# Federalism and Technological Change in Blood Products

Mark Zachary Taylor

Georgia Institute of Technology

**Abstract** Recent research has shown how federalism affects health care finance. health care reform, and health policy innovation. The purpose of this article is to extend this research program to study the linkages between federalism and technological change. It does so using comparative case studies spanning five countries to examine innovation and diffusion of two blood technologies - enzyme-linked immunosorbent assays (ELISA blood tests) and heat treatment — in response to the threat to the blood supply posed by HIV during the 1980s. Prior research has produced three contradictory models of the federalism-innovation relationship. This article attempts to resolve these contradictions, posits new hypotheses, and highlights sources of omitted variable bias that have important implications for understanding technological change. The case studies show that overall decentralization, rather than federalism alone, aids technological progress by allowing its supporters to "venue shop" around political resistance. Decentralization also makes the state less vulnerable to capture by status-quo interest groups. Moreover, political decentralization may have a positive effect on technological diffusion, but a far weaker effect on innovation. Thus, prior research that conflates these two effects should be revisited.

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#### Introduction

This article will investigate the effects of formal political decentralization on two health care technologies, with a special focus on federalism. Studies published in previous issues of this journal have examined the effects of federalism on health care finance (France 2008), health care reform (Sparer 2004), and health policy innovation (Oliver and Shaheen 1997). The purpose of this article is to extend this research program to study the linkages between federalism and technological change.

Health care scholars already recognize the political nature of technology (Lehoux and Blume 2000) and have examined the effects of particular policies (Yin 2008), business strategies (Hourd and Williams 2008), and organizational factors (Robinson and Casalino 1996) on medical technological innovation. However, these studies often neglect the fact that the major players — firms, regulators, policy makers, and others — act within a broader institutional context, that of government structure. Indeed, since many innovation studies examine technological change only within a single country, they can miss the effects of different government structures that might turn up in a cross-national comparison such as the one conducted here.

But why should federalism matter? Here we must go beyond the health care debate and look at innovation politics more generally. A large body of theory and research argues that political decentralization in general, and federalism in particular, aids long-run technological innovation. Often citing its informational and competitive benefits, this school of thought emphasizes the political-economic advantages of political decentralization in creating environments conducive to investment in new technologies. However, a contradictory set of theory and research highlights the high coordination and transaction costs that accompany innovation. These obstacles demand a strong centralized government for producing, distributing, and maintaining the public goods necessary for successful innovation. More recently, quantitative researchers have attempted to resolve these opposing views by conducting statistical analysis of cross-national innovation data (Taylor 2007). But these tests have merely rendered the null hypothesis, thus creating a third line of argument that neither centralization nor decentralization has a significant effect on national innovation rates and that theories asserting otherwise are either incomplete or emerge from a few anomalous cases.

This article will attempt to resolve the dispute by identifying and then addressing the shortcomings of these three lines of empirical research. It will report the findings of comparative case studies of innovation and diffusion of two blood technologies (1981-1987) in the United States, Germany, Japan, France, and Great Britain. Unlike much previous qualitative research, these case studies were conducted with specific attention to the influence of political decentralization (especially federalism) on technological innovation and on the causal mechanisms by which such influences might be conducted. This research adds further value in that it does not focus on the effects of devolution of health care itself (Bossert 1998, Rico and Costa-Font 2005).<sup>1</sup> Rather, this article examines government structure more generally, so as to also capture causal forces from outside the health care sector that affect medical technologies and possibly any field of technology. Finally, these case studies were performed with a focus on identifying important omitted variables and other forms of specification error which may have plagued recent analysis. Therefore, rather than offer yet another volley in the debate over federalism's effects on innovation rates, this article posits new hypotheses for consideration in future research.

Together, these case studies suggest a simple but significant theory modification: that technological innovation should be considered separately from technological diffusion. Furthermore, political decentralization may have a positive effect on diffusion, but no general relationship with innovation. A conflation of innovation with diffusion by some scholars might explain why previous qualitative research on technological development found a correlation with decentralization, which the quantitative research then failed to confirm. The case studies also posit various mechanisms by which political decentralization in general, rather than federalism alone, may affect technological diffusion. Specifically, decentralization appears to aid the adoption of new technology in four ways: by allowing its supporters to "venue shop" around political resistance, by making the state less vulnerable to capture by status-quo interest groups, by changing the incentives of local governments, and by allowing political deals over policy design to be conducted more efficiently at lower levels of interest group aggregation. In many of these aspects, horizontal decentralization (i.e., division of powers) may be as important for technological diffusion as federalism.

The following section reviews the decentralization-innovation debate.

<sup>1.</sup> Note that variation in health care devolution across the countries in my sample does correlate well with the variation in political decentralization. Therefore, decentralization of one component cannot be argued to have been counteracted by centralization of the other.

The third section then briefly discusses country selection. The fourth section introduces two health technologies (ELISA blood tests and heat treatment) and provides background on the primary problem that they were designed to solve (contamination of the blood supply with HIV). The cross-national case studies which follow suggest that federalism had the potential to affect the trajectory of these blood technologies at four major points in their evolution: problem identification, funding for research and development (R&D), innovation, and diffusion.<sup>2</sup> The final section concludes with a discussion of the contributions of this research.

## **Literature Review**

Political decentralization is defined here as an increase in both the number and equality of centers of political power and policy making. While many scholars focus solely on federalism, existing theories concerning government structure and technological change demand that I be more flexible in my definition and allow decentralization to be either vertical or horizontal. In vertically decentralized states, authority has been shifted away from the central government and toward local governments, the classic example being federalism (Rodden 2002). In horizontally decentralized states, authority is shared between an executive, legislature, judiciary, and in some cases even a powerful bureaucracy or autonomous military.<sup>3</sup> In practice, many states decentralize even further, with power formally divided between different houses of the legislature, competing bureaucracies, or branches of the armed forces.

Why might political decentralization foster long-run technological innovation? The literature suggests multiple causal paths for such a relationship. First, decentralization proponents argue that federalism increases the number and diversity of political and economic units participating in, funding, and demanding innovative activities (Drezner 2001; Mokyr 1990, 2002; Weingast 1995; Nelson 2005; Acemoglu, Johnson, and Robinson 2005; Rosenberg and Birdzell 1986; Surowiecki 2004). Second, scholars assert that federalism increases competition, thus increasing the incentives

<sup>2.</sup> Technology is defined here as a physical product, or a process of handling physical materials, used as an aid in problem solving. More precisely, technology is a product or process which allows people to perform entirely new activities or established activities with increased efficiency. Innovation is the introduction, discovery, or development of new technology or the adaptation of established technology to a new use or to a new physical or social environment. Diffusion is the process by which an innovation is propagated.

<sup>3.</sup> This is much the same concept as "balance of power" or "checks and balances."

for, and preserving markets conducive to, investment in innovation (Weingast 1995; Qian and Weingast 1997). Third, theory holds that federalism leads to superior information, policy design, and public goods provision at the local level (Hayek 1945; Tiebout 1956). These should in turn mean more efficient allocation of resources toward, and proper incentives for, local investors and innovators. This could alternately be interpreted as precisely the kind of national environment conducive to producing Richard Florida's (2002) "creative cities." Fourth, several scholars argue that overall political decentralization aids national innovation rates by making the state less vulnerable to capture by status-quo interest groups (Drezner 2001; Mokyr 1990, 2002; Rosenberg and Birdzell 1986; Weingast 1995; Acemoglu, Johnson, and Robinson 2005).

But what is often ignored in the rush to promote the advantages of decentralization is that there is also substantial theoretical support for the *opposite* conclusion. For example, one can extrapolate a state-level argument from Ronald Coase's theory of the firm. Coase (1937) holds that centralization in the form of the firm significantly reduces the transactions costs associated with economic, hence innovative, activity. By analogy, government centralization should similarly reduce the administration and coordination costs associated with producing, distributing, and maintaining the public goods necessary for technological innovation (R&D funding, standard setting, etc.). This argument simply reverses the logic employed by several federalism scholars who posit that decentralization allows subnational politicians to act as veto players and thereby complicate national policy making in areas such as privatization, fiscal policy, and inflation management (Treisman 2000; Rodden 2002; Wibbles 2000).

In order to resolve these contradictory lines of theory and evidence, Taylor (2007) recently conducted statistical analysis of twenty years of innovation data across more than seventy countries. Surprisingly, with but a single exception, none of these statistical regressions yielded a significant coefficient for the effects of political decentralization on national innovation rates. The results were triangulated using three distinct and independent measures of national innovation rates, four different measures of political decentralization (both vertical and horizontal), and more than a dozen different control variables prompted by different theories and critiques. The lone case in which the null hypothesis could be rejected occurred when countries were subdivided by wealth, but here the effect was fairly small, applicable only to the wealthiest subset of nations, and was not consistent across different measures of decentralization. This is not what one would expect from such a well-theorized and widely debated causal relationship.

In response, this article takes a less superficial approach than previous research. It recognizes that both quantitative and qualitative methods have weaknesses that are not being directly addressed in this debate; thus its participants are often talking past one another. On the one hand, while theoretically robust, proponents of both decentralization and centralization tend to use single case studies for their empirical evidence. The classic critique here is that the number of observations in small-N research is too small to produce generalizable conclusions. A more urgent criticism may be that the case studies performed by decentralization-innovation researchers are often stylized, occur too far back in history to produce sufficient or clear data, or take observations at a level that is too high and are therefore too distant from the hypothesized causal mechanisms. Furthermore, in some case studies the linkages made between political decentralization and technological innovation are implicit or indirect and therefore do not constitute explicit tests. Nor does this line of research tend to consider outlier or deviant cases which might contradict theory.

On the other hand, quantitative analysis also has its weaknesses. The classic critique here is that statistical analysis can show correlation but not causation. Hence, it does not allow researchers to test or directly observe the causal mechanisms at work. Similarly, statistical analysis is a poor tool for revealing omitted causal variables or other forms of specification error that might be obscuring linkages between political decentralization and technological innovation. This is especially relevant here since quantitative tests of the decentralization-innovation linkage consistently produced the null hypothesis, which could well be a result of precisely such problems. Finally, statistical findings are only as good as the data on which they are based. Thus, the accuracy of quantitative indices of innovation, an infamously difficult phenomenon to measure objectively, is problematic.

The remainder of this article will report the results of several case studies designed to address each of these weaknesses. Specifically, the cases attend to measurement issues, causal mechanisms, and specification error in a manner not possible by statistics alone. They also examine data with explicit attention to the relationship between political decentralization and technological change, in a manner not pursued in previous qualitative research.

#### **Country Selection**

The countries chosen for the case studies were the United States, Germany, Japan, France, and Great Britain, which can be grouped with confidence into three categories of relative political decentralization. Certainly scholars might quibble about differences between the United States and Germany, or between France and the United Kingdom, but my assignment of these states to the more general categories below should not be controversial.

The two relatively decentralized states are the United States and Germany, both of which formally divide power vertically between the federal, state, and municipal governments and horizontally between the executive, legislative, and judicial branches. In both countries, at the federal and subnational level, substantial checks and balances exist to reinforce the horizontal division between the three branches of government. While many important powers are reserved for the federal government, both the U.S. states and the German *Länder* (federal states) enjoy residual power over all those responsibilities not expressly given to the federal government in their constitutions. Also, in both countries, actions by the federal and local governments are subject to judicial review by a vertically divided, independent court system.

Opposite them, during this period (1981–1987), sat Great Britain and France. During the 1980s, each of these two countries was a relatively centralized unitary state with policy-making power concentrated on a single branch of government and little formal autonomy or significant power to "check" or "balance" given to the subnational governments or even the other branches of government. In the United Kingdom, the lower house of Parliament dominated government, determining the leadership of the executive bureaucracy, as well as dictating policy to local and regional governments. While popularly elected, local governments had little or no input into policy. Regional issues were handled by central government and quasi-governmental bodies. The British judiciary was neither independent nor possessed of any substantial power of judicial review; at best, it could question the authority of individual actions and thereby force Parliament to formally clarify its policies (Norton 1994).

In France, power was centered on the president, elected independently of Parliament. The president appointed the prime minister and could guide the composition of the executive bureaucracy's leadership.<sup>4</sup> The

<sup>4.</sup> Rarely have the president and parliamentary majority been elected from competing political parties. In France, the former tends to dominate defense and foreign affairs, leaving most

French president also had wide authority to make political appointments (including many positions in the judiciary), sign and promulgate laws and decrees, force Parliament to reconsider its own legislation, replace the prime minister, and even dissolve Parliament itself. The two houses of Parliament were fairly equal in power, though the lower house had priority in approving the budget and sole authority to censure and dismiss the government. However, while the French constitution specifies parliamentary authority over many domestic issues, the decision-making powers of the French legislature were limited, especially when compared to those in the United States and most other European democracies. These limits extended vertically as well. Although then President François Mitterrand increased their ability to collect revenue, the various subnational governments merely administered the policies passed down to them from above, their power existing at the whim of the national government. Even in local government, the national Parliament was generally restricted to establishing general principles, which the executive then detailed and implemented by decree. The French judiciary fell under the administration of the executive bureaucracy and could not rule upon the constitutionality of statutory law. France's Constitutional Council, composed of past presidents and temporary presidential appointees, did provide an aspect of judicial review not present in the Japanese or British systems. However, this body's purview was limited to statutes affecting the organization of public powers, and it could only act when issues were brought before it.

Japan held the middle ground between the two extremes above. Although not a federal state, during the 1980s Japan was not as centralized as the United Kingdom or France. It possessed a relatively strong executive bureaucracy, supported by a legislature dominated by a single party and poorly balanced by a weak judiciary and subnational governments. Meanwhile, Japan's provincial and municipal governments had powers beyond those found in the United Kingdom or France. Japan's subnational governments were composed of a mix of elected and appointed officials, with a small but significant degree of local autonomy over fiscal and policy matters. However, they did not approach the autonomy allowed in the United States or Germany. Via the executive bureaucracy, the Japanese central government generally constrained the actions of local governments and frequently dictated them (Samuels 1983; Reed 1986).

domestic affairs to the prime minister. However, for most of the period considered below, both the French executive and legislature were dominated by the Socialist Party, with its leader, François Mitterrand, as France's president.

The relative differences between these government structures are perhaps easier to see in table 1, which shows three attempts at quantification from three independent datasets. The first set of measures are indices devised by Arend Lijphart (1999) that rank countries on either a four- or five-point scale in terms of federalism, bicameralism, and judicial review. The second set of measures, from the World Bank Political Institutions Database, gauges aspects of vertical decentralization. The final column employs the Political Constraints (POLCON) Index developed by Witold Henisz (2000). This measure is included because government structure can have both formal de jure components (those expressed in law or constitution) and informal de facto components (e.g., the extent of party alignment across different branches of government or the extent of preference heterogeneity within each legislative branch). We therefore want to eliminate the possibility that the effects of the de jure components are being overridden by the de facto components. The POLCON Index allows us to do this. It is a 0–1 measure which takes into account the number of independent branches of government with veto power over policy, modified by the extent of party alignment across branches of government and the extent of preference heterogeneity within each legislative branch. It therefore allows us to check for states that may be formally decentralized but may suffer ineffective de facto checks and balances. This final column shows that, at least for these five countries, the relative rankings of formal de jure components and informal de facto components of government structure correlate highly.

These five countries were chosen to maximize variation in the primary independent variable (political decentralization) while controlling as much as possible for major conditional variables (e.g., level of development, size, culture, ideology). Note that where potentially significant differences do exist between nations, they tend to cut across the federal-unitary divide, thus enhancing the comparison. For example, within the group, the United States and Great Britain share similar economic ideologies and cultural heritage, yet the two nations are opposites in terms of government structure. Conversely, where the degree of government decentralization is similar, the nations tend to vary significantly on many other axes.

ומחוב ו			אפווווופוור ח	הרבוות מוולמתו	11			
	Ar	end Lijphart Indice	Sa	Wo	rld Bank Political	Institutions Data	abase	Henisz <sup>b</sup>
				Subnational govts. have				
			Indivial	extensive	Constituencies	بالممم ا	I ocolly	Dolition1
	Federalism	Bicameralism	review	spending, or	of senators	elected	elected	Constraints
	1 = low	1 = low	1 = low	regulatory	are states/	provincial	municipal	$Index^{f}$
	5 = high	4 = high	4 = high	authority	provinces	govts.	govts.	(1981–1987 avg.)
U.S.	5.0	4.0	4.0	Yes	Yes	Yes	Yes	0.85
Germany	5.0	4.0	4.0	Yes	Yes	Yes	Yes	0.84
Japan	2.0	3.0	2.0	No	Yes	Yes	$No^{e}$	0.75
France	1.3	3.0	2.8	$No^{c}$	No	$No^d$	$N_{O^e}$	0.74
U.K.	1.0	2.5	1.0	No	No	$\mathrm{No}^{\mathrm{e}}$	$\mathrm{No}^{\mathrm{e}}$	0.74
<sup>a</sup> See Lijj <sup>b</sup> See Hei <sup>c</sup> Authori <sup>d</sup> Govern <sup>e</sup> Increas, <sup>f</sup> Lower 1 0.23; standå	phart 1999. nisz 2000. ity increased after 19 ors are appointed; le e in locally elected F aumbers mean fewei ard deviation = 0.31.	983. egislature, elected. positions after 1985. r political veto points	(i.e., greater co	oncentration of po	olitical power). For	1985, <i>n</i> = 167 coun	(tries; range = 0	.00-0.89; average =

 Table 1
 Cross-National Measures of Government Decentralization

# Innovation in Blood Products Technologies (1981–1987)

#### Background

The cases below examine innovation and diffusion of two technologies (HIV tests and heat treatment) devised to protect the blood supply against contamination by HIV, the virus that causes AIDS. The AIDS epidemic surfaced in the industrialized world in June 1981.<sup>5</sup> Most public concern has been with the sexual transmission of the HIV virus, but here we focus on transfusion. As a blood-borne disease, AIDS posed a deadly threat to all transfusion recipients, especially hundreds of thousands of hemophiliacs whose lives depended on sometimes weekly transfusions of blood derivatives known as antihemophilic factor (AHF).

The technological solution to this transfusion problem ultimately consisted of two innovations. The first was a blood test: an enzyme-linked immunosorbent assay (ELISA) adapted to identify the presence of the HIV virus in blood and blood derivatives. The second was a heattreatment process designed to kill HIV virus in transfused blood and blood products.

The first HIV ELISA tests were developed and applied in French research laboratories during July-August 1983, and the first successful heat-treatment process was licensed to its German industrial developer, Behringwerke A.G., in 1981 (Montagnier 2000; Institute of Medicine 1995). Firms and laboratories in other countries soon developed their own indigenous versions of these technologies. However, these new technologies took years, until 1985–1986, to diffuse into wide enough use to effect a solution to the problem posed by HIV. More interestingly, these technologies diffused somewhat faster in the decentralized United States and Germany than in centralized Great Britain, France, and Japan. In the meantime, tens of thousands of people contracted transfusion AIDS and died, sometimes not before unknowingly passing the virus on to others. Given the widespread and lethal nature of the threat and the relative simplicity of the technological fixes,<sup>6</sup> it is puzzling that the technological solutions took so long and that months, if not years, passed between the lead and late adopters.

<sup>5.</sup> Blood and tissue evidence suggest that HIV entered the West as early as the 1950s. However, the new disease was not recognized by the medical community until 1981.

<sup>6.</sup> Most, if not all, of the component technologies that formed the foundations of the HIV ELISA and heat treatment had existed for at least a decade.

At first, one might expect that certain obvious *non*structural variables would best explain this variation in technological response times. However, a number of these variables are obstacles that were similarly faced by the governments of all five countries; this commonality suggests their possible elimination as explanatory factors. These variables include the following: the uncertainty regarding the nature of the disease and its transmission; competing demands to solve other, clearer national problems (such as the ongoing Soviet threat and domestic economic troubles); a desire to tighten budgets and reduce taxes; and, common to all the countries studied, the lack of full social acceptance of homosexuality.

Also, in each of the five countries studied, many of the interest groups most affected by the AIDS threat (blood banks, gays, hemophiliacs) ironically sought to impede a technological solution for a variety of reasons. For example, many politically active gays perceived testing as a tool for discrimination and therefore opposed it (Shilts 1987). Hemophiliacs, only recently granted "normal lives" by the invention and diffusion of AHF in the 1960s, were initially wary of any technological changes that might affect its quality, availability, or cost. The blood industry saw HIV tests and heat treatment as technologies of questionable effectiveness that were certain to drive up costs. Also, HIV tests would drive away gay blood donors, highly valued in some regions, while attracting potential AIDS sufferers seeking free and anonymous diagnoses. And since heat treatment increased the price of blood products by upward of 60 percent, neither the blood banks, their customers, nor the medical insurers were enthusiastic about the effect on their bottom lines, especially since the etiology of the disease was open to debate (U.S. Congress 1995: 69). Each of these groups took advantage of the uncertainty about the science of AIDS and the uncertainties surrounding the HIV antibody tests and the heat-treatment process to defend their political and economic interests by slowing technological change.

Differences between the five countries that do not correlate with the different rates of innovation or diffusion also suggest factors that might be eliminated as causal variables. First, seroprevalence does not, prima facie, appear to have been a major determining factor. The United States and France were the earliest to be hit by AIDS and suffered among the highest infection rates outside of Africa; however, the United States was a leader in the diffusion of HIV tests and heat-treatment processes, while France was a lead innovator but late diffuser. Nor does scientific capability appear to be significant since the United States and France were both at the frontiers of the science and technology of AIDS, while neither

Japan nor Germany appears as a major scientific contributor prior to the late 1980s, despite the fact that both countries had globally competitive scientific and technological capabilities.

Culture, admittedly a poorly understood variable in political economy, does not seem to have played a deciding role here since both lead and late innovators fell within similar cultural groupings. Taking, for example, the religious dimension, Germany and France were heavily Catholic; the United States and the United Kingdom, Protestant; and Japan, a mixture of Shinto, Buddhist, and Confucian. Nor do popular attitudes toward homosexuality or its relationship to AIDS correlate well with the innovation or diffusion of technological solutions to what was often perceived, even among hemophiliacs, to be a homosexual affliction. For example, the French scientific establishment tended to see sexuality as incidental to AIDS and generally avoided this red herring which for years dogged American researchers, who at first perceived of AIDS as a strictly "gay disease" (Shilts 1987). Meanwhile, in Japan, hemophiliac sufferers far outnumbered either gay or intravenous drug-related victims of AIDS making it less of a "moral" issue (Feldman and Yonemoto 1992). For many Japanese, the impurity of an AIDS patient's blood was more taboo than the homosexual connotations of the disease.

The broad structure of national health care systems did not seem to determine rates of technological change either. Every country but the United States had near-total national health coverage, each with significant but varying degrees of government participation. Also, within both the whole blood market and the blood plasma market, innovation fails to correlate with how collection was organized. Private and public actors, as well as for-profit and nonprofit, attempted to slow innovation in different countries. Nor do the activities of these organizations correlate with political decentralization. For example, in Japan, private commercial firms used their influence over government (industrial) policy to prevent technological competition, while in France government institutions and nonprofit nongovernmental organizations did likewise. If we are concerned about technological diffusion, similar results prevail.

Finally, neither the political ideology of the ruling party nor changes of government appear to correlate with innovation or diffusion rates. During this period, the conservative LDP (Liberal Democratic Party) maintained its decades-long dominance in Japan. Meanwhile, in France, the conservatives lost to the first Socialist-Communist coalition in fifty years. Conversely, the Thatcher, Kohl, and Reagan eras began on either side of the Atlantic.

	Effect of Gover	rnment Structure
Problem to Be Solved	No difference	Political decentralization helps
Identification of a threat to		
the blood supply	Х	
Provision of R&D funding to		
find a technological solution		Х
Innovation of ELISA and		
heat-treated blood products	Х	
Diffusion of ELISA and		
heat-treated blood products		Х

**Table 2** Summary of Hypotheses Generated by the Case Studies

Notes: R&D = research and development; ELISA = enzyme-linked immunosorbent assay

The brief survey above obviously does not completely eliminate the importance of nonstructural variables, nor is it intended to do so; rather, it should serve to discharge some prevalent and initial hesitations and allow us to proceed for now to a consideration of federalism.

The case studies of HIV-related blood safety technologies below generate hypotheses about how federalism potentially intersects with technological innovation and diffusion at four major points, summarized in table 2. First, federalism seems not to have affected the identification of HIV as a problem affecting the blood supply. Second, political decentralization overall, rather than federalism alone, does seem to have affected the funding of research and innovation to address the threat of HIV, with legislators in decentralized states moving to fund innovation over the objections of the executive branch. Third, government structure did not systematically affect the rate of technological innovation in blood products, with centralized states paradoxically aiding relative innovation rates by not participating in early research and development. Fourth, the decentralized states appear to have diffused blood testing and heat technologies somewhat faster than the centralized states where Stiglerian capture of the executive branch by industry groups resulted in highly effective regulatory hurdles which obstructed distribution of the new health technologies for months, if not years. The remainder of this article will examine each of these points in greater detail.

# Federalism and the Problem of Problem Identification

In order for technological progress in blood safety to occur, AIDS first had to be identified as a problem in need of a technological solution, a process that by some measures took decades. One might hypothesize that federal states, with their localized control over public health issues and attendant proximity to information about local health conditions, might overcome this obstacle faster. Conversely, federalism might drive up communication and coordination costs, thereby giving centralized states the lead in identifying AIDS. However, the evidence from the blood case studies supports neither hypothesis.

In the blood cases, there appears to be no correlation between federalism and problem identification. Thanks to the monitoring activities of the U.S. Centers for Disease Control (CDC) and the relatively high rate of infection in the United States, many of the epidemiological "firsts" occurred there; however, such was the reputation of the CDC that its pronouncements were rapidly communicated to health policy and medical elites throughout the world. Specifically, none of the public health elites in France, Japan, West Germany, or the United Kingdom can credibly claim to have been relatively less aware of the AIDS threat than the others. And although AIDS may have arrived in these countries at different times, none of the governments appear to have experienced a significant delay in identification of domestic AIDS cases once the virus did cross their borders. Nonetheless, AIDS constituted a rare, complex, and relatively new challenge to modern medical experts in each country, who for years struggled under terrific uncertainty as to the nature of the disease, which did result in innovation and diffusion delays common to all nations.

AIDS was not a sudden and highly visible blow like a Pearl Harbor or the oil shocks; rather, it built up slowly and somewhat confusedly, drawing out its identification over time. This gave the various countries' executive branches, which were generally the first points of contact in government for the slowly accumulating information on AIDS, the same room to stall and equivocate. And stall they did, each similarly refusing to fund to AIDS research for very similar reasons, regardless of political structure or rate of technological progress.

At first, since the mere existence of viral AIDS was uncertain and because clearer policy issues existed, the problem was generally ignored by the executive branches of each country. As the evidence for an AIDS virus accumulated, the problem was denied: in America it was a "gay

#### 878 Journal of Health Politics, Policy and Law

disease"; in Europe, "an American problem"; and in Japan it was "foreign, distant, and unthreatening" (Shilts 1987; Feldman and Yonemoto 1992: 339). As consensus grew on the science of AIDS, policy makers in the executive branch, as well as representatives of the blood industry and other supporters of the status quo, used the remaining uncertainties about AIDS, its potential to infect the blood supply, the accuracy of the ELISA tests, and the effectiveness of heat treatment to deny that there was a problem to be solved or to argue that a change from the status quo was unnecessary or unwise. Technological solutions were often objected to because of "uncertain science" despite the fact that uncertainty in medicine was arguably impossible to eliminate and cut both ways. Yet the executives of centralized governments were able to hold this line longer than those of the decentralized governments. As shall be shown below, in the United States and Germany, the legislature and subnational governments were able to circumvent the executive's agenda, while in Japan, France, and the United Kingdom, despite rising infection rates and increasing evidence of HIV in the blood supply, political executives managed to restrain technological progress until conditions favored key interest groups, especially domestic industry.

#### Federalism and Innovation Funding

Why did action by the executive branch matter? Put simply: funding. A technological response to the AIDS threat posed a collective action problem that could be solved only through the efficient cooperation of thousands of specialized workers and other inputs. The various histories of early AIDS science and technology all attest to the importance of highly trained scientists and technicians, advanced research equipment, the construction of specialized facilities, and sometimes massive epidemiological studies to the discovery of the AIDS virus and its means of transmission (Grmek 1990; Epstein 1996; Mann and Tarantola 1996; Shilts 1987). The expense of these resources was beyond the budgets of most private research institutions and difficult to fit into existing public research projects. Moreover, during the early years of the disease, there was no clear profit for industry. This left government as the main provider of scientific research on AIDS. And since government research generally falls under the jurisdiction of the executive branch, the policy agenda of the executive helped to determine the speed of the initial response to AIDS.

In the blood cases, overall political decentralization, rather than federalism alone, helped the funding of technological progress by allowing competing branches and levels of government to override the fiscal opposition of the executive. None of the executives in the countries surveyed responded to the advent of AIDS with significant budget outlays for scientific or technological research. Their reactions were typified by that of the United States, where the appearance of AIDS as a public health issue coincided with the presidency of Ronald Reagan. Reagan had been elected on a conservative platform of fiscal restraint, smaller government, lower taxes, deregulation, and a strong military. His administration proceeded with deep budget cuts across almost all nonmilitary functions of government, which included the budgets of both the CDC and the National Institutes of Health (NIH), and Reagan continued this course even after AIDS had been declared an epidemic. Where spending on AIDS was permitted at all, rather than spend any new money on the disease, the Reagan administration insisted that government resources be redirected toward AIDS from other existing projects (Shilts 1987).

The Thatcher government had priorities quite similar to those of the Reagan administration, and AIDS research was considered "very small fry" throughout the early 1980s (Berridge 1996: 33). Medical research in the United Kingdom was controlled by the Medical Research Council (MRC), a government agency funded entirely by the Department of Education and Science, which also controlled funding for the top universities (Teeling-Smith and Taylor 1984). Until 1987, the MRC allocated less than a million dollars annually toward AIDS research, often splitting between multiple projects tiny sums that were heavily weighted toward information gathering rather than research (Street and Weale 1992).

In France, the only country in this survey headed by a socialist prime minister, the executive branch's interest in AIDS research was also all but nonexistent. France's Ministry of Research and Higher Education (MRES) controlled the research funding for most public research institutes and all of the universities, which meant that most of the top schools and research centers essentially ignored AIDS until the MRES changed its agenda (Kellerman 1988). And since France had a large state-run business sector, this meant that even industrial research was affected by funding decisions at the executive level. Within the pharmaceutical industry, comparatively little spending was dedicated to addressing the AIDS threat. For example, although the Pasteur Institute had detected HIV in French AHF by August 1983, it was not until late 1984 that the state-run National Center for Blood Transfusion's lead fractionator, Lillie, began to grow urgent about heat treatment research (Steffen 1999). To avoid belaboring this point, suffice it to say that the Japanese and West German responses were variations on

the theme displayed by the United States, France, and Great Britain, with little if any government spending allocated for AIDS research (Feldman and Yonemoto 1992; Feldman 1999; Dressler 1999).

At this juncture political decentralization appears to have played a role, for in the decentralized states the competing branches and levels of government were able to override the fiscal prerogatives of the executive, an option not available in the centralized democracies. For example, the American technological response to AIDS was in large part a product of battles between the executive and the legislature and of independent action by the subnational governments. At first, individual federal legislators from heavily gay districts initiated congressional probes into both the disease and the government's tepid response to it, pressuring members of the U.S. Public Health Service on their lack of spending on the disease (Shilts 1987: 143). Soon, senators and representatives alike began to insert subsidies for AIDS research into various funding bills. In September 1982, this resulted in what has been termed "the first gay pork-barrel": \$5 million and \$10 million respectively for AIDS research at the CDC and NIH (ibid.: 187). For at least the next three years, federal AIDS research was funded in this manner, with the legislature financing AIDS research over the objections of the executive, which continually criticized the unrequested outlays.

This phenomenon was repeated in the governments of several U.S. states. For example, in California, Republican governor George Deukmejian was likewise concerned with reducing deficits, taxes, and the role of government and consistently allocated funds for AIDS research below levels recommended by health authorities. The state legislature then forcibly supplemented Deukmejian's research budgets, eventually overriding his vetoes in order to subsidize research. In a similar move, researchers at California's premier state universities were able to temporarily circumvent resistance to AIDS research by appealing directly to the legislature and successfully won millions of funding dollars. Where the federal and state governments did not act, the city and county governments stepped in, providing some of the first public funding for research, education, and clinics. These were regions where gays were politically powerful, or where seroprevalence was high. San Francisco took the lead in this respect and provided a model for action by other cities or, in the case of New York City's sluggish response, a basis for critical comparison by voters (Shilts 1987).

Conversely, in France, the political structure during the early 1980s was fairly centralized on all axes. Enormous power and autonomy was given to the executive branch, with limited capacity for initiative to the French

parliament and few if any access points for the general public to participate in policy making. And while the subnational governments appointed the upper house members of the national legislature, these regional institutions had little real power at the time.<sup>7</sup> Moreover, France's national health coverage meant that wholesale testing and heat treatment for HIV would entail significant public expenditure and therefore required cabinetwide approval, a prospect made even more difficult by the fact that the strongest supporter of these technologies, the Ministry of Health, sat low in the powerful bureaucratic hierarchy (Hayward 1973). In this environment, the French executive, like that of the United States, preferred to spend its money on other priorities. But unlike their American counterparts, French legislators could not override the executive's conservative budget or insist that more money be allocated to address the AIDS problem. This capacity was simply not available in the French government system where individual legislators were relatively powerless, especially if they were not members of the governing party elite (Suleiman 1974, 1978; Hayward 1986). Moreover, the gay communities in France were not extremely politically active, perhaps due to this very lack of public access to French policy making, which left little to be gained by collective action by such a small and marginalized minority (Fillieule and Duyvendak 1999; Duyvendak 2001). Finally, in the United States, even before individual members of Congress could be prompted to act, spending by the state governments of New York and California was triggered — again, an option not substantially available in unitary France, where subnational administrations have little budgetary leeway. Consequently, the French public research establishment remained relatively detached from AIDS research until roughly 1989; compare this to the United States, where lack of executive interest kept the NIH out of the game for a year or two but did not prevent scientists at state universities or private industry from taking action (Steffen 1992).

Similarly, in the United Kingdom the Thatcher government had relatively free reign in its AIDS policy, which until 1986 was typified by a distinct absence of action of any kind. Opposition parties attacked this wait-and-see policy early on; however, with few venues by which to affect policy making, legislators from the Labour Party could do little more than criticize in open Parliament. This impotence came from the fact that the United Kingdom was one of the most centralized democracies in existence, with power largely concentrated on the elites of the majority party of the House of Commons in London. Once elected, the executive branch,

<sup>7.</sup> The reforms of 1983–1984 not withstanding, see Loughlin and Mazey (1995).

which was further supported by an equally inaccessible, elite, and secretive bureaucracy, had a relative monopoly on power. Hence, attempts to introduce policy change were limited in parliamentary session to questions about the safety of the blood supply (July 1983) and criticism of Britain's lack of research (spring 1984), neither of which moved the Thatcher government to take substantive action (Berridge 1996: 32, 40).

While focus thus far has been on the ability of the legislature or subnational governments to override the executive, in the West German case we find the judiciary playing an indirect role in the government response to AIDS. Early on in the crisis, a hemophiliac brought suit against the federal government for malfeasance, calling for the German Federal Constitutional Court to force legislative action to protect him. Though dismissed, this case had three important effects. First, the lawsuit put pressure on the federal government, forcing a prima facie case to be presented to defend it against the charges of inaction. Even though the courts found enough evidence to dismiss the hemophiliac's charges, the case served as a warning sign to government actors that the judiciary was a viable political venue for oversight and redress. Second, by dismissing the case the court implicitly rejected the claim that AIDS was a "special" disease in need of special action and thus removed some of the legal basis for a more centralized command-and-control response that could have been manipulated by industry, as will be discussed below (Frankenberg 1992; Frankenberg and Hanebeck 2000). Third, court cases in general, and especially at the level of the Constitutional Court, provided a source of unwanted media attention and therefore greater public scrutiny on government action.

While the West German experience might seem somewhat toothless, compare it to the performance of the judiciaries in France and Japan. In both of these countries, the courts got involved only after the crisis had passed and thousands of people infected by transfusion AIDS sought justice after the fact. In France, it took until the latter half of the 1980s for a case against the government to appear before a court; then it was not until late 1992 that a ruling was made. And even though the French ruling came down against the executive branch, none of the senior bureaucrats who were jailed or fined for their actions were members of the Socialist party, which had governed during their tenure (Feldman 2000). In Japan, the judiciary is not a distinctly independent branch of government and falls under the control of the cabinet; as a result, progress in one's judicial career depends upon the favor and support of the ruling government party (Ramseyer and Rosenbluth 1993; Rosenbluth and Thies 2002). During the 1980s, approximately 40 percent of those testing HIV positive were hemophiliacs,

but lawsuits were not filed until 1989 and then only against the pharmaceutical industry (Feldman 1999). These cases dragged on for years, until the brief occupation of both the prime minister's office and MWH by the Japan Socialist Party in 1995 put into power senior politicians sympathetic to the hemophiliacs' situation, and within a year settlements were quickly concluded in favor of the plantiffs (Feldman 2000). Finally, in the United Kingdom, the judiciary simply has little or no power to contradict the will of the legislature; hence, the judiciary was impotent as a tool for redress. Admittedly, we cannot turn the clock backward and rerun history with an independent judiciary in France and Japan and a subservient judiciary in Germany. But the comparison above is intriguing.

#### Federalism and Technological Innovation

Technological innovation does not appear to have been slower in the centralized states than in the federal states. (See table 3 and figure 1.) Although French and British AIDS researchers suffered from a lack of government funding, they were yet able to make major advances on par with, if not ahead of, those in the United States, where research suffered paradoxically from the political interests of the executive branch that backed it. For example, in mid-1982, one of the top researchers at the U.S. NIH's National Cancer Institute (NCI), Dr. Robert Gallo, developed a side interest in AIDS research (Gallo 1991; Shilts 1987). As part of the "war on cancer" Gallo had gained global recognition in 1980 by showing that a certain kind of virus, a retrovirus, caused a leukemia common in Japan. Gallo felt that AIDS was similarly caused and saw it as an opportunity to further develop his own line of research on retroviruses. However, Gallo's interest in AIDS was, like the NCI's, only a sideline and progress was slow.

In April 1983, with AIDS afflicting thousands of Americans and the NCI embarrassed by its lack of effort, Gallo's AIDS research was made an NIH priority. The majority of federal support was soon focused on Gallo while other AIDS research labs at the NIH foundered for lack of resources (Shilts 1987). However, in France, researchers led by Luc Montagnier at the private Pasteur Institute had been pursuing the AIDS virus for months and had succeeded in isolating it back in January 1983 (Montagnier 2000). Montagnier's discovery was of a lentivirus, a special type of retrovirus that destroyed T-cells en masse, rather than infecting them and multiplying as Gallo's leukemia virus did. But Gallo's was the best-supported research team in the U.S. federal system, which meant that the Reagan administration, now heavily criticized for its lack of action,

		First Domestic	Domestic	Domestic		
	First Domestic	Transfusion AIDS	ELISA	Heat	ELISA	Heat
	AIDS Identified	Identified	Innovated	Innovated	Diffused	Diffused
U.S.	June 1981	July 1982	Apr. 1984	Feb. 1983	Mar. 1985	Mar. 1983
Germany	Oct. 1982	Oct. 1983	July 1984	May 1981	Apr. 1985	Feb. 1985
U.K.	Dec. 1981	Spring 1983	Autumn 1984	1984	Oct. 1985	Oct. 1985
France	June 1981	July 1982	July/Aug. 1983	Summer 1985	Aug. 1985	Sept./Oct. 1985
Japan	July 1983	July 1983	Nov. 1986	Early 1986	Feb. 1986	July 1985

Technologies
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Sources: Montagnier 2000; Feldman and Bayer 1999; Starr 1998; Institute of Medicine 1995; Kirp and Bayer 1992; Grmek 1990; U.S. Centers for Disease Control 1981, 1982 Notes: ELISA = enzyme-linked immunosorbent assay; Heat = heat treatment



Figure 1 Months Elapsed before Innovation

Sources: Montagnier 2000; Feldman and Bayer 1999; Starr 1998; Institute of Medicine 1995; Kirp and Bayer 1992; Grmek 1990; U.S. Centers for Disease Control 1981, 1982

*Note*: ELISA = enzyme-linked immunosorbent assay

<sup>a</sup>Dated from the first international recognition of the disease, June 1981

<sup>b</sup>Dated from the first international recognition of the possibility of transmission via transfusion, July 1982

had a considerable stake in Gallo's research. For years, the combination of Gallo's prestige, NIH's reputation, and the fact that both the NIH and the Reagan administration had invested substantial political capital in an American solution, combined to cloud and limit recognition of Montagnier's 1983 discovery (Shilts 1987; Epstein 1996).

Thus, in France, despite the general lack of support from the government, researchers at the private Pasteur Institute were able to achieve early leadership in the science of AIDS, which in turn enabled rapid innovation in HIV testing technologies. Montagnier, who was the leading French AIDS researcher, had entered the field in autumn of 1982 at the request of the Pasteur Institute's industrial subsidiary, Pasteur Institute of Production (IPP). IPP wanted to investigate the possibility of AIDS transmission via plasma that had been imported from the United States and used by IPP to produce vaccine for hepatitis B. In the course of their research, the Pasteur Institute invented many of the first working HIV antibody tests. In March 1983, Montagnier used a radioactive assay developed the previous month to become the first scientist to identify the HIV virus.<sup>8</sup> By July–August

<sup>8.</sup> Montagnier had isolated the virus two months earlier.

1983, his laboratory had perfected a simpler ELISA for HIV antibodies; he submitted patents for the assay in Europe on September 1 and, for the United States, to the U.S. Patent Office on December 5. Using these tests, the Pasteur Institute confirmed the presence of HIV in French supplies of AHF in August 1983 and immediately informed the French government. Hence, French researchers were at the forefront of science and technological innovation in regard to describing and detecting HIV and its antibodies; however, as shall be shown in the next section, transition from laboratory to mass production was longer in coming.

As for Gallo, he turned out to be a determined competitor within the U.S. research establishment. He not only absorbed valuable funds, equipment, and personnel at a time when such resources were scarce, but he also used his considerable clout to oppose the funding, pursuit, and scientific acceptance of competing lines of research by other laboratories, including Montagnier's (Shilts 1987; Epstein 1996; Montagnier 2000). And since Gallo's line of research was ultimately wrongheaded, this postponed the U.S. discovery of the AIDS virus and the development of commercial HIV tests for as long as a year. Yet the Reagan administration still insisted on backing Gallo, giving him credit for the discovery of HIV. In April 1984, Secretary of Health and Human Services Margaret Heckler proclaimed side by side with Gallo that the United States and the Reagan administration had "discovered" the AIDS virus and that an HIV blood test would soon follow, despite the fact that a patent application for Montagnier's HIV test had already been submitted to the U.S. Patent and Trademark Office in December 1983. In a final twist, on closer inspection it was later found that Gallo's 1984 AIDS virus was actually the lentivirus originally discovered by Montagnier and had come into Gallo's possession either by cross-contamination or outright theft (Crewsdon 2002; Epstein 1996). Ultimately, a treaty was needed to resolve the patent and lawsuits that resulted (Crewsdon 2002; Epstein 1996).

In Britain, researchers fought not only against the lack of government support, but also a widely held perception in the British scientific community that French and American AIDS research could not well be competed against. Nevertheless, British researchers were able to make some notable achievements. For example, as early as December 1983 Cambridge virologist Abraham Karpas published an electron micrograph of what turned out be the HIV virus months before its identification by Robert Gallo in the United States (Berridge 1996). And, like Gallo, a British leukemia researcher diverted funds from his cancer research to help to lay the foundation for the first commercial British HIV antibody test. The laboratory



Figure 2 Months Elapsed before Diffusion

*Sources*: Montagnier 2000; Feldman and Bayer 1999; Starr 1998; Institute of Medicine 1995; Kirp and Bayer 1992; Grmek 1990; U.S. Centers for Disease Control 1981, 1982

*Note*: ELISA = enzyme-linked immunosorbent assay

<sup>a</sup>Dated from the first international recognition of the disease, June 1981

<sup>b</sup>Dated from the first international recognition of the possibility of transmission via transfusion, July 1982

versions of the British test were developed in autumn 1984 by another researcher, Richard Tedder, and were used to conduct viral research and epidemiological studies, including analysis of sera from hemophilia centers (ibid.). However, as in France, the transition from the laboratory to the production line was not as timely.

## Federalism and Technological Diffusion

Government structure may have played its strongest role in either aiding or retarding the diffusion of the new blood technologies (see fig. 1). Regardless of the origins of the ELISA test and heat treatment technologies, once innovated and adapted for commercial production they were physically available for rapid diffusion. Again, this is an area where government could have speeded technological progress, perhaps by subsidizing consumption or lowering regulatory hurdles to diffusion. However, in each country, the interests of industry interfered to capture and delay the process. In some cases, industry capture even predated the discovery of HIV and interfered with the innovation process itself. But while some degree of industry capture resulting in technological delay occurred in each of the countries surveyed, capture seems to have been more effective in the centralized democracies than in the decentralized states.

In France, one major reason for the delay between innovation and diffusion seems to have been that, with so much authority concentrated on the executive, industry capture in the French case was more effective than in the decentralized states. Within the Ministry of Health, the General Department of Health (DGS) was given authority to oversee all collection and distribution of blood, monitor the blood banks, and fix the uniform prices for blood products. These functions in 1981 were performed by a single nonmedical bureaucrat advised by specialists from the very industry that he was supposed to regulate. Likewise, the authority to license blood products and blood tests and to guarantee their safety fell under the Ministry of Health's technical branch, the National Health Laboratory (LNS), which had only two administrators assigned to this task (Steffen 1999).

The most successful instance of antitechnology industry capture in the French case occurred at a May 9, 1985, interministerial meeting called by the prime minister's office to discuss the blood safety issue. In spite of the Pasteur Institute's rapid advances in the laboratory, the production runs of the French ELISA test were not ready in time to compete with the first American test, which had received its U.S. licenses in March 1985 and was available commercially within a month at half the cost of the Pasteur test. Abbott Laboratories, anticipating opportunities in the large European market, had applied for a French license for its ELISA on February 11, 1985. Facing an election, it would have been to the Socialist government's advantage to announce the immediate introduction of mandatory blood screening, which would simultaneously appease conservative voters, the scientific establishment, and the increasingly sensationalist press. After all, heat-treated products were already available from American producers, as was the inexpensive Abbott Labs ELISA, which was awaiting approval by the LNS. However, at the May 9 meeting in which these options were discussed, the interests of business and finance came out victorious over those of public health. Opening the market to heat-treated imports was denied, since imports of foreign blood would divert profits from domestic industry; meanwhile, the LNS was instructed to temporarily block the approval of Abbott's ELISA in order to buy time for Diagnostics Pasteur (formerly IPP) to perfect its HIV antibody test. Pasteur's ELISA test eventually received its license on June 21, 1985, with plenty of time to ramp up production for compulsory national blood testing which was put off until August 1. Abbott Labs did not receive its license until July 25, less than a week before mandatory testing was to begin (Feldman 2000; Steffen 1992, 1999).

The Japanese case reveals some important parallels with the French case, with similar aspects of centralization, industry capture, and delays in technological response. Certainly, the Japanese state does not tend to own or operate manufacturers as is done in France; however, there does exist an intimate relationship between business and government in Japan, which some scholars have attributed to incentives resulting from a combination of a relatively centralized government structure and electoral laws (Ramseyer and Rosenbluth 1993). With regard to blood and blood products, regulatory jurisdiction in Japan, including the licensing of foreign products and the monitoring of their distribution, fell under the Ministry of Health and Welfare (MHW) and its Biologics and Antibiotics Division (BAD). As in France, the MHW sat low in the bureaucratic hierarchy and BAD was small, poorly staffed, and subject to industry capture (Feldman 1999). The MHW relied heavily on advisory committees (shingikai) consisting largely of people who had a financial stake in MHW regulatory decisions. Top MHW officials were regularly employed by the pharmaceutical industry in a practice known as amakudari (practiced as pantouflage in France). Thus, market share was often a consideration in MHW regulatory decisions (Johnson 1983; Suleiman 1978; Feldman 1999). Finally, as in France, Japanese industry was able to assert its interests in the policy-making process at the executive level to restrain the diffusion of technological solutions that would hurt the profits or market share of domestic firms.

Despite its appearance in Japan in 1983, neither the Japanese government nor the general population perceived AIDS as a domestic health threat until some four years later, when the death of a Kobe prostitute sparked national debate. Prior to this, AIDS was popularly seen as a foreign problem. Nonetheless, in 1983 Japanese hemophiliacs responded quickly to the first U.S. reports of transfusion AIDS, demanding that the government ban imports of U.S. blood products (Feldman and Yonemoto 1992). Cheap foreign imports were, however, an important source of profit for Japanese physicians and hospitals, who were reimbursed by the government at more expensive domestic price levels (Feldman 1999). Hence, the Ministry of Health and Welfare, which had regulatory jurisdiction over pharmaceutical imports and was advised by members of the medical community who profited from them, did nothing (Feldman and Yonemoto 1992). Indeed, it was not until the second half of 1985 that the Japanese government terminated distribution of unheated blood products, and blood testing was not introduced until November 1986 (Swinbanks 1986; Feldman 1999).

While some of these technological delays can be ascribed to the relatively low incidence of AIDS in Japan, some blame must also be given to the ability of the Japanese executive branch to keep AIDS policy and information confined to backdoor meetings. In doing so, the executive delayed recognition of the disease and thereby impeded action to address the problem. The first recorded AIDS death in Japan was that of a hemophiliac in 1983 (Isomura and Mizogami 1992; Swinbanks 1985; Feldman 1999). Yet despite a positive diagnosis by visiting CDC researchers and warnings about the existence of transfusion AIDS, the MHW's newly formed AIDS Task Force refused to report the 1983 case (Swinbanks 1988, 1996). The first "official" Japanese AIDS victim was not reported until March 1985, the case of an artist returning from an extended stay in the United States. Some scholars suggest that the 1985 case was more culturally acceptable to the Japanese since he was by profession and locale a social outlier (Feldman 1999). However, in being an outsider, the 1985 victim also did not present a domestic problem that demanded a response from government. More importantly, the 1985 case did not suggest a threat to the domestic blood supply and hence to the domestic blood industry which maintained strong ties with the MHW.

The Japanese case also points to the domestic pharmaceutical industry's ability to obstruct the diffusion of foreign technology via capture of the executive branch. During the early 1980s, when transfusion AIDS first hit Japan, the Japanese blood products market was dominated by Japan's largest pharmaceuticals firm, Green Cross (ibid.). Founded in 1950 as a commercial blood bank, the Green Cross (then called Nippon Blood Bank) had become influential in MHW regulatory policy early on. During the mid-1950s, it successfully lobbied the MHW to classify blood as a pharmaceutical, which entitled its sellers to lucrative reimbursement by the national health plan and thereby helped eliminate Green Cross's nonprofit competition. By the 1980s, Green Cross had switched production to blood derivatives and controlled half of the Japanese market (Starr 1998). Its main foreign competitor was Baxter Healthcare in the United States, which had perfected its heat-treatment process in 1983 and quickly applied to the MHW for permission to sell its products in Japan. At the time, Baxter had less than 20 percent of the Japanese market and saw the absence of a Japanese competitor in heat-treated blood derivatives as an opportunity to expand (Feldman 1999). However, despite the fact that unheated Bax-

ter products were sold widely in Japan, the MHW refused to license any U.S. heated blood derivatives (Agress 1983; Feldman 1999). Government identification of a hemophiliac AIDS victim would have compounded the situation and posed a significant threat to the livelihood of Green Cross, which did not produce heated-product and held vast unsold inventories of unheated AHF. This fact is important since the Japanese pharmaceutical industry, and Green Cross in particular, were heavily represented in the 1983 AIDS Task Force, which made the policy and reporting decisions regarding the HIV threat. The chair of the 1983 AIDS Task Force was later found to have accepted money from Green Cross and to have demanded payment from Green Cross's rivals in exchange for backing clinical testing of their heated blood products (Dearing 1992; see also Swinbanks 1988). Also, via amakudari, other members of the AIDS Task Force and their superiors at the MHW had wound up in powerful or lucrative positions in either government or the pharmaceutical industry, including senior positions at the Green Cross Corporation and its affiliates (Feldman 1999). While bribery and industry capture are by no means scarce in either the United States or Germany, in these countries, where health reporting and policy are split vertically between the federal and subnational levels, government structure may have made it more difficult to advance to the levels achieved in Japan.

In comparison to France and Japan, West Germany seems to have diffused with some alacrity in response the AIDS threat. While the French and Japanese cases reveal instances of substantial industry capture at the executive level, the delays in the West German case read more like a lack of urgency. Certainly the blood industry in West Germany sought to delay a costly technological fix to a persistent health problem. Nor was the executive branch enthusiastic about spending money on AIDS research or even on information and education programs.<sup>9</sup> However, they were unable to stall innovation and diffusion in the same manner, perhaps due to the decentralized nature of the West German government, with its competing jurisdictions, judicial oversight, multiple access points, and lower thresholds of political participation.

Power regarding health issues in Germany was shared between the federal government and the *Länder*, all of which fell under the scrutiny of an assertive court.<sup>10</sup> The Federal Ministry of Health (BMG) oversaw the federal apparatus, such as the Federal Health Office (FHO), the Paul-Ehrlich-

<sup>9.</sup> Federal research was not initiated until 1987 (Miesala-Edel and Schops-Potthoff 2000).

<sup>10.</sup> These roles are specified in Article 74 of the Basic Law of the German constitution.

Institute (PEI), and the Institute for Pharmaceutical and Medicinal Products (BfArM) (Miesala-Edel and Schops-Potthoff 2000; Frankenberg and Hanebeck 2000). However, while the PEI and BfArM were responsible for testing and licensing new health products, the direct regulation of production of these technologies fell under the jurisdiction of the *Länder*, which had their own State Health Ministries.

What is interesting about the German case is that Bonn had at its disposal many of the same, if not more severe, policy tools that were available for use, or exploitation, to the executive branches in Paris and Tokyo (though not in Washington, D.C.). For example, the Federal Epidemics Control Act and the Federal Venereal Diseases Act could have been used to address the problem in a far more conservative manner and then easily been exploited for Stiglerian purposes. These laws granted the federal government the authority to handle the AIDS threat in virtually any way it saw fit, including product regulation, government surveillance and investigation of suspected carriers, quarantine, and even imprisonment (Frankenberg 1992). Although reminiscent of Germany's darker past, these types of solutions were strongly advocated by the state government of Bavaria, which not only enacted aggressive, if not somewhat repressive, tactics to fight AIDS within Bavaria but also pressed the federal government to follow suit on a national level. Chancellor Helmut Kohl is reported to have "had sympathy" for this type of approach, and in 1984 the BMG announced that strict legislation, the Act for the Control of Diseases Transmitted by Sexual Contact, was being devised (Frankenberg and Hanebeck 2000; Frankenberg 1999). Whether nationalization of the Bavarian strategy would have resulted in the technological delays that plagued France or Japan or, conversely, sped the adoption of testing and heat treatment, we can never know. For, while the government of Bavaria was controlled by the conservative Christian Social Union party, its drive for a national command-and-control response to AIDS was defeated due to opposition from the other Länder and by members of Parliament with more liberal or gay constituencies. And since the Bavarian government shared policy authority with the federal government, even its stricter state policies were moderated. Contributing to this result was the fact that the German gays had been politically active for almost a decade, initially asserting themselves in the trade unions and in the Social Democratic and Liberal parties and, later, more strongly in the Green party. By the time AIDS hit, there were approximately two hundred organized gay interest groups in Germany (Frankenberg 1992). And since German political parties had low electoral hurdles for winning seats in government, these groups were able to find responsive representatives at all levels of government.

Delays due to industry capture also occurred within the United States but without the same effect as in some of the centralized democracies. During the 1980s, responsibility for regulating the safety of the blood supply fell under the jurisdiction of the Blood Products Advisory Committee (BPAC) within the Food and Drug Administration (FDA). While BPAC had no direct policy-making power, it did advise the FDA on blood regulation when granting licenses and approvals for new blood products (Feldman 2000). At the time of the AIDS crisis, BPAC was chaired by Dr. Joseph Bove, who simultaneously led the American Association of Blood Banks, the same industry that the FDA was supposed to regulate. Bove and the industry he represented consistently denied the existence of transfusion AIDS until 1984–1985; Bove also used his position at the FDA to downplay the threat of AIDS and argue against regulations that might drive up the costs of production, including testing and heat treatment. For example, immediately after the December 1982 announcement of the hemophiliac AIDS cases, Bove went on network television to declare that no evidence existed that transfusions spread the disease (Shilts 1987). When the CDC called a meeting with the blood industry the following January to warn against the dangers of transfusion AIDS, Bove cautioned against overreacting just because "one baby got AIDS" (ibid.). In August 1983, Bove continued this argument in testimony before Congress.<sup>11</sup> However, neither the dominance of the BPAC by the blood industry nor the strong voice of industry within the FDA seems to have directly influenced the patenting of the HIV ELISA or the use of heat treatment. Rather, the delay in patenting and licensing an ELISA appears to have been due more to the stronger political position of Gallo's research versus Montagnier's within both the regulatory and scientific communities. As for heat treatment, American pharmaceutical companies were producing FDAapproved heat-treated blood products by March 1983, only two months after being warned by the CDC of the dangers of transfusion AIDS. Space constraints prevent discussion of the British case; the details of delay there are somewhat less overtly Stiglerian than in the French or Japanese cases. However, we still find some of the same dynamics.

There is an important caveat here: as one can see from the charts, the relationship between federalism and technological diffusion is rough and, from some perspectives, minor. For example, it took the United States and Germany only forty-five to forty-six months from the first knowledge of AIDS to diffuse ELISA blood testing. It took France and Great Britain

<sup>11.</sup> Bove ultimately changed course in 1984 after mounting evidence; see Shilts 1987 (478).

fifty to fifty-two months, only a four- to seven-month difference. This time lag may not be sufficiently weighty to support a theory testing the impact of centralized state structures on technological diffusion. But I do not seek to test a diffusion hypothesis here, only to generate one.

# Conclusions

The research reported above suggests that the contradictory findings regarding a decentralization-innovation relationship result from a combination of measurement error and specification error. The blood cases suggest that innovation should be considered separately from diffusion and that overall political decentralization (not federalism alone) may have a positive effect on diffusion but little relationship with innovation. Since both innovation and diffusion manifest themselves in the appearance of new technology, these two phenomena can be easily mistaken for one another at a superficial level. And given that much of the existing evidence for or against the decentralization-innovation thesis involves high-level observations, stylized facts, and sometimes anecdotal case studies, the empirical observations being reported may be instances of diffusion that have been misidentified as innovation. More testing is needed to confirm this hypothesis. Therefore, in order to more firmly establish this distinction, future research may benefit from revisiting the varieties of capitalism or national innovation systems debates, which have thus far failed to produce general explanations of state-level technological change.

The more novel contribution of this research has been to identify new mechanisms by which overall political decentralization may affect technological change. First, technology and the problems that technology solves are not neutral; rather they create winners and losers, and the losers act politically to defend themselves. The key mechanism here seems to be policy capture by resisters in order to slow or obstruct technological change. Policy capture appears to be less difficult or costly when government is centralized in a single capture "point," whereas decentralized government offers diffusers the chance to venue shop around political resistance. Second, the case studies also point to the importance of horizontal decentralization, often ignored in prior research focused on the effects of federalism. More specifically, in the blood cases resisters to new technology captured fiscal policy to prevent the funding of R&D for technologies that competed with the status quo. They also captured trade and licensing policy to prevent entry by new technologies in existing markets. Interestingly, free market actors behaved just as anticompetitively as public or nonprofit actors. Finally, the case studies also revealed instances in which decentralization allowed for the location of decision-making power at a lower level of aggregation, where political deals concerning technological progress could be made away from national political fights and without linkage to distant interests or issues that might complicate or confound a political solution. Again, we should be careful not to overstate these findings, since they are observations generated by a single set of case studies that represent a relatively brief period. That is, I do not argue in this article that I have proven a general causal relationship, only that I have produced new hypotheses. But, while each of these mechanisms needs to be tested further, perhaps in the context of the "veto-players" debate, the insights produced by this article do appear to reframe the debate and imply more specific avenues of research.

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#### 898 Journal of Health Politics, Policy and Law

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