent agencies established in its name (eg, for disease surveillance [comparable to CDC], for environmental protection, and for other traditional public health activities), the many government documents and reports on this concept (meaning, implementation, etc), its inclusion in the mission of state institutions (ministry of agriculture, regional health agencies, etc), and its place as a separate entry in Wikipedia. In contemporary France, the concept of *sécurité sanitaire* and its attendant institutions occupy significant new symbolic and material space within the panoply of the state, going a long way to fill the public health vacuum that existed prior to the blood crisis.

Among the first—and arguably the most critical—of the steps in construction of this new policy arena was the fabrication of a French FDA—the AM. By fabrication, we do not refer to bricks and mortar, but to an intense, highly contentious series of organizational discourses extending over a period of years. These discourses are recorded in cabinet archives and parliamentary reports and debates and continued to reverberate in the retrospective oral history interviews we conducted. Contentious discourse did not end with the legislative enactment of the AM in December 1992. Nevertheless, the discourse we will analyze here, extending from 1988 through 1992, established the framework for all subsequent debate, constructing not only a new regime of pharmaceutical regulation but also wholly new understandings of the political and social arena in which such regulation was placed.

The groundwork for the AM was laid well before the blood crisis. It was, nevertheless, the offspring of that crisis both in the timing of its enactment and in the particular form that it took. In describing the tortuous process of its founding, we hope also to shed light on 2 broader questions: First, under what circumstances are adverse public health episodes transformed into “crises” worthy of political and policy attention? And, second, when, why, and how do public health “crises,” even if perceived as such, become vehicles for institutional reform? Both

our formulation of these questions and our approach to data collection and interpretation are grounded in a substantial body of literature in sociology and political science addressed to questions of political agenda setting and organizational and policy change.⁹⁻¹³ We do not engage this literature directly in the paper. Nevertheless, the French case we describe does nicely illustrate many of the ideas and concepts these scholars have advanced, and the direction of our work greatly benefited from the signposts they put down.

As a term of art in the social sciences, “crisis” refers to an event or series of events that destabilize existing institutions and the routine normative and behavioral expectations associated with those institutions.¹⁴ The destabilizing impact of the French blood crisis of 1991-92 on key institutions—not only the blood system but also the medical profession and the health care system more broadly—was profound, undermining settled assumptions as to these institutions’ character and integrity and leading, ultimately, to their wholesale reconfiguration. The first, critical step in examining these events is to establish their location in time and space and in relation to other events that came before and after.

The Agence du Médicament

Sources and Approach

The AM came into being in the winter of 1992-93 when all France was racked by the unfolding drama of HIV-contaminated blood; it was the drama of HIV-contaminated blood that gave birth to the AM and shaped its form as a regulatory arm of the French state. But the path to its creation was a long and tortuous process and, with the critical exception of its denouement, had little to do with the blood scandal. Understanding of this process requires that we pay careful attention not only to the blood story but also to the prior history of pharmaceutical regulation in France.

Our sources for these narratives include primary and secondary documents and 7 extended oral history interviews with principal actors in the events we describe. These actors were almost all government ministers, high-level civil servants, and members of the French Parliament. (With the exception of pharmaceutical industry representatives, actors outside

the executive, administrative, and legislative branches of government played little or no direct role in debate on the AM.) Data on how and why the AM was born, repeatedly blocked, and ultimately revived and passed come from our oral history interviews with the principal architects of this revival as well as from 2 sets of primary documents: (1) cabinet archives of the French health ministry from June 1988 through March 1993, deposited with the French National Archives; and (2) the full texts of relevant French parliamentary debates (available online), as well as pertinent parliamentary reports (available from the library of the French Senate). These sources are listed in Table 1. Additional sources include reports from the major French national newspapers, along with a substantial secondary literature on the blood crisis and its aftermath.

The story we have to tell is complicated not only by the need to weave together and thematically integrate data from multiple sources but also to attend to 2 parallel narratives: the primary narrative—the death and resurrection of the AM—and the second, but equally critical, narrative of the contaminated blood; its interpretation by politicians, the media, and the public; and its role as a catalyst for creation of the French FDA and, more broadly, for the reinvention of public health in France.

Pharmaceutical Regulation in France

The production of medicines in France before World War II was in many respects a cottage industry, rooted in the 19th century when pharmacists compounded drugs in the backrooms of their many small shops. The industry was regulated by a law passed by the revolutionary government in 1803 with the principal object of protecting the monopoly of pharmacists over this trade.^{15,16} Even today, many pharmaceutical companies are family businesses. Only in 1961 was the public health code modified to allow outside (nonfamily-controlled) investment capital; requirements for participation of licensed pharmacists in the management of pharmaceutical firms are still in place.^{16(p485)}

The first law requiring some form of evaluation before a medicinal drug could be put on the market was promulgated by the Vichy government in 1941.¹⁵ State regulation of the pharmaceutical market increased gradually over time, driven by an often paradoxical combination of economic, scientific, social, and public health pressures, in which economic pressures tended to dominate.¹⁷ The cost of medicinal drugs to the consumer has been covered by the French health insurance system

Table 1. Primary Texts

Ministry ^a	Health Ministry Archive Folders ^b	Parliamentary Reports and Debates ^c	Other Government Reports
ROCARD 1988-1991 (Evin) (Durieux)	1/1988-9/1990: Hemophilie/ Notes du cabinet 7/1988-4/1989: Hemophilie/ Sida 8/1988-3/1991: AIDS 12/1988-3/1991: Blood transfusion: Blood donors 7/1988-5/1991: Médicaments 10/1990-3/1991: Politique de santé: financement de la protection sociale 9/1987-3/1991: Industrie pharmaceutique		3/1989: The French pharmaceutical industry (Dangoumeau and Biot Report) 2/28/1991: Proposed reforms of French pharmaceutical drug policy instruments (Weber Report) 9/1991: Blood transfusion and AIDS in 1985 (Lucas Report)

Continued

Table 1. *Continued*

Ministry ^a	Health Ministry Archive Folders ^b	Parliamentary Reports and Debates ^c	Other Government Reports
CRESSON 1991-1992 (Bianco) (Durieux)	5/1991-10/1991: Médicaments	PL 2219 – Agence du med 9/11/1991: Text submitted to Parliament 9/26/1991: Report: Deputy B. Charles 10/3/1991: Assembly (1) 10/3/1991: Assembly (2) 10/4/1991: Assembly 10/23/1991: Report: Senator H. Missoffe 10/28/1991: Senate 10/30/1991: Senate 12/11/1991: CMP Report: Charles and Missoffe ^d 12/16/1991: Senate 12/17/1991: Senate	6/11/1992: Report of the (Senate) commission of inquiry on the transfusion system with a view to its reform (Sourdille and Huriet Report)
BÉRÉGOVOY 1992-1993 (Kouchner)	9/1992-3/1993: Création de l'Agence du Médicament 7/1992-3/1993: Médicaments 7/1991-3/1993: Affaire du sang contaminé (multiple subfolders)	PL 92-1279 – Pharmacie et médicament 5/19/1992: Senate 6/30/1992: Assembly (1) 6/30/1992: Assembly (2) 11/26/1992: Assembly	

Continued

Table 1. *Continued*

Ministry ^a	Health Ministry Archive Folders ^b	Parliamentary Reports and Debates ^c	Other Government Reports
	4/1992-3/1993: Fonctionnement générale du cabinet Bernard Kouchner 4/1992-3/1993: Programme du travail de Bernard Kouchner (par journée) 4/1992-3/1993: Restructuration du ministère de la Santé 4/1992-3/1993: Interventions 4/1992-3/1993: Moyens et fonctionnement de la Direction générale de la santé	11/5/1992: Senate PL 3003 – Blood 11/19/1992: Report: Deputy A. Calmat 11/26/1992: Assembly (1) 11/26/1992: Assembly (2) 11/27/1992: Assembly 12/9/1992: Report: Senator C. Huriet 12/16/1992: Senate 12/19/1992: CMP Report: Calmat and Huriet 12/21/1992: Senate	

^aPrime ministers are in caps. Health ministers are in parentheses.

^bThe French National Archives (FNA) identify cabinet archives by box (ie, cardboard carton) number. Within each box are multiple folders, loosely organized by topic. In the text, we refer to these materials by box number and, where appropriate, by date.

^cA "projet de loi" is a proposed law submitted to Parliament by the government in power. "Projets de loi" referenced in this table are (1) PL 2219: "Projet de loi" concerning the 'Agence du médicament' and the regulation of expenditures covered by obligatory health insurance programs"; (2) PL 92-1279: "Projet de loi" concerning pharmacy and medications"; and (3) PL 3003: "Projet de loi" concerning the gift and therapeutic utilization of human blood and the organization of blood transfusion."

^dCMP = "Comité mixte paritaire." It is the equivalent (more or less) of a House-Senate Conference Committee.

since the end of World War II. Not surprisingly, a primary concern of governments has been to keep down the drain of these costs on the health care budget. At the same time, governments have had the not always easily reconcilable goals of protecting public health and increasing the competitiveness of the French pharmaceutical industry.^{16,17} Daniel Carpenter observes that “French officials [in the 1950s] . . . kept a close eye on American developments, in part seeking information from an understanding that French testing requirements were years behind the clinical test requirements of American authorities.”^{18(p692)} The requirement that new drugs be officially approved before being put on the market (the AMM, or *autorisation de mise sur la marché*) based on quality, safety, and effectiveness was written into the public health code in 1967. The task of proposing an AMM, as well as recommending levels of reimbursement by the insurance system, was put in the hands of a commission (eventually called the Transparency Commission) composed of scientific experts, representatives of the pharmaceutical industry, and ministry officials. Final decisions on whether to grant an AMM were made by government ministers.¹⁷ (It is noteworthy that blood and blood products were not covered by these arrangements. Blood products came under the control of the new drug agency in 1993, whole blood in 1998.)

The cornerstone of premarket licensing is systematic evaluation, testing, and control of new drugs (accomplished in the United States by scientists at the FDA). Prior to creation of the AM, those activities were carried out in France by scientists and technicians directly employed by the Ministry of Health and outside scientists under contract to the ministry. Over the 15 years before 1993, funding for the 2 responsible entities within the ministry (the National Health Laboratory and the Directorate of Pharmacy and Medicines) had declined and their personnel was reduced and spread over several geographic sites.¹⁹ At the same time, as medicinal drugs became more scientifically sophisticated and the pharmaceutical industry expanded and globalized, these small subdivisions of the health ministry were confronted by a constant increase in demands for an AMM, resulting in a backlog that increased correspondingly, long delays in issuing an AMM, a diminished reputation—“the national scientific laboratory is incontestably one of the weak points in the French health care system”^{19(p10)}—and the threat that “big pharma” would seek market authorization from other countries with more “efficient” regulatory processes.²⁰ Given the corresponding loss of revenue from the fees pharmaceutical companies paid for regulatory review of

their products, this was a serious threat. Yet another problem, one that was less openly expressed but strongly implied in our interviews, in cabinet documents, and in parliamentary debate, was that decisions to issue an AMM were subject to undue influence from government officials and the pharmaceutical industry.

Creation of the AM was intended to fix these problems, bringing the National Health Laboratory and the Directorate of Pharmacy and Medicines together as a single entity and at a single site, endowing its director with final authority over the AMM, and providing it with sufficient resources in funding and in scientific and technical personnel to accomplish its mission of pharmaceutical drug evaluation and control.²¹ These objectives were well expressed in the opening paragraph of the January 4, 1993, law by which the French FDA was created:

In order to guarantee the independence, the scientific competence, and the administrative effectiveness of studies and controls relative to the manufacture, [clinical] trials, and therapeutic properties, and the use of medicinal drugs; in order to ensure, at a reasonable price, the health and security of the population and to contribute to the development of the industry and of pharmaceutical research, there is created a public establishment of the state, to be named "*Agence du médicament*"²² (authors' translation).

Importantly, the new *agence* was to have *no responsibilities* in the domain of pharmaceutical pricing and cost control. We turn now to the tortuous process that preceded the act of its creation.

Budgets, Medicines, and the EU

The French government in the late 1980s was confronted with major challenges on multiple fronts. They were acutely aware of some of these challenges; others were just coming into view. Managing the budget of the health care system was an ever-present challenge. By the spring of 1991, the budget issue had become acute to the point of panic, evidenced in repeated intraministerial communications (FNA: Box 10070575/1). Expenditures for pharmaceutical drugs were among the major contributors to the costs of medical care assumed by the French system of health and social security, and a major component of the government's fiscal strategy was to bring pharmaceutical costs down. Plans put forward by the cabinets of the various ministries concerned (eg, health, finance, and that of the prime minister, not necessarily in concert and often

internally inconsistent) included manipulation of drug prices, limitations on drugs to be reimbursed by the health insurance system, a ceiling on pharmaceutical company advertising expenditures, and campaigns to reduce French consumption of prescription drugs (the highest in Europe). More generally, the pharmaceutical industry came to be perceived by the French government as both a drag on the economy and a potential cash cow.

At the same time, the fragile state of the French pharmaceutical industry—in particular its lack of competitiveness in world markets, but also its lag in the introduction of new drugs relative to European and North American competitors—was an argument repeated over and over in parliamentary debates on the subject (most vociferously by the more conservative members, accompanied by attacks on the government's "stranglehold" on the industry, and somewhat less frequently by a socialist government caught between its desire to support French industry and its need to reduce the costs it paid for medical care).²³⁻²⁵ Contributing to the unflattering portrait of this industry in France were the reiterated weaknesses of the existing system for regulation of pharmaceutical drugs, located in weak and under-resourced divisions of France's historically weakest ministry.⁷ (France was by no means the only country in Europe without a specialized agency for control of medicinal drugs. It was not until very late in the 20th century that the majority of European countries put comparable agencies in place.²⁰)

Finally, and perhaps of most importance, were pressures from the European Union (EU) to bring French pharmaceutical practices into conformity with directives from the European Commission. These directives, issued in 1989 with an "at the latest" effective date of January 1, 1992, required that medicinal drugs (including blood products) be thoroughly evaluated for quality, safety, and effectiveness by either a state- or other-designated laboratory and be subject to formal authorization before being put on the market.²⁶ Once this authorization was obtained, it would be valid throughout the EU. The need for parliamentary action (ie, legislation) to comply with these directives was a constant theme in intragovernment communications from 1989 on and was one of many bones of contention once the relevant legislation came before Parliament. Adding fuel to this fire was the dual threat that not only other European states (under the same EU pressures as France) but also the EU itself (as it had already proposed) would move quickly to

develop their own specialized agencies, offering French pharmaceutical companies (and their international competitors) multiple other venues to pay their fees and obtain market authorization and, therefore, be free to sell their products throughout Europe.²⁰

A French FDA?

The European directives were issued in late May 1989. During the subsequent year and a half, periodic memos advocating the creation of a new “instrument of control and protection of human health” (June 8, 1990) and, more specifically, an “*agence du médicament*” (October 29, 1990) were generated from within the health ministry and directed upward in the cabinet hierarchy and to the prime minister. The context for these memos has been described. Their aims were to see France endowed with an institution for drug control comparable to those already in existence elsewhere (principally the United Kingdom and the United States) and planned by the EU, and to bring France into compliance with the EU directives. (Indeed, French scholar Boris Hauray, although acknowledging the importance of the blood crisis in France, argues that intra-European competition, propelled by these directives, was the principal impetus for creation of drug agencies throughout Europe. He notes that by 2004, only 3 European countries had not adopted this form of drug control.²⁰)

Repeated over and over in cabinet documents were statements that the current French system was not up to the job; in the absence of change, French drug companies would seek authorization for their drugs from outside the boundaries of France. By December 1990, the decision to create an “*agence du médicament*” in 1991 had been taken by the then prime minister, Michel Rocard. In a letter dated December 22, Rocard asked Jean Weber, a former head of the drug-control unit within the Ministry of Health, to prepare a detailed plan for the agency—its structure, its responsibilities, and its resource requirements—including a proposed text for the government to put before Parliament that spring. Rocard described the missions of the agency as both scientific (drug evaluation prior to market authorization) and economic (cost control).

It will be helpful to begin our narrative of the AM as it unrolled between February 28, 1991, when Weber submitted his report, and

December 19, 1992, when the AM passed both houses of Parliament, by identifying the key players. The original law incorporating the AM was a government project (as are most French legislative proposals) proposed, introduced, and ultimately passed under the aegis of 3 Socialist prime ministers: Michel Rocard, who requested the Weber report; Edith Cresson, who introduced and then withdrew the original bill; and Pierre Bérégovoy, under whom it was passed. Shepherding the law through Parliament (the National Assembly and the Senate) was largely the responsibility of the minister of health—first Bruno Durieux, who served under Rocard and Cresson, and then Bernard Kouchner under Bérégovoy. (Kouchner was a “full” minister, while Durieux, as a “delegated” minister, had considerably less power.) Key actors in Parliament were the chairs of the responsible parliamentary committees and, in each house, the *rapporteur* who presented his or her committee colleagues’ views on and suggested amendments to the bill before the assembled deputies (in the Assembly) or senators. Strategic intervention by Claude Huriet, the Senate *rapporteur* for Kouchner’s bill to reform France’s blood system, was instrumental to the creation of the French FDA. Huriet was a physician, politically conservative, and highly respected for his parliamentary work in both medical ethics and AIDS.

Active behind the scenes in this political drama were ministerial cabinets, not only of the health minister but also of the several other ministries with an interest in this legislation (eg, the Ministry of Finance and, of course, the prime minister). The unique power of French ministerial cabinets has been well described by Ezra Suleiman: “In its organization, personnel, and responsibilities, the cabinet is a peculiarly French institution” handpicked by the minister, devoted to his or her interests, and with considerable influence in shaping the minister’s actions.²⁷ Finally, even further behind the scenes but with important connections in parliament and the ministries (evidenced in our data by the presence of its representatives on the health minister’s meeting agenda and as witnesses before parliamentary committees) was the pharmaceutical industry. (Although the blood crisis engaged many other actors [eg, the judiciary, hemophiliacs and their spokespersons, the medical profession], there is no evidence in our data of their participation in the debate over the AM despite the key role of this crisis in the AM’s creation.)

The path to the AM’s creation was nothing if not convoluted. Tables 2 and 3 lay out the chronology of its passage in 2 acts. Act I dates from the presentation of the Weber report to Prime Minister Rocard at the

Table 2. Agence du Médicament: Act I, 1991

A French FDA?

2/28/1991	" <i>Proposition de Rénovation des Instruments de la Politique Française du Médicament</i> " (Weber report) submitted to French prime minister. Proposes creation of a strong, independent drug control agency, modeled on US FDA.
9/11/1991	Prime minister (on behalf of government ^a) proposes law to create Agence du Médicament. Law is titled: " <i>Projet de loi relatif à l'Agence du médicament et à la régulation des dépenses de médicaments prises en charge par les régimes obligatoires d'assurance maladie</i> ." (Law concerning the Agence du Médicament and the regulation of drug expenditures covered by the health insurance system.)
10/3/1991	National Assembly opens discussion of proposed law.
10/4/1991	Government invokes Article 49.3 of French constitution, declaring the law adopted by the Assembly without a vote.
10/7/1991	Cabinet meeting stating that the purpose of the law was to bring France into conformity with EU directives, and irrelevant material was added (by Parliament).
10/28/1991	Senate opens discussion of proposed law.
10/29/1991	Senate adopts series of amendments to gov. proposed law, intended to render AM more powerful, more independent, more "scientific." Government (as represented by health minister) opposes those amendments. Law is adopted on party-line vote with Senate amendments. ^b (conservatives for, socialists and communists against).
12/11/1991	CMP (Assembly/Senate Conference Committee) agree on text as redacted by Senate, incorporating amendments opposed by the government.

Consignment to the Ash Heap

12/17/1991	Government will not put CMP agreement before Parliament. MOH: "The agreement by the CMP is very interesting, but it puts in place a system profoundly different than what the government had in mind, hence the decision of Madame the Prime Minister [not to put the agreement before Parliament]."
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^aIn line with French usage, we use "government" to refer to the executive branch (as distinct from Parliament).

^bSenate in 1991 was controlled by conservatives. Assembly (as well as executive branch) was controlled by socialists.

Table 3. Agence du Médicament: Act II, 1992

4/5/92	Bernard Kouchner (BK) takes over as minister of health (MOH).
5/13/92	Fax from chair of National Assembly Commission on Social Affairs to BK to complain of government action preventing vote on Agence du Medicament (AM) ("First time Parliament treated like that since the beginning of the Vth Republic"). ^a
5/19/92	Senate questions BK repeatedly on AM.
5/25/92	Memo from responsible cabinet official to BK: " <i>Pourquoi une Agence du Médicament, vite?</i> " ("Why an AM, <u>quickly</u> ") (underline in original). Repeats earlier financial and competitive arguments. Nothing new.
6/23/92	Memo from director of Division of Pharmacy in MOH to BK cabinet director on need for AM. Emphasis on division's insufficient resources to carry out responsibilities in domain of drug approval. No new arguments.
6/30/92	Assembly questions BK repeatedly on AM.
11/26/92	" <i>Projet de loi</i> " to reform French blood system (blood law) introduced and discussed in National Assembly.
11/26/92	In course of that discussion, deputy <i>rapporteur</i> for AM law introduced in 1991 (see Table 2), states, "We need an AM like all the other European countries." BK replies, "For the time being, the AM does not exist. We may regret it, but that's the way it is."
12/11/92	Memo from responsible cabinet official to BK titled: "Argument for the AM": AM reframed as (1) essential to " <i>sécurité sanitaire</i> ," and (2) when combined with the blood law, "totally innovative in the domain of public health, creating a new forward-looking dynamic."
12/15/92	BK meets with prime minister (PM). Argues for amendment to blood law incorporating AM. Amendment will be proposed by Senator Claude Huriet.
12/16/92	Senator Huriet introduces amendment to include AM in blood law. Passed by Senate.

Continued

Table 3. *Continued*

12/18/92- 12/19/92	Back and forth between BK and PM. PM says insufficient control of AM by the state. BK says no further changes/amendments will be tolerated. BK wins.
12/21/92	Blood law incorporating AM passed by both houses. No further amendments.

^aThis deputy (Belorgey) had been chair of the CMP (Conference Committee) that voted unanimously for the agreed-upon AM text.

end of February 1991 to December 1991, when Prime Minister Cresson refused to put the law as agreed upon in conference committee (the *Comité Mixte Paritaire*) to a vote in parliament. Act II begins with Kouchner's appointment as minister of health in April 1992 and ends in December 1992 with passage of the law incorporating the AM by both houses of parliament. We refer back to these tables as our narrative unfolds.

As it made its way through ministerial cabinets and the houses of parliament, the 2 principal hurdles confronted by the proposed drug agency were, first, the balance of its scientific and economic missions (the latter left extremely vague in the prime minister's letter to Weber) and, second, the extent of its independence from ministerial oversight and (alleged) politically and/or economically motivated interference with its "scientific" decisions. Would this be a "strong" drug-control institution on the (explicitly articulated) model of the US FDA or would it be a relatively "weak" agency constantly subject to meddling by the numerous ministries with powerful and frequently conflicting stakes in its decisions? The model put forward by Weber in his report to the prime minister was of a strong and independent agency, and—over the objections of Prime Minister Bérégovoy, the former minister of finance—the Weber model was the one adopted by parliament in December 1992 (see Table 3). How this (rare) parliamentary victory was accomplished is the subject of our narrative (see, eg, Helgeson on the weak position of French parliaments relative to the executive branch²⁸).

The Weber report, submitted to the prime minister on February 28, 1991, was greeted with something less than enthusiasm by its intended recipients. The report proposed an institution of the "highest quality"

endowed with the resources in money and personnel necessary to ensure its international standing. (Material quoted in the next 2 paragraphs is taken directly from the Weber report.) Absorbing the 2 existing units and regrouped physically in a single location, the AM would have authority over all phases of drug evaluation and control, following internationally recognized “best practices”; it would decide whether a drug could be marketed or should be withdrawn from the market; and it would have control over pharmaceutical advertising. To accomplish these objectives, Weber believed, required “a new category of public establishment.” None of the existing models carried the requisite authority: in particular, the requisite “transparency, independence, and competence.”^{19(p41)} In his statement of these latter requirements and in the proposed law text, Weber made quite clear his intention that the agency be positioned to exercise its authority not only in confrontation with pharmaceutical manufacturers but also with government ministries: “decisions taken by the director general of the [AM] in application of [articles of the proposed law spelling out the agency’s responsibilities] are not subject to any hierarchical authority.”^{19(p53)} This meant that the director’s decisions could not be overridden by authorities higher up in the political or bureaucratic chain of command (eg, the minister of health, the minister of finance, the prime minister), a perceived erosion of ministerial power that the government found unacceptable.

A second reason for government displeasure was the report’s resolution of what it described as the need to deal with pharmaceutical pricing: “the government will not be able to consider and put before parliament a proposed law on the *agence*, as it clearly intends to do, without presenting simultaneously its plans regarding the price system. . . . The 2 subjects must be treated simultaneously, even if they are quite distinct.”^{19(p2)} Weber proposed a “*Haut comité économique du médicament*” to make decisions regarding which medicines should be reimbursed by the social security system. The director of the *agence* would sit on this committee, and the *agence* would have other “economic” responsibilities, largely to do with data collection necessary to the activities of the “*haut comité*” (literally, high committee). The government rejected the “*haut comité*,” preferring to leave reimbursement (as well as marketing) decisions where they always had been, under the thumb of the ministries.

Consignment to the Ash Heap

The government's reservations about the agency model advocated in the Weber report are clear from memos and meeting notes recorded in the spring of 1991, immediately following the report's submission. The proposed agency was, for example, vehemently attacked by the director of social security (within the Ministry of Health) on the grounds that while determination of "quality, harmlessness, and therapeutic effect" of drugs might be a scientific matter, putting drugs on the market has "social, political, and economic implications that should be decided by the state, not by scientists" (FNA: 970576/1, March 13, 1991). A transfer of authority for such decisions to the *agence*, argued the director, risked conflict between the *agence* and the state.

Heeding these and similar objections to the "strong" agency model, the "project of law" put before the lower house of parliament in the fall of 1991 was a greatly watered down version of what Weber had proposed. Objections had come largely from the ministry of finance and the office of the prime minister and were reflected in internal ministry of health cabinet memos during the months following submission of the Weber report. The government was engaged in active negotiations with the pharmaceutical industry throughout this same period focused primarily on the highly controversial issues around pharmaceutical pricing. (The then head of the French pharmaceutical industry association told us that he personally had been supportive of a strong drug agency, although with reservations as to how deeply the industry would be taxed to pay for it. The position of French manufacturers was less clear, divided as they were between large drug companies [eg, Roussel, Rhône Poulenc] that would benefit from strong French representation in the councils of Europe and the many small companies that feared for the disruption of their hitherto cozy relationships with the Ministry of Health [interview, February 20, 2013].)

The full title of the original bill as introduced on September 11, 1991, was "*projet de loi relatif à l'Agence du médicament et à la régulation des dépenses de médicaments prises en charge par les régimes obligatoires de l'assurance maladie*" ("project of law concerning the Agence du Médicament and the regulation of expenditures covered by the national health insurance system"; see Table 2). This bill had 2 parts. Title I put in place the Agence du Médicament. Title II instituted a new system for pharmaceutical pricing, incorporating a range of what were from the government's

perspective critical economic measures (eg, price controls on pharmaceutical products, limits on expenditures for pharmaceutical advertising). The terms of this bill brought France into compliance with the EU directives of 1989. Deputies and senators of both parties supported creation of a French Drug Agency (Title I), although one with considerably more power and independence than the government proposed. The economic measures outlined in Title II were far more contentious for 2 reasons: (1) a perception by many parliamentarians of an inadmissible mixing of “scientific” with “economic” objectives and (2) undue government interference in the pharmaceutical industry (an issue primarily in the Senate, dominated by conservatives).

We can summarize very briefly the fate of this bill once it came before parliament in the fall of 1991 (see Table 2). Anticipating on the basis of its negative reception in the National Assembly (despite domination by members of its own party) that the proposed law would be voted down in that body or passed with amendments unacceptable to the administration, Prime Minister Cresson invoked a provision of the French constitution that allows the government to immediately end debate and declare its version of the law adopted without a vote. (This strategy was employed by Socialist governments of the period at a rate of close to once a month, far above the rate of governments before or since.) The National Assembly cannot override this decision without toppling the government, an action it has so far not taken in the history of the Fifth Republic.²⁸ The bill then went to the Senate, where its reception was even more negative than in the Assembly, primarily due to its price-control provisions (Title II), although the Senate was also determined to restore to the AM the powers envisaged in the Weber report (and was, indeed, accused by the government of using the Weber report as its “bible”).

The law text produced by the Senate’s Commission on Social Affairs and adopted by a majority of the Senate in October 1991 (see Table 2) was intended to accomplish 3 things: first, to create an entirely “new” institution for the control of pharmaceutical drugs with powers comparable to its counterparts in other countries (ie, the United States); second, to clearly separate the “scientific and technical” missions of that institution from the “economic” missions associated with pharmaceutical pricing; and, third, to restructure those economic missions under the aegis of a “*Haut comité du Médicament*.” (As in the government’s version of the law, the AM was spelled out in Title I, economic measures in Title II.)

The Senate's text was adopted unanimously by a conference committee of the 2 bodies (equivalent to a House-Senate conference committee). Members of the Senate learned on December 17, 1991, that the government would not bring that text before Parliament for a final vote (on the insistence of then Minister of Finance Bérégovoy, who opposed the projected transfer of administrative and economic power outside of direct ministry control). Explaining this decision to the Senate, the minister of health stated that "the agreement reached by the [conference committee] is very interesting, but it puts in place a system profoundly different than what the government had in mind."^{29(p5464)} To summarize, the government's underlying purpose in this series of maneuvers was to block the adoption of a law that it feared would move significant institutional and economic power away from its ministries and lodge this power externally in the AM and the *Haut comité*. It accomplished this purpose in the Assembly by forcing the adoption of its own, weak version of the law, and in the Senate, by blocking a vote on the Senate's strong version of the law.

Senators' response to the government's decision was one of unmitigated fury. "It is unusual enough that we [the Assembly and the Senate] agree. Of what use is Parliament? . . . It is no longer necessary to vote on the law, if you present us a text and we are expected to end up with exactly the same text, which makes no sense! Parliament no longer exists!"^{29(p5464)} "It is inadmissible that a text resulting from an agreement in the [conference committee] is not submitted to Parliament under the pretext that it does not suit the government."^{29(p5464)} (A bill for the sole purpose of bringing French law into conformity with the 1989 EU directives was introduced by Kouchner as minister of health in May 1992 and finally passed the following November, drawing innumerable caustic comments from both houses of Parliament to the effect of, "Where is the Agence du Médicament to implement these directives?")

The arguments advanced by both government and Parliament throughout the debate leading up to the demise of the government's legislative project (and of the AM) in December 1991 were almost wholly economic: The aims of this project were to bolster the fortunes of the French pharmaceutical industry; increase its competitiveness in Europe and globally; and, at the same time, keep pharmaceutical prices under control. Given the government's economic aims, any suggestion that an agency *independent* of its control would have a deciding

role in pricing or marketing decisions was anathema: such decisions must remain under the thumb of the relevant ministries, where they had always been. The effect of the blood crisis was to upend these calculations.

From Health “Catastrophe” to Political Crisis

Blood donations in France were voluntary, unpaid, and anonymous. At the time of which we write, the French blood system was highly fragmented, consisting of close to 200 independent blood transfusion centers: “private community nonprofits and public community hospitals . . . responsible for collecting and distributing blood throughout the country.”³⁰⁽¹⁴²⁸⁾ In principle, each center reported to the director general of health in the Ministry of Health. In practice, oversight was minimal.³¹ The effect of the blood crisis was not only to call almost every aspect of the blood system into question, but also to shake the public’s faith in health institutions more broadly.

Writing in 2004, François Grémy (among the doyens of French public health) observed: “Everything began with AIDS and the affair of the tainted blood. Like a clap of thunder in the sky of good health and medical progress, the entire society found itself caught in the winds of panic, traumatized, disoriented in relation to its most constant beacons. There was a profound loss of confidence in health officials, but also in physicians, in all those in the health system perceived as no longer capable of guaranteeing the public’s health.”^{32(p195)} There is virtual unanimity among French scholars, politicians, and journalists^{31,33,34} (personal communication, Nau 2011) in dating the “clap of thunder” to April 25, 1991, when an article by medical journalist Anne-Marie Casteret, titled “The Report That Accuses the National Blood Transfusion Center,” was published in a modest biweekly news magazine.³⁵ The centerpiece of this article was the verbatim record, marked “confidential,” of a meeting on May 29, 1985, of the executive committee of the Paris blood bank. This record made clear, first, that the committee had known in the spring of 1985 that the blood used in the center’s manufacture of blood products for hemophiliacs was HIV-contaminated; second, that it made a conscious decision not to withdraw those products from the market; and third, that this decision was driven by financial considerations.

The National Blood Transfusion Center (which we refer to for the sake of clarity as the “Paris blood bank”) was not, in fact, a national center but one of 7 large blood transfusion centers in France (the remaining centers were much smaller). Located in Paris, it was the most influential and prestigious of those centers, actively engaged in both the scientific and industrial (ie, fractionation) aspects of the blood system. The doctors on its executive committee were the elite of France’s blood transfusion system, specialists in hematology with important hospital appointments. Critically, the Paris blood bank advised the government on blood matters and had the sole authority to import blood products from outside of France. Its power within the French blood system far outweighed that of the single staff member devoted to blood affairs within the Ministry of Health.^{31,36}

Reflecting a few months after Casteret’s publication on the impact of her revelations, 2 prominent French medical journalists wrote: “The brutal discovery of a reality unknown to the public and poorly understood by physicians cannot but precipitate changes in an archaic system that [now] appears very different than the one—magnified and idealized because it was built on the benevolence of donors—to which we were accustomed.”³⁷ The context of this “brutal discovery” was the sacralized status of the French blood system, mythologized in word and in print since its inception after World War II. For over 4 decades, the French system had been portrayed as wholly reliant on the “benevolence” of donors and untainted at any level by “profane” monetary concerns (in explicit contrast to the image of a crassly monetized US system). The discovery that this idealized system did not protect against HIV was, of course, particularly brutal.

There is a long and complicated backstory (the most immediately relevant elements of that story are outlined in Table 4). The health catastrophe—HIV contamination of the blood supply leading to the massive infection of hemophiliacs—unrolled in France largely out of the public eye. The majority of infections occurred prior to the institution in 1985 of blood screening and the heat treatment of blood products. Further, rates of HIV infection from blood products were not higher in France than in other developed countries. As of 1991 when the blood scandal broke, the proportion of transfusion-related cases (among total AIDS cases), estimated by Sourdille and Huriet at 5.9%, was not markedly different from the rest of Europe, which ranged from a low of 1.2% in Spain to a high of 7.5% in Belgium; both Greece and Sweden

Table 4. Condensed Chronology of Blood Affair in France^a**Before the Storm**

1982	CDC publishes account of three cases of pneumocystic pneumonia among hemophiliacs, stating that "although the cause of the severe immune dysfunction is unknown, the occurrence among the three hemophiliac cases suggests the possible transmission of an agent through blood products."
1983	Council of Europe recommends that its members take necessary measures to prevent AIDS transmission by blood or blood products. French Public Health Administration (DGS) publishes circular directed to all the transfusion centers in France recommending that blood donors with specified risk factors be excluded. This circular is largely ignored by blood banks.
1985	
<i>January</i>	Second circular on donor selection is issued by the DGS.
<i>February</i>	Abbott (US-based pharmaceutical company) asks for French government approval for blood screening test.
<i>May</i>	In closed session, executive committee of Paris blood bank decides not to recall blood products known to be HIV-contaminated.
<i>June 19</i>	Prime minister announces obligatory blood screening for HIV.
<i>June 21</i>	French government approves Pasteur (French-based pharmaceutical company) blood test.
<i>July</i>	French government approves Abbott blood screening test.
<i>October</i>	Health system will no longer pay for non-heat-treated blood products, effectively withdrawing them from the market.
1988	First lawsuits against blood banks brought by HIV-infected hemophiliacs. Letter to prime minister on behalf of organized hemophiliacs demands attention to their plight.
1988-1990	Ongoing demands from hemophiliacs to government (Ministry of Health) for compensation. Ongoing efforts by ministerial cabinet to limit both publicity about and scope of response to hemophiliacs.

Continued

Table 4. *Continued***Storm Breaks**

1991

<i>April</i>	Article in news magazine reproduces "confidential" minutes of May 1985 blood bank meeting where decision was taken not to recall contaminated blood products.
<i>June 1</i>	Director of Paris blood bank resigns.
<i>June 5</i>	Government asks its watchdog agency (IGAS) for full report.
<i>June</i>	Director of Paris blood bank and two other blood system officials are indicted.
<i>October</i>	IGAS report (known as "Lucas report") is released, reproducing minutes of May 1985 meeting along with 30 more government and blood system documents from 1983 to 1987.

^aSources for this table include cabinet archives and other French government documents listed in Table 1, newspaper clippings archived at the libraries of Columbia University in New York and at Sciences-Po in Paris ("France 474/111 *Sida post-transfusionnel. Affaire du sang contaminé*") as well as articles accessed directly via LexisNexis, and multiple secondary sources (eg, Chauveau,³¹ Feldman and Bayer,³⁹ Hermitte⁴⁰).

had larger percentages than France.³⁸ Based on 1994-95 data from 20 countries in Europe and North America, France ranked seventh in the rate of AIDS cases among hemophiliacs.³⁰ It was the disclosure in 1991 that blood bankers had known of this contamination in 1985 or before, had failed to take immediate preventive action, and had done so for financial reasons—anticipated loss of profit from the center's sale of untreated blood products and expenses that would be incurred if already-sold products were recalled—that precipitated the political crisis. Knowledge of the health catastrophe spread gradually in the period between 1985 and 1991, primarily through the agency of militant infected hemophiliacs to whom HIV infections and deaths among their number were increasingly visible. This knowledge was nonetheless limited to some (not all) hemophiliacs and blood bankers; to government officials, who did everything in their power to keep the catastrophe under wraps (documented in cabinet archives listed in Table 1); and

to a few journalists whose work received little attention until the bombshell dropped by Casteret in *l'Événement du Jeudi* on April 25, 1991. What made Casteret's bombshell uniquely explosive was her revelation of blood bankers' *economic* motives, in shocking contrast with the French public's image of their blood system as being guided solely by altruistic benevolence.

The immediate sequelae of this event are shown in Table 4. Within little over a month, the highly prominent director of the Paris blood bank resigned, he and 2 of his associates (one a former head of the French public health administration) were indicted, and the government acknowledged that "mistakes were made" and called for a complete report from its official watchdog agency (Inspection Générale des Affaires Sociales [IGAS]). This report—titled "Blood Transfusion and AIDS in 1985"—was released in September 1991. It reproduced—and thereby legitimized—the key incriminating document that Casteret had made public in *l'Événement du Jeudi*. The Lucas report (named for Michel Lucas, the director of IGAS, who signed the report) was quickly followed in the fall of 1991 by the appointment of a Commission of Inquiry by the French Senate. Hearings before this commission as well as the trial of those prominent officials (all of whom were physicians) indicted in the spring of 1991 continued well into 1992. In November 1991, the once and future (conservative) health minister and prominent public figure, Simone Veil, appeared on television to pronounce the entire public health system in France a "failure."

Fassin observes that "the political crisis born of the blood affair, which everyone invokes in support of their call for the reform of public health, has had the effect, besides shedding light on the dysfunctions of the public health system, of legitimizing a discourse calling for a new public health order. . . . We must take the portrait of an absence of a culture of public health in France less as an accurate representation of reality than as a manner of acting on that reality."⁴¹(p60) "Acting on that reality," using the major political crisis created by the blood affair as a stepping-stone not simply to reform the blood system but to create an entirely new space for public health, a space that would ultimately extend not only to drugs but also to disease surveillance and control, the environment, and beyond, was the aim of Kouchner's cabinet almost from its inception (documented in the cabinet archives).

Enter Kouchner

The principal architect of Fassin's legitimizing discourse—the locale where the discourse was framed and action strategies were developed—was the ministerial cabinet of Bernard Kouchner, minister of health from April 1992 through March 1993. As part of a cabinet reshuffle within the socialist government, Kouchner, a physician, the founder of Médecins Sans Frontières (Doctors Without Borders), and already a charismatic figure in French political life,^{7,8} took office as minister of health on April 5, 1992. Elections scheduled for March 1993 were expected to drive the socialists out of power, and there was intense pressure on Kouchner and his cabinet to accomplish a great deal in a short time, in particular to orchestrate a strong and highly visible response to what the government *now* perceived as a social and political crisis: the affair of the contaminated blood. Kouchner “actively campaigned to be minister of health. . . . [The previous health minister] was incapable of managing the blood crisis. Kouchner was appointed because he was seen as charismatic, ‘médiatique,’ and able to do it” (interview with former cabinet official, December 1, 2011).

Upon their arrival in April 1992, the young men and women of Kouchner's cabinet (his cabinet director was barely 30) were plunged into what they recall as a scene of chaos: “Everyone was terrorized. . . . Matignon [the office of the prime minister] was terrorized . . . and had confidence in Kouchner. The administrative services were not on top of this. . . . They responded to demands [*commandes*] from the cabinet, but [it was the cabinet] who had the responsibility [*portaient le dossier*], who wanted to carry out reforms, who wanted to go as far as they could. . . . No one knew exactly what to do, we had to understand something that affected everything, and no one was rushing to tell us what to do. . . . We worked night and day, and truly night and day” (former cabinet official, interviewed October 2010). “We were a group of friends, of men, of practitioners who arrived at a moment when the system was collapsing. . . . We had to put things in order” (former cabinet official, interviewed June 2010).

“Institutional entrepreneur” is a term of art in economics, sociology, and political science used to describe innovative individuals able to marshal institutional resources to effect change^{10,42-45} Fligstein and McAdam emphasize that “the position of entrepreneur is not a disposition or a quality of an individual, it is instead a role that is available

under certain conditions of social fields,"^{13(p181)} specifically, "a generalized sense of uncertainty within the field and a shared motivation to engage in innovative contentious action to advance or protect group interests."^{13(p177)} These were precisely the conditions created, first, by the blood crisis and, second, by the government's initial fumbling response to that crisis. Framing this state of affairs as an unprecedented opportunity not only for reform on a grand scale but also to add to the stature of the health ministry in general and of *their* minister in particular was the work of Kouchner's cabinet. In an early memo outlining a ministerial program for the coming months, his cabinet director wrote to Kouchner: "You were installed as the minister of public health at the very moment when the state was accused of failing in that domain." The director went on to describe the minister's mission as that of "restoring confidence" and to spell out how that should be done so as to confirm Kouchner's "very strong position as the minister who restored confidence." The director concluded with the statement that this proposed program "opens up a new . . . approach to health policy, clarifying administrative and individual responsibilities and the place of *solidarité* in the health system. It offers the opportunity to imprint even more clearly the brand, KOUCHNER" (FNA: 97/005/1-19970575/1, July 27, 1992, capitalization in original). In this quintessential act of institutional entrepreneurship, the director laid down a program to remake public health in France and employed less than subtle flattery to convince his boss of its merits. The program envisioned in this memo went well beyond reform of the blood transfusion system to include "therapeutic risks" more generally (eg, nosocomial infections), bioethics, drug addiction, and "public health" as an administrative activity. There can be no doubt of the cabinet director's intent to use the blood crisis as a stepping-stone to large-scale public health reform.

The work of Kouchner's cabinet was preceded and accompanied by a Greek chorus of journalistic narrative (eg, new "discoveries" of official malfeasance) and editorial commentary along with the commentaries reporters elicited from public figures. Embedded in these texts was a sense of betrayal on multiple levels: What we thought was pure—a Frenchman's blood—is now discovered to be dangerous; what we thought was sacred—a transfusion system built on republican solidarity—is now discovered to be profaned by the intrusion of filthy lucre; the medical profession whom we trusted is now discovered to have feet of clay. Anger at the medical profession, as reflected in contemporary journalistic

accounts as well as in the substantial literature on the blood affair and its sequelae, extended well beyond blood bankers. Physicians with high public profiles who had reassured the public that blood was safe, health officials now under indictment, and doctors who had failed to warn their patients were all tarred with the brush of complicity in the blood scandal.^{31,33,46} The cabinet's work of "restoring confidence" came to rest on 2 critical innovations, one ideological and the other institutional: (1) to construct a new and sacred space for the domain of public health in France and (2) to purify activities that had been stained by scandal and commerce by moving them into that sacred space.

Reinvention: The Discovery of Sécurité Sanitaire

The idea of *sécurité sanitaire* was invented within the Kouchner cabinet. One of its principal authors recollected: "The idea was to summarize the methods, the reflections that we had tried to elaborate in the face of what we had just seen [ie, the blood affair], and it was necessary to organize that around an approach. . . . I liked the word [*"sécurité"*] and kept that from the start because it meant security of the health system. For me that was the [blood] contamination, the undesirable effects of medicinal drugs, nosocomial infections, medical accidents, all the risks that were produced by the health system itself [a conception that extended well beyond the immediate problem presented by the blood system]. . . . The expression was easy to remember, and everyone understands security: in politics "*sécurité*" carries its own weight, that is its power" (former cabinet official, interviewed October 2010). Framing public health in the culturally powerful language of '*sécurité*' revolutionized both the meaning of public health as a set of activities and, more significantly, its place—its relative autonomy and capacity—in the hierarchical structure of the French state, as this same cabinet official went on to explain: "When I first came to the Ministry of Health, one of the things that really shocked me was the contempt for the ministry—of, I was going to say everyone outside the ministry—but at least the ministry of finance, the technical ministries, their scorn for public health (about which they knew very little). But even within the ministry, the people who dealt with hospitals or with health insurance were condescending toward those concerned with public health. Public health was viewed as not serious: 'We who deal with big budgets, we who build hospitals, we

are concerned with serious matters.’ And the idea of *sécurité sanitaire* was very clearly a way of establishing the importance of public health in the structure of power. . . . It was a lever to raise the stature of public health.” (“Public health” as understood by the speaker corresponds to disease prevention, Duffy’s “community action to avoid disease,” the prevention or mitigation of disease risks in all their forms.)

These are, of course, recollections in retrospect, colored inevitably by the subsequent amplification of “*sécurité sanitaire*” to become, as we noted in our introduction, the centerpiece of an entire policy arena, an arena nurtured in part by the writings and actions of some of these same cabinet members in the years that followed.^{34,47} An archived memo to Kouchner from his cabinet director makes clear, however, that amplification had been a central element in cabinet strategy from the beginning: “France has never had the resources for its health policy. Before 1992 it didn’t have the tools for *sécurité sanitaire*. The blood affair is a unique opportunity for a kick in the pants [*coup de gueule*], the only thing that will make fundamental reform of the system possible” (FNA: CAB 97/005/1-19970575/1). We emphasize again that by “reform of the system,” the cabinet director was referring here not just to the blood system but to the public health system writ large.

The process of innovation itself, as our interlocutors described it, was one of *bricolage*, crafting something new out of “a stock repertoire of furnishings,”^{48(p66),49} more specifically out of an old and discarded legislative text. Nor did symbolic and institutional construction follow one another in linear fashion; they were interwoven, with institution building sometimes preceding symbolic framing and sometimes following it: “We didn’t say to ourselves, ‘ah, *sécurité sanitaire*, that’s a good idea.’ We did things, things that made sense, and in the process we tried to formalize them and give them a name—but on the run, on the run” (former cabinet member, interviewed June 2010). Two of the things that “made sense” were first and foremost, a complete reorganization of the blood system, and second, and much later, creation of a French FDA, the AM. The immediate political priority for the cabinet was reform of the blood system: “How could we do otherwise? We couldn’t leave this bazaar. It was bedlam, these transfusion centers each one independent of the other” (former cabinet official, interviewed June 2010). A reorganization plan that included the creation of a new state agency (Agence Française du Sang, or French Blood Agency) was sent to the prime minister within 3 weeks after Kouchner took office (FNA: CAB 97/005/1-19970575/1).

Work on this plan—and the meanings that its implementation was intended to convey—are reflected in multiple archived cabinet notes and memos dated from April through September 1992. It would reassure the French public that a blood scandal would not happen again, it would restore public confidence in the *security* (a word repeated over and over) of the blood system, and it would reinforce Kouchner's image as "Mr. Public Health."

Many industrialized countries reorganized their blood systems in the wake of HIV contamination of the blood supply.^{30,39} Framing the symbolism of this event and its institutional implications, first to encompass, and then to reinvent aspects of the field of public health more generally was unique to France and is exemplified by construction of the French FDA, the AM. The critical accomplishment of Kouchner's cabinet was to move the AM from the profane space of markets and commerce—now (in 1992) problematic from multiple perspectives—into the sacred space represented by the newly invented *sécurité sanitaire*.

Resurrection: A French FDA

Although the AM had been officially buried in December 1991, it lived on in the hearts and minds of parliamentarians (see Table 3). Among the early visitors to Kouchner as health minister was the chair of the AM conference committee, followed the next day by a memo spelling out his displeasure with the previous ministers' actions (FNA: Box 19930245/2, May 13, 1992). As noted earlier, members of parliament raised the issue with Kouchner at every opportunity in public debate. Kouchner and his team appeared supremely disinterested. In a "work program" for May 1992, submitted to Kouchner by the head of his cabinet, he is warned that "the fate of the Agence du Médicament may resurface" in the course of a scheduled parliamentary debate, a risk that should be "avoided" (FNA: Box 19990575/1, April 30, 1992). In response to queries that did, indeed, surface in the course of that debate, Kouchner appeared weary of the topic, stating that "the government could not accept a text that was exactly the contrary of what it wanted to do."⁵⁰ And, although occasional intracabinet memos did appear in the period between April and November 1992 advocating for an AM, they had little urgency and no new arguments were advanced. The AM continued to be framed in primarily economic terms, as essential to French industrial competitiveness in pharmaceuticals, emphasizing the

deficiencies in resources and personnel of the existing pharmaceutical drug-control system.

The government's bill to reform the French blood system was introduced in the National Assembly on November 26, 1992 (see Table 3). The AM was mentioned in debate on this bill merely as a thorn in the side of certain deputies, and of Kouchner, who continued to patiently acknowledge its nonexistence: "I repeat myself . . . the '*agence du médicament*' does not exist. We may regret it, but that's the way it is."^{51(p6126)} Nevertheless, for the first time in this yearlong series of debates, "security" was linked to medicines and medicines were linked to blood, not by Kouchner but by the deputy (himself a pharmacist), who had been *rapporteur* in the Assembly for the original (1991) bill to create the AM: "We must have an agency that brings together the divisions of pharmacy and medicines and the French national laboratory to offer in the domain of medicines the security that public opinion rightly demands in the case of blood."^{51(p6093)} The first documented evidence from Kouchner's cabinet that a pathway to the AM might be found through the drama of contaminated blood was contained in a memo dated December 11, 1992 (FNA: Box 19970575/1). That memo, prepared by the responsible cabinet official and directed to Kouchner and to his cabinet head, proposed nothing less than a complete reinvention of the AM, from an instrument of economic competitiveness to one of *sécurité sanitaire*, assimilating the safety of medicines to the safety of blood and framing both as protection of the French population: "To associate the AM and the French Blood Agency in the same law is to produce legislation totally new in the field of public health and to create a dynamic that looks entirely to the future." The proposed "association" of the 2 agencies would be accomplished logistically in the form of an amendment to the bill creating the French Blood Agency, an amendment, this official stated, that the *rapporteur* for the blood bill, Senator Claude Huriet (a consummate institutional entrepreneur), would present to the Senate in the name of its Commission on Social Affairs.

The important remaining hurdle to be overcome were the objections to the AM from Bérégovoy (the former finance minister, now the prime minister) and certain members of his staff, objections essentially unchanged from a year earlier: the AM as designed by the Senate was too powerful an institution, and the AM bill overall did too little to control the costs of pharmaceutical drugs. The solution, agreed to on December 15 in a morning meeting between the prime minister, the health minister, and the health minister's cabinet director, was to excise all

“industrial” and price-control considerations from the AM bill, leaving solely intact the strong, Senate version of the bill’s first section (Title I), creating the AM. Huriet presented his “surprise” amendment the very next day. The blood law with its amendment passed the Senate by voice vote (and was passed by both houses one week later), establishing the AM as a purely “scientific” institution for the evaluation of pharmaceutical drugs, uncontaminated by any reference to the economic market.

Discussion

We frame our discussion around the 2 questions posed in the introduction: First, under what circumstances are adverse public health episodes transformed into “crises,” worthy of political and policy attention? And, second, when, why, and how do public health “crises,” even if perceived as such, become vehicles for institutional reform?

Happenings, Events, and Crises

In the evocative language of Marshall Sahlins, “The event is a happening interpreted—and interpretations vary. . . . Events . . . cannot be understood apart from the values attributed to them: the significance that transforms a mere happening into a fateful conjuncture. What is for some people a radical event may appear to others as a date for lunch.”⁵²(p154) Sewell takes the point one step further, arguing that “events can be distinguished from uneventful happenings only to the extent that they violate the expectations generated by cultural structures.”⁵³(p199) (Both Sahlins and Sewell prefer the more neutral-sounding “event” to the word “crisis,” but the meaning as a term of sociological art is essentially the same.) Events/crises are both culturally significant and painful. These qualities do not inhere in the event itself; they are attributions that make sense within a particular historical, political, and cultural framework.

In 1991, the occurrence of HIV-contaminated blood in France was publicly framed in ways that violated 2 deeply held cultural beliefs: first, in the sanctity of a blood system wholly divorced from the stain of commerce, and, second, in the benevolent authority of doctors. We have described the mythology surrounding the blood system, a mythology kept alive by a well-organized and powerful donor association and its supporters among medical and political elites. Not only was that mythology discredited by evidence of systemic venality, but

doctors—including the managers of the blood system, physicians who treated hemophiliacs and gave blood transfusions, and the National Academy of Medicine—were portrayed in the media and perceived by their patients as at best ignorant and lacking foresight and at worst as actively (and even criminally) deceptive.^{31,33,40}

Attributions of meaning do not happen in a vacuum; they are made by interested parties with agendas of their own. Reflecting on a case with strong parallels to the one we have described, Carpenter observed that “the reason . . . scholars and pundits call some adverse events ‘tragedies’ and that others fail to enter the annals of popular and recorded history is that active political agents seek to frame and reinterpret episodes into tragedies.”¹⁸⁽¹⁰⁸⁾ In France, as we have pointed out, 2 sets of actors were critical in transforming the episode (ie, happening) of HIV-contaminated blood into a “tragedy” (ie, event/crisis): hemophiliacs and journalists. Their success was, in several respects, counterintuitive. Organized lay (as opposed to physician-led) health advocacy groups drawn from civil society have a historically weak presence in French politics. They are seen as representing “private” interests as opposed to the “general” interest embodied by the state.³ Medical journalism, prior to the 1991 transformation of HIV in the blood supply into a *cause-célèbre*, had, with limited exceptions, been deferential to medical authority and essentially apolitical.⁵⁴ AIDS, and in particular AIDS in the blood supply, not only shattered long-standing myths about blood, medicine, and physicians, but it also empowered groups of actors new to the French political stage.

Culturally resonant attributions of meaning and the work of interested actors may account for the transformation of HIV-contaminated blood into a political crisis. They cannot, however, explain the further evolution of that crisis into a vehicle for public health institutional reform. Essential to that process was not only a very different category of actors, but also a uniquely French political institution: the powerful ministerial cabinet.

From Crisis to Reform

The clap of thunder that brought the blood affair to public attention in the spring of 1991 came about through the agency of militant hemophiliacs and the few journalists who listened to them. Once on

the public agenda and—more significantly—embraced by the government in power as an affair of state, resolution of the *political* problem this affair represented became a matter for the health ministerial cabinet, acting essentially behind the scenes in the name of, and solely beholden to, its minister. The central place of this issue on the health ministerial agenda is documented not only in the oral history interviews cited earlier, but also by an examination of Kouchner's daily diary (FNA: CAB 97/005/1-19970575/1). Over a period of 4 months (April-May and November-December 1992), the blood affair dominated the minister's schedule (appearing 20 times, as compared with its nearest competitor, a contemplated law on bioethics, mentioned 14 times).

The *substance* of actions undertaken by Kouchner's cabinet was highly innovative both ideologically—the reinvention of public health as *sécurité sanitaire*—and institutionally—the resurrection of a French FDA by shifting its meaning from profane (ie, crassly economic) to sacred (ie, disease prevention). Their *form*—exercise of institutional power in the name of the minister—was wholly consistent with the traditional character of French cabinets, reflecting a political culture that privileges central government power and construes that power as exercised in the public interest. The institutional and cultural dynamics that concentrate power in the ministerial cabinet were reinforced in the present case by the “terrorization” (as reported by one of our respondents) not only of government entities outside the cabinet but also of medical professionals—ranging from blood bankers to the Academy of Medicine—who might have been supposed to have an interest in addressing the blood crisis. (The latter point is well documented in our interviews and in the secondary literature.^{31,33}) The remarkable institutional entrepreneurship exercised by Kouchner's cabinet was contingent not only on an existing highly centralized hierarchical structure of executive power but also on a situationally produced power vacuum. The crisis simultaneously made cabinet action imperative and silenced potentially competitive voices. Arguably, this same power vacuum facilitated the institutional entrepreneurship exercised by Senator Huriet, who was aided as well by the political necessity that forced the prime minister to stifle his objections to the AM in order to pass the blood reform bill, to which the AM—by entrepreneurial slight-of-hand—had become inextricably attached.

A brief comparison with the United States will further highlight the contingencies that shaped the drama of contaminated blood as it played

out in France. The United States considerably surpassed France in AIDS cases (rates per million) among hemophiliacs and also in transfusion-related infections, although by a smaller margin.³⁰ Yet, although the Institute of Medicine's (IOM) authoritative report *HIV and the Blood Supply*⁵⁵ labeled contamination of the blood supply and its consequences for hemophiliacs and transfusion patients in the United States a "public health crisis" and others have described it as a "disaster" and a "catastrophe,"⁵⁶ these occurrences never rose to the level of a *political* crisis nor did they result in a wholesale reconstruction of the public health landscape, as they did during the 1990s in France. This is despite the considerable overlap both in the key actors in each country (eg, blood bankers, government health officials, legislators, militant hemophiliacs) and in many of the issues at stake. The IOM report, as well as scholarly^{56,57} and popular⁵⁸ writing, all point to one or more institutional failures parallel to those identified in France, including delay in implementation of measures to protect the blood supply, financial and other conflicts of interest among the various actors involved, and questionable relationships between the regulators and the regulated. Hemophiliacs' sense of betrayal by the physicians who treated them is well documented in both countries.^{33,59} Given these similarities, together with comparable rates of infection, what accounts for the differences in these 2 countries' responses?

We propose several reasons why HIV infection of the blood supply did not become a political crisis in the United States. First, and perhaps of most importance in accounting for differences between the 2 countries, is that the health care system in the United States was not identified with the state. However decentralized the French blood system was at that time (1991-92), its costs were borne by the state (eg, hospital costs for transfusion were reimbursed by the state insurance plan), and the state was, in principle at least, responsible for the system's regulation.³⁰ More generally, state orchestration is embedded in French culture as the principal source of political order. *Disorder*—as in the case of the blood crisis—will almost by definition be blamed on the state.⁶⁰ The blood system in the United States, although publicly regulated, is privately owned and operated, and its costs to hospitals are reimbursed (apart from Medicare and Medicaid) by private insurance. The American state did not orchestrate, and was not perceived as orchestrating, that country's blood supply.

Second, the aura surrounding the blood system in France—the symbolism of voluntary blood donation as a reflection of French national identity, solidarity, and patriotism—did not and has never existed in the United States. The distinction between paid and unpaid donors—almost of biblical proportions in France—had little meaning in the United States where it was institutionalized in the bifurcated American blood system. In the IOM's executive summary and recommendations, this distinction was never mentioned. (Interestingly, contrary to what Richard Titmuss might have predicted based on his analysis in *The Gift Relationship*,⁶¹ America's for-profit suppliers of blood plasma reacted more quickly to protect their products from AIDS than did the nonprofit blood banks.⁵⁷) Historically, blood system authorities in the United States were far more concerned with policing racial boundaries between black blood and white blood than with moral boundaries between blood that was remunerated and blood that was not.⁶² Further, the United States had (and has) no national association of blood donors, represented in every city, town, and village and devoted to perpetuating and reinforcing the blood system's foundational myth of altruistic gift giving. We suggest that the effect of French-American differences in health care systems, in political ideology, and in interest group organization was to limit the scope of the HIV-blood affair in the United States and to amplify it in France.

Finally, there were marked differences between the 2 countries in their public health, pharmaceutical, and political landscapes at the time the HIV-blood episode unrolled. Unraveling the relative importance of each element in limiting escalation of the affair in the United States (and amplifying it in France) is beyond the scope of this article. We would emphasize, however, that the relatively robust public health infrastructure in the United States as compared with France^{3,4} both increased the former's capacity to manage (however imperfectly) the public health crisis created by HIV infection of the blood supply and also created fewer incentives to catalyze reform by wholesale denunciation of existing structures.

The deployment of crisis as a path to institutional reform is not unique to France. Carpenter describes in detail the iatrogenic disease crisis that led in 1938 to the modern FDA; the parallels in trajectory (ie, revival of stalled legislation, crisis framing, and entrepreneurial action) to the French case over 40 years later are striking.¹⁸ Health crises (eg, gun violence) *may* catalyze institutional reform, but these cases suggest that

whether reform occurs, or even whether adverse episodes are labeled as crises, is highly contingent on circumstances of time and place and are, therefore, extremely difficult to predict or control.

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