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**INSTITUTIONS AND INDUSTRIAL PERFORMANCE:
THE PHARMACEUTICAL SECTOR IN FRANCE,
GERMANY, BRITAIN, AND THE U.S.¹**

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I. Varieties of Capitalism and National Product Market Strategies

The Varieties of Capitalism (VOC) approach to political economy asserts that domestic producers are able to secure a competitive advantage in the global economy by pursuing production strategies that emphasize the institutional advantages that for historical reasons are available within their countries. This VOC analysis arose as a reaction both against the prior focus on aggregate demand conditions emphasized by Keynesian analysis (Streeck 1992, 2), as well as in response to trade theories targeting aggregate factor endowments as a source of comparative advantage (Hollingsworth 1997, 283). Advocates of VOC argue that nationally distinctive institutional contexts of production have self-reinforcing mechanisms that make them likely to persist over time. The institutional configuration of labor training and supplier contracting “function as constraints and opportunities simultaneously,” at once raising the cost of alternative product market strategies and creating a comparative advantage in existing strategies (Streeck 1992, 29). This comparative advantage argument implies that globalization in trade creates competitive forces that perpetuate and intensify national institutional distinctiveness. Distinctive institutional forms should therefore play a central role in setting patterns of trade among the advanced industrial countries. Thus the VOC model offers an account both of the sources of prevailing national product strategies, and of the patterns of globalization that are likely to emerge among countries with similar factor endowments (land, labor, capital) but organized through different national institutions. I test the predictions of the VOC approach against the experience over the past thirty years of the pharmaceutical industry in Germany, France, Britain, and the United States.

Researchers working in the VOC mode have generated a range of substantially consistent theories linking the institutional form of production to product market strategies. David Soskice has focused on nationally specific configurations of the financial system, the industrial relations system, the education and training system, and the inter-company system. He finds that variation in the institutional configuration of these four systems falls into two broad production strategies: liberal market economies and coordinated market economies (Soskice 1996a, 102-5). Coordinated market economies push manufacturers toward a product market strategy that emphasizes high-quality products and incremental innovation. Liberal market economies foster product market strategies that emphasize lower quality and more radical forms of innovation (Soskice 1996b). Working in a similar framework, Wolfgang Streeck focuses on worker skill formation and the nature of supplier relations. Where worker skills are high and supplier relations congenial, as in Germany, companies excel in product market strategies that emphasize diversified quality production (Streeck 1992, 4). Streeck argues, for example, that the institutional context of diversified quality production in Germany has kept German automobile manufacturers from importing Japanese-inspired strategies of lean production (Streeck 1996).

This paper tests the hypotheses emerging from the VOC model against national performance in the pharmaceutical sector in France, Germany, Britain, and the United States. In both the Soskice and the Streeck models, Germany occupies one product-market extreme while the United States and Britain both occupy another. Because the pharmaceutical industry is innovation-intensive, the Varieties of Capitalism approach suggests that the United States and Britain should excel in this sector, especially in relation to new kinds of products such as those developed through bio-engineering. A recent comparative study of the British and German pharmaceutical sectors by Steve Casper and Catherine Matraves (1997) supports this hypothesis.

While the United States is closely associated with Britain under the liberal market economy category, the place of France in this schema remains disputed. Michel Albert (1991) argued in the early 1990s that France teeters between the seductive allure of the Anglo-American model of liberal market economy and the more prudent austerity of the Rheinland model of coordinated market economy. Jonah Levy (1999) cautions that France simply lacks the institutional infrastructure — in the form of social capital, associational density, and decentralized control mechanisms — to pursue the Rheinland model successfully. Alternatively, Bob Hancké (1999) has proposed that, even in the absence of such associational capacities, France has nonetheless been able to adopt coordinated industrial strategies by taking advantage of state-centered elites capable of promoting high-end industrial strategies through government-managed labor and capital policies. Nick Ziegler's research on French elites finds that the French approach may only succeed in certain kinds of network industries but not in industries that require decentralized reforms (Ziegler 1997). I provisionally include France in the category of coordinated market economies, with the underlying assumption that France will not enjoy a comparative advantage in the innovation-intensive pharmaceutical market.

The paper presents its findings in two sections. The first section tests VOC hypotheses against industry performance indicators for France, Germany, Britain, and the United States. Performance is measured first from the perspective of industry itself, focusing on profitability, sales, and foreign market penetration. A second measure of performance focuses on indicators of particular interest to national governments: employment, balance of trade, total drug bill, and innovation. Where possible, I present historical performance data in order to place current trends in a longer perspective. These data show that the VOC model explains some but not all of the variation in national competitiveness in the pharmaceutical industry. As predicted, Britain does out-perform Germany in pharmaceutical innovation and export. Yet Germany also out-performs the United States in a number of indicators, a finding not expected under the VOC model.

The second section of the paper traces national approaches to regulating domestic pharmaceutical markets, focusing first on safety and efficacy regulation, then on price regulation. How countries have regulated pharmaceutical products along these dimensions appears to have played a role in setting industry product strategies. In France, where direct price restraint has been unusually

comprehensive, pharmaceutical firms have sacrificed new drug development in favor of a low-cost, high-volume strategy of domestic sales. In Britain, industry profits are negotiated between producers and the government based on the research and export intensity of individual firms. British firms have therefore emphasized R&D and export activities, while de-emphasizing their domestic sales effort.

This paper confirms many of the predictions of the Varieties of Capitalism approach. But it also finds that a more thorough explanation of product market strategy in the pharmaceutical industry must incorporate the institutions that set national conditions of product demand. Recent research in business management has suggested that demand conditions may be important determinants of industry strategy (Porter 1990, 87; Kogut 1991, 36; Albach 1994, 269; Storper and Salais 1997; Gholz 1999, Chapter 4). One cross-national study of the impact of different kinds of regulation, for example, finds that product market regulations are nearly twice as important to national economic prosperity as are labor market regulations (Koekijk et al. 1996).

This emerging body of research suggests that national constellations of product market regulations may have a strong impact on industry strategy. In many cases these product market effects may complement the impact of distinctive national production systems as described in the Varieties of Capitalism literature. But the forms of national product market regulation do not necessarily mirror national production institutions in a simple way. In the British pharmaceutical industry, for example, the government assigns profit targets for manufacturers based on their research investment and export success, and then imposes drug prices such that each firm's profitability target is met. The approach looks decidedly illiberal with respect to the economic autonomy of the firm, and therefore antithetical to the liberal market economy ideal type. But it nevertheless serves to bridge the potentially conflicting interests of shareholder value and government budget restraint. This example suggests how a broader approach to the Varieties of Capitalism analysis, one that incorporates national configurations both of production institutions and of consumption institutions, may help to explain important dimensions of observed variation among national industry strategies.

II. Indicators of Pharmaceutical Industry Performance

This section tests the VOC hypotheses against aggregate indicators of industrial performance for the pharmaceutical industries of France, Germany, Britain, and the United States. Because industrial performance is often in the eye of the beholder, we consider first industry-oriented standards of performance, then government-oriented standards of performance. We then evaluate the impact of supply-side institutions, those conventionally addressed in the VOC literature, on differential performance in the four test countries. We conclude that the VOC approach, as currently deployed, helps to explain some but not all national variation in industrial performance.

The VOC approach makes two broad predictions about how the pharmaceutical industry will perform in different countries. In those dominated by coordinated markets, such as Germany and France, we should expect to see poor industry performance due to an inability to sponsor the kind of radical innovation required for success in the pharmaceutical industry. By contrast, we should expect a high degree of success by British and US pharmaceutical firms. The second and related prediction of the VOC model is that these differential national capabilities should drive patterns of pharmaceutical globalization. Britain and the US should enjoy a strongly positive balance of trade in pharmaceuticals. France and Germany should experience a correspondingly weak balance of trade. We should also see signs that pharmaceutical producers in the coordinated market economies are moving research and production activities to liberal market economies that offer greater advantages for innovation.

How do the pharmaceutical industries in these countries measure up? The evaluation proceeds in two parts. The first section below takes the perspective of industry, and asks how each national industry is performing by comparison with producers in other nations. Here we look at the bottom line: profits, volume of production, exports, and ownership. The second section takes the perspective of the national government. It asks what costs and benefits the pharmaceutical industry is bringing to consumers, to the government, and to the larger economy. This section looks at the national drug bill, the trade balance of the drug industry, the employment opportunities it provides, and the extent to which pharmaceutical firms invest in health-improving research. Where possible I provide historical data, which permits us to see how current patterns have emerged over time. For most indicators I also present a per capita measure for the latest year available. While these per capita measurements often convey little useful meaning on their own, they do permit us to account for the very different sizes of the case countries, especially the disparity between the United States and the smaller European countries.

Industry's Perspective on Pharmaceutical Performance

This section focuses on performance indicators of interest to managers and owners in the pharmaceutical industry. For owners, the main interest is return on investment, and therefore company profits. For managers, success is defined by profits, but also by sales volume, export success, and in part also by acquisition of foreign firms.

Profitability data on pharmaceutical manufacturers strongly affirm the VOC hypothesis about the relative strength of liberal market economies in an industry characterized by radical innovation. British pharmaceutical firms enjoy a particularly high level of profit, which, at 28.7 percent, is nearly twice as high as profitability in the United States. France, at 5.8 percent, has the lowest profitability of the four. In Germany, profits, at 11.3 percent, are greater than in France but less than in the United States or Britain. This pattern of national profit margins is consistent with the central role attributed to the stock market in liberal market economies, with the dominant role of longer-term sources of investment

finance in coordinated market economies, and with the hypothesized innovative advantage of liberal market economies.

Figure 1. Pharmaceutical profit margin, percent of revenue.

	1983	1991
France	7.8	5.8
Germany	13.8	11.3
Britain	32.1	28.7
US	n/a	15.2

Source: Burstall and Reuben 1987, 120; Finkelstein and Bittinger 1993, 4-5.

Production figures, however, complicate the picture. French pharmaceutical companies, taken together, enjoy higher sales than do German or British pharmaceutical firms. While US firms outsell all others by a wide margin due to the large size of the country, a comparison of sales measured on a per capita basis reveals that, relative to the size of the economy, French pharmaceutical producers also far outsell manufacturers in the United States. From this perspective, German sales are the lowest of all four countries. It is interesting to note that as recently as 1990, Germany produced more pharmaceuticals than did France or Britain. Indeed in 1983, Germany produced twice as many drugs as Britain and half again as much as France. This sign of strong sales by France and, earlier, Germany, is surprising given our expectations about the relative capabilities of liberal and coordinated market economies.

Figure 2. Pharmaceutical production, \$ billions.

	1961	1970	1983	1990	1997	1997 in \$ per capita
France	0.6	1.4	7.9	14.1	22.3	381
Germany	0.6	1.7	11.2	15.9	19.8	241
Britain	0.5	0.7	5.6	11.9	17.5	297
US	3.2	6.8	23.9	41.9	75.8	284

Source: ABPI; BPI; Matraves 1998, 26; Möbius et al. 1976, 101; PhRMA; SNIP.

The record of export success of pharmaceutical producers in these countries holds similar surprises. Most notably, the volume of US drug exports is lower than those of France, Germany, or Britain, despite the substantially larger size of the US economy. Indeed, the historical trend shows that the United States has lagged behind the European countries in export volume since the 1970s. In

terms of actual volume, the most successful drug exporter has long been Germany, which exports 50 percent more pharmaceutical products than does the United States. For France, strong production figures have not translated into a strong export success (although France does exceed the United States in export volume). This suggests, as we will see below, that the French themselves consume a larger volume of drugs, measured on a per capita basis, than do the other countries studied. Taking the 1997 figures on a per capita basis, Britain emerges as the best export performer, followed closely by Germany and then France. This measure indicates just how poorly the United States performs in drug export compared to the other countries. One of the reasons for this is, as we will also see below, that US pharmaceutical companies have favored producing overseas rather than exporting finished products.

Figure 3. Pharmaceutical exports, \$ billions.

	1961	1970	1980	1990	1997	1997 in \$ per capita
France	0.10	0.16	1.09	2.85	8.5	145.04
Germany	0.14	0.32	1.28	3.61	12.7	154.78
Britain	0.15	0.25	1.13	3.14	9.6	162.69
US	0.27	0.18	0.66	1.33	7.9	29.61

Source: Industrie pharmaceutique 1996, 36; ABPI.

Taking exports as a percentage of total sales (see Figure 4 below), we see that Germany and Britain lead France and especially the United States in export intensity. Once again, we observe a pattern of industrial performance that, by cutting across the coordinated/liberal market division, confounds the VOC hypothesis about success in drug trade. Note the extraordinary growth in German exporting over the course of the 1990s, during a time when the introduction of radically new technologies, especially biotechnology, were expected to put Germany at a disadvantage. Notice also that the overall export intensity of pharmaceutical producers has grown importantly in all four countries (doubled in France and Britain, tripled in Germany and the United States) over the past decade. Finally, note the drop in trade intensity from 1961 to 1970, which reflects the impact of a period of intensive safety regulation for the pharmaceutical industry that followed in the wake of the Thalidomide (Contergan) tragedies. As these trade figures show, the export intensity of the pharmaceutical industry has increased dramatically only beginning in the 1990s.

Figure 4. Export as a percentage of total sales.

	1961	1970	1990	1997
France	16.7%	11.4%	20.2%	38.1%
Germany	23.3%	18.8%	22.7%	64.1%
Britain	30.0%	35.7%	26.4%	54.9%
US	8.4%	2.6%	3.2%	10.4%

One reason for the relatively low export intensity of US producers is their strategy of developing and manufacturing pharmaceuticals in their target markets. US drug companies have bought or established a large number of production sites in France, Germany, and Britain. Likewise, producers in these countries also own drug companies in the United States and in other European countries. The trade data presented above are based on the geographical location of a company, not on its ownership. But ownership matters to company management, and especially to shareholders, and thus must be considered in our assessment of industrial performance. Figure 5 below describes the share of drug sales in each country according to the nationality of the producers. Shaded squares indicate the percentage of national consumption served by national pharmaceutical producers. As these data indicate, only in the United States do domestically-owned companies provide more than half of the drugs consumed in the country. In Britain, incredibly, only 26 percent of domestic consumption is provided by British pharmaceutical firms. France and Germany are in an intermediate position, with 33.8 percent of the French market served by French firms, and 46.6 percent of the German market served by German firms. These figures attest to an astounding degree of globalization in ownership in the pharmaceutical industry.

Figure 5. Share of country market consumption according to the nationality of producers, measured as percentage of domestic consumption, in 1997.

		country markets			
		Germany	France	Britain	USA
nationality of producers	German	46.6	12.9	8	7.5
	French	5.1	38.8	4.6	1.5
	British	6.1	8.2	25.8	12.3
	US	19.7	23.6	31.3	63.9
	all other	22.5	16.5	30.3	14.8

Source: SNIP.

US firms have extended heavily into German, French, and especially British markets. Nearly a third of all drugs sold in Britain come from US producers. Britain, in turn, has been the most successful of the European countries in penetrating the United States market, with 12.3 percent of market share. Germany has captured 7.5 percent of the US market. France has only managed to take over 1.5 percent of the US market. Success in the US market is particularly significant for European firms because the market is so large. Thus it provides a useful indicator of the relative market penetration of European firms (Casper and Matraves 1997, 2). From this we conclude that the US pharmaceutical industry has been most successful at penetrating foreign markets, followed by Britain, Germany, and, in last place, France.

The picture that emerges from these industry-oriented performance indicators is inconsistent with respect to the VOC model. Profitability figures reinforce VOC claims about the different innovative strengths of liberal and coordinated market economies. Figures on the saturation of foreign markets reinforce the view that British and US firms are most successful. But production figures, especially when measured on a per capita basis, show that France sells *more* pharmaceuticals than do the United States or Britain. This finding is surprising in a coordinated market economy. Equally surprising is the distribution of export success of the four countries studied. In a pairing that cuts directly across the VOC categorization, British and German pharmaceutical industries are export intensive.

Governments' Perspective on Pharmaceutical Performance

Before addressing these apparent inconsistencies we must also consider the performance of the pharmaceutical industry as viewed from the perspective of national governments. National interests include employment, trade balance, cost to society, and innovative capacity, which in the long term promises to generate more effective medicines.

Measured in terms of employment, Germany's pharmaceutical industry is a strong performer, with 114,000 pharmaceutical employees in 1997. See Figure 6 below. France lags behind Germany, with 73,000 employees. Counted per thousand of population, France falls only slightly behind Germany in the overall contribution of pharmaceuticals to employment. Britain, by contrast, has the smallest number of pharmaceutical workers, and indeed had to reduce the work force by 11,000 between 1990 and 1997. Britain lags behind Germany and France both in absolute employment figures and as a portion of population. The United States, which has the largest number of pharmaceutical employees, nonetheless has the smallest workforce in relation to the country's population. Hence the European countries in general, and France and Germany especially, have been successful in sponsoring employment in the pharmaceutical sector. For France, this high level of employment is consistent with the very high sales in the country. For Germany, however, where per capita production is the lowest of all four countries, the high employment suggests a low labor productivity. Hence, the performance of the French and German pharmaceutical industries on the employment scale is more favorable than the performance of the British or US

industries. This finding is consistent with the profitability figures above, and with the expectations of the VOC model, since excessive employment, enforced through rigid labor market rules, works to restrain productivity growth.

Figure 6. Pharmaceutical sector employment, thousands.

	1975	1983	1990	1997	1997 per thousand
France	56	65	66	73	1.25
Germany	n/a	87	100	114	1.39
Britain	67	67	71	60	1.02
US	n/a	153	189	208	0.78

Source: ABPI; BPI; European Community 1997, 65-66; PhRMA; SNIP

National governments also have an interest in the trade balance of industry, preferring in general to export more than they import. While trade deficits are not in themselves bad, an overall negative balance of trade forces a country to finance excess imports through borrowing, which in turn increases the cost of government borrowing. Trade balance figures for 1997 show that Germany exports far more pharmaceuticals than it imports. This is also true, to a lesser extent, for Britain and for France. The United States in 1997 ran a trade deficit in pharmaceuticals. Given that liberal market economies are expected to excel in the pharmaceutical sector, poor US trade performance runs contrary to the VOC model. The poor US trade performance is due largely to the decision of US producers to develop and manufacture drugs for foreign markets in the target countries.

Figure 7. Trade balance in 1997, \$ billions.

	exports	imports	balance
France	8.5	5.7	2.8
Germany	12.7	6.8	5.8
Britain	9.6	5.6	4.0
US	7.9	9.3	-1.4

Source: ABPI.

The pharmaceutical industry is unusual in that governments pay, directly or indirectly, much of the consumer's bill. This gives governments a strong interest in lowering per capita drug consumption, whether the drugs come from domestic producers or from foreign sources. The interest of the government in lower overall drug consumption should therefore depend on how much of the

total national drug bill they are expected to pay. The government burden is significantly different in the four countries we study. At the extremes, the British National Health Service pays for nearly 90 percent of the national drug bill, while the United States government pays for only about 40 percent. The French and German governments each pay just over 60 percent of the total cost of drugs (Elgar et al. 1992, 47). This suggests that the government of the United States has the least budgetary incentive to keep drug spending low. This cost indifference is indeed reflected in a relatively high level of spending on drugs, averaging 319 dollars per person in the United States in 1997. By the same logic, the high burden of payment of the British government is reflected in an unusually low per capita drug cost, only 233 dollars per person in the same year. Consistent with this analysis, Germany's drug bill has an intermediate value between the United States and Britain. The surprise is France, which despite a relatively high government contribution to drug payment, has experienced the largest drug bill of all four countries. This finding is consistent with, and indeed must be considered the proximate cause of, France's large domestic pharmaceutical production, noted above. The French are, in fact, the biggest drug users in the world, in per capita consumption, followed in close second by Japan (PhRMA 1999). This high level of domestic consumption may be good for French producers but it is bad for the French state, which pays much of the bill.

It is interesting to note the historical trend in national drug consumption. First, Britain has always, or at least since the early 1960s, consumed fewer drugs than its counterparts. France, by contrast, has not always been the biggest consumer. Prior to the mid-1970s, consumers in the United States spent more on drugs than did French consumers. In fact the surge in French drug consumption emerged only in the 1990s. French drug spending grew 63 percent from 1991 to 1997, during a period of relatively low inflation. Britain experienced an even greater surge during this period, of 120 percent. This rapid growth in part reflects the very low level of drug consumption in 1991, when British consumers used less than half as many drugs, measured by cost, as consumers in the remaining three countries. But the rapid growth trend has led British officials to worry today about drug spending despite the current low cost in Britain relative to other countries. By comparison, German spending grew by only 34 percent over this time, and US spending by 49 percent. As we will see below, these spending trends, which have been formative for national industries, have their source not merely in cultural orientations toward medicine, but also in distinctive strategies of product market regulation adopted by the national governments.

Figure 8. Per capita drug consumption, \$.

	1961	1970	1979	1991	1997
France	11.4	25.3	81.1	215	351
Germany	8.4	23.2	81.5	220	294
Britain	6.8	8	35.8	101	233
USA	16.4	31.6	51.5	214	319

Source: Burstall 1985, 10; Faibus 1984, 5; Finkelstein et al. 1993, 25; Möbius 1976, 103; PhRMA.

Finally, governments have an interest in the long-term health of their citizens and of their drug industries, and therefore place a high value on research into new kinds of drugs that may benefit society in the future. Because drug research is a chancy business, with the fortunes of companies hanging on the success or failure of single compounds, we consider both effort and success in pharmaceutical research. Effort is measured in terms of spending and employment in research and development. Success is measured in terms of the number of new discoveries, specifically new drug substances. Both indicators confirm VOC expectations about the innovation-emphasis of liberal market economies.

Considering research and development (R&D) effort, Britain and the United States systematically outspend France and Germany. See Figure 9 below. In both absolute and per capita terms, British and US pharmaceutical firms spend more on R&D than French and German firms. It is interesting to note, however, that France and the United States spend nearly the same amount, per person, on R&D. Germany spends far less per person on R&D than do the other three countries. This findings is surprising given the strong export orientation of the German industry, but it is consistent with the VOC view that radical innovation is not an area of comparative advantage for coordinated market economies.

Figure 9. Pharmaceutical R&D spending, \$ millions.

	1964	1973	1980	1991	1996	1996 \$ per capita
France	40	173	261	1,880	2,794	48*
Germany	27.5	299	990	2,330	3,136	38
Britain	29	145	292	2,120	3,206	55
USA	282	828	1,242	6,750	13,230	50

Sources: BPI; Finkelstein 1993, 4-5; Industrie pharmaceutique 1995, 9; *1995 Möbius 1976, 120; OECD 1985, 30; SNIP.

Another way to evaluate R&D intensity is as a percentage of total sales. See Figure 10 below. These figures confirm the research-orientation of British and US pharmaceutical firms. In 1996, British and US firms invested almost 50 percent more of total sales revenue into R&D activities than did French and German firms. The groupings are surprisingly strong. Moreover, this pattern of R&D investment has been consistent since at least the early 1980s. Note the overall growth in the research intensity of the pharmaceutical industry over the past 35 years. In France and the United States, the portion of sales revenue re-invested in R&D has grown almost three times since 1964; in Germany and in Britain, R&D intensity has grown over four times in the same period.

Figure 10. Pharmaceutical R&D spending as a percentage of sales.

	1964	1973	1983	1993	1996
France	4.8	7.9	7.1	12.5	14*
Germany	3.2	9.2	8.4	14.2	14.1
Britain	4.8	13.4	11.7	17.1	20
USA	7.2	9.4	10.6	16.7	19.9

Sources: Industrie pharmaceutique 1995, 9; Möbius 1976, 101, 120; OECD 1985, 30; SNIP. *1995

Finally, patterns of employment in research and development reinforce the findings from R&D spending. In France and Germany, 14 and 13 percent of employees work in R&D, respectively. In Britain, with the strongest R&D effort, fully one third of the workforce is focused on R&D, over twice as much as in France or Germany. In the United States, one quarter of employees work in R&D. Comparing these employment figures with R&D spending, it is interesting to note that R&D activities are more capital intensive in France and Germany than in Britain or the United States. In France and Germany, R&D accounts for roughly 14 percent of employees and 14 percent of revenues. In Britain, R&D accounts for 33 percent of employees but only 20 percent of revenues. The tendency is repeated but less marked in the United States, where R&D accounts for 25 percent of employees and 20 percent of revenue. This finding appears to reconfirm the VOC insight that radical innovation in coordinated market economies is more difficult and therefore, measured per employee, more expensive. It appears to cost more to run an R&D lab in France or Germany than it does in Britain or even the United States.

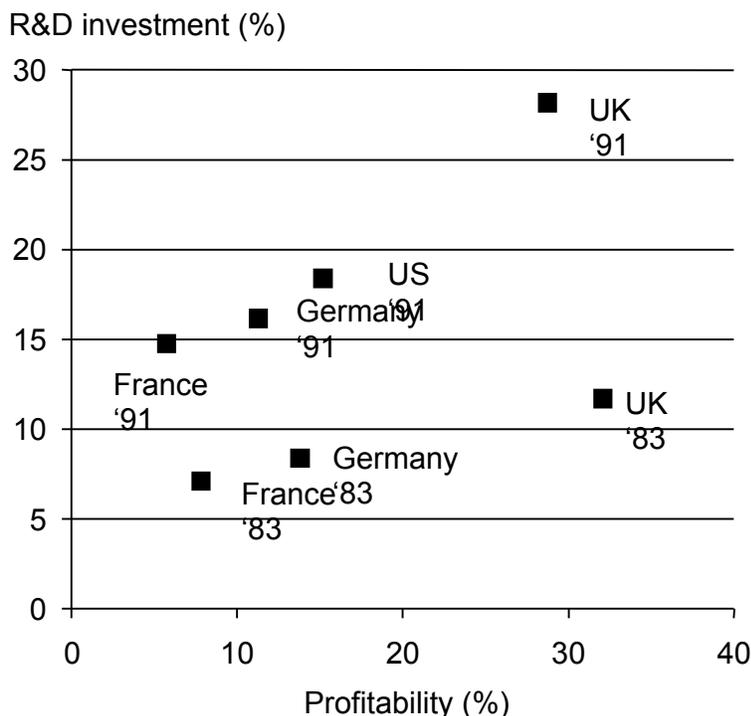
Figure 11. R&D employees as a percentage of total employment, 1975-1997.

	1975	1983	1990	1997
France	11%	12%	17%	14%
Germany	n/a	13%	15%	13%
Britain	15%	17%	26%	33%*
US	n/a	26%	23%	25%

Sources: ABPI; BPI; European Community 1997, 65-66; PhRMA; SNIP. *1998

Why do British and US pharmaceutical firms pursue more R&D than do their French and Germany counterparts? Is it because, as the VOC model suggests, they face a comparative disadvantage in this area of radical innovation? One indication is that R&D spending is very closely linked to company profitability. Figure 12 below shows R&D investment, measured as a percentage of revenue, plotted against profit, also measured as a percentage of revenue. Data for 1983 and 1991 are included. For each year, we observe a striking correlation between profit and R&D investment. Comparing the two years shows how dramatically the emphasis in R&D has increased in the pharmaceutical industry as a whole in the intervening 8 years. Hence we see a broad trend towards greater R&D investment over time, plus a consistent trend linking greater R&D investment to greater profit.

Figure 12. Pharmaceutical profitability and R&D spending as a percentage of total sales, 1983 and 1991.



Source: Burstall and Reuben 1987, 120; Finkelstein and Bittinger 1993, 4-5; Matraves 1998, 26.

How are we to interpret this finding? Does greater R&D investment generate greater profits? Or do greater profits make more R&D investment possible? If the former is true, this provides strong support for the VOC model. Germany and France, in this interpretation, enjoy a comparative disadvantage in pharmaceutical innovation. They therefore invest less in R&D, with the long-term consequence of lower profits. While this scenario seems plausible, I show in the following section that it is mostly incorrect. For at least two of the countries considered, France and Britain, profit levels for industry are strongly influenced by government regulation.

Given the differences in national R&D efforts, how successful have these countries been in finding new drugs? Innovation indicators are notoriously unreliable for cross-country comparisons. This is particularly true of the most common indicator of new drug development, the number of new drug substances, or new chemical entities (NCEs), that are introduced each year. Moreover, uncertainty in the discovery process generates strong national variation, even with new drug discoveries grouped into five-year periods. But given these caveats, broad trends in NCE data can be instructive. See Figure 13

below. First, and most clearly, the US pharmaceutical industry has generated more new drug substances than the other three countries in each of the five year periods. This follows from the large size, and consequently large R&D investment, in the United States. Second, Britain has only contributed a high number of new drug compounds in the last period, from 1990 to 1994. This finding is surprising given the important resources that British firms have invested in R&D activities. Finally, France and Germany have fluctuated strongly in their success in finding new drug substances. French performance today, however, falls far behind a prolific period of new drug discovery prior to 1974, a time when France came very close to the level of discovery of the much larger United States.

Figure 13. New drug substances by country of discovery, 1965-1994.³

	1965-69	1970-74	1975-79	1980-84	1985-89	1990-94
France	92	78	37	8	49	14
Germany	48	39	50	32	4	22
Britain	20	14	17	6	12	24
USA	93	87	71	46	90	85

Source: SNIP data.

How do these unlicensed innovations translate into market success? Figure 14 below presents the cumulative record of new drug substances during the twenty-year period from 1975 to 1994, along with various measures of success in the international marketplace. The fundamental lesson from these data is that new drug substances do not translate in an obvious way into drugs that are competitive on the world market. In the clearest case, France and Germany have generated the same number of new drug substances over this period, yet twice as many of German drugs became successful in all seven major national markets. Moreover, Britain discovered very few new drug substances, as noted above, but those discovered were highly successful in the international market. Britain exports nearly twice as many drugs as Germany, and four times as many drugs as France, to the seven major world markets.

³ Also called new chemical entities (NCE) or new molecular entities, these are new therapeutic drugs in dosage form that have not yet been submitted for regulatory approval. They may consist of new complexes, simple esters, or salts of already approved drugs (FDA definition).

Figure 14. Cumulative innovation indicators, 1975-1994.

	new drug substances	drugs selling in 4 of the 7 major markets ⁴	drugs selling in all 7 major markets	Innovative and global (7 major markets)	Innovative and Global products (weighted for market size) ⁵
France	108	24	5	3	12
Germany	108	38	11	8	30
Britain	59	14	21	11	96
US	292	90	68	30	30

Source: Finkelstein and Bittinger 1993, 3; Industrie Pharmaceutique 1996, 28.

Data for the United States shows signs both of success and of failure. On the one hand, the United States produces more successful new drugs than any of the other three countries. Indeed it produces more than the other three countries combined, by any measure. On the other hand, because the United States is so much larger than individual European states, it dedicates more resources to innovation and should therefore be expected to generate more innovative products. Finkelstein and Bittinger (1993, 3) attempt to weight a combined innovation and global sales indicator in order to offset the differential impact of domestic market size. This index, presented in the last column of Figure 14, finds that the United States and German perform equally well in terms of marketing new innovations. Britain, on this scale, performs extremely well, earning triple the score of Germany and the United States, despite its low performance in discovering new drug substances. France performs particularly poorly on this weighted scale, earning only 12 points.

Summary of Performance Indicators

What conclusions can we draw, based on these diverse indicators, about the relative industrial performance of the pharmaceutical sectors in these countries? One way to summarize the individual findings, including those primarily of interest to industry and those primarily of interest to the government, is by employing an ordinal ranking of performance on each indicator. In Figure 15 below, the countries are ranked from 1 to 4 based on their most recent performance on each indicator, discounting, where possible, for the effect of country size. A score of 4 indicates highest rank, a score of 1 lowest rank. Same levels of performance are scored the same. The last column indicates whether country rankings are consistent with VOC predictions about patterns of pharmaceutical innovation. A plus sign (+) indicates support for the VOC model;

⁴ Britain, Canada, France, Germany, Italy, Japan, and United States.

⁵ In this scale, proposed by Finkelstein and Bittinger (1993, 3), the number of global and innovative products is weighted to offset the effect of domestic market size. The weighting factors are: France, 4.1; Germany, 3.7; UK, 8.7; and US, 1.

a question mark (?) indicates ambiguous findings; a minus sign (–) indicates contradiction of the VOC model.

Figure 15. Summary of Pharmaceutical Industry Performance in France, Germany, Britain and the United States.

	France	Germany	Britain	US	VOC
<i>Industry interest</i>					
profitability	1	2	4	3	+
production	4	1	3	2	?
export ⁶	2	3	4	1	?
foreign penetration	1	2	3	4	–
score	8	8	14	10	
<i>Government interest</i>					
employment	3	4	2	1	+
trade balance	2	4	3	1	?
drug bill	1	3	4	2	n/a ⁷
R&D spending ⁸	2	1	4	3	+
successful innovation ⁹	1	2.5	4	2.5	+
score	9	14.5	17	9.5	

Several of the indicators of industrial performance support the VOC model as applied to the pharmaceutical industry. Drug companies in the liberal market economies (Britain and US) are more profitable than those in the coordinated market economies (Germany and France). As predicted, the US and Britain appear to invest more in research and development than Germany and France, and that investment appears, on the whole, to generate more useful innovations. Finally, the higher level of employment in the pharmaceutical industries in France and Germany is consistent with more rigid labor market regulations that

⁶ This refers to per-capita drug exports, not export intensity, since the measure of export intensity rewards lower levels of domestic sales with a higher score. This does not correctly reflect the emphasis of an industry-oriented performance evaluation.

⁷ The VOC model makes no predictions about the relative level of consumption in the different countries.

⁸ This refers to per capita R&D spending. This I take to be the fundamental government interest. In any case, this ranking is quite similar to rankings for R&D employment and for R&D investment as a percentage of revenue.

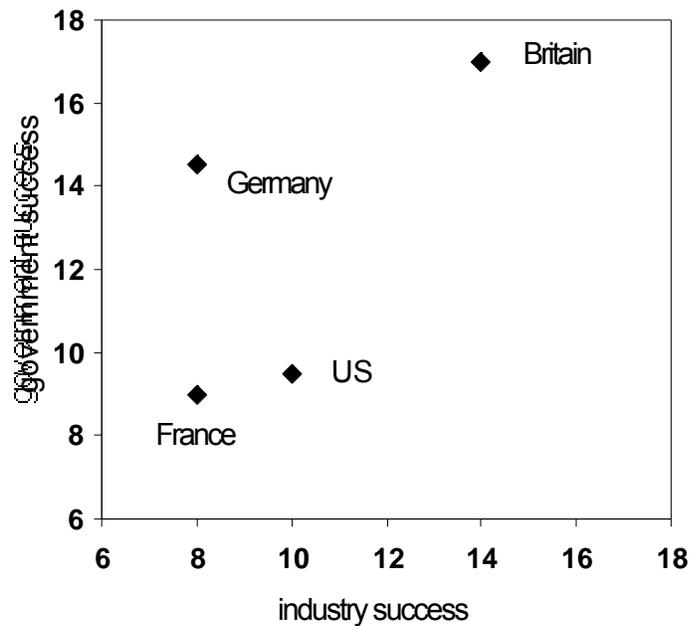
⁹ This refers to the Finkelstein/Bittinger weighted scale of innovative and global drugs. Because what matters from the perspective of the government are only drugs that are effective, I do not include a ranking of new drug substances.

discourage labor mobility and may in turn hurt innovation and profitability. The higher employment and lower profitability of pharmaceutical industries in coordinated market economies follows directly from the configuration of labor and capital markets in these countries. More rigid labor market discourage work-force reduction. The predominance of bank lending and institutional ownership reduces pressures for profitability.

But there are also several indicators for which the VOC model does not appear to explain observed patterns of national performance. These relate primarily to the kind and market experience of actual pharmaceutical products. In production, trade, and trade balance indicators, the liberal market economies show uneven performance. Whereas Britain performs well, the United States performs poorly. The coordinated market economies, by contrast, perform surprisingly well. France enjoys the largest per capita production of the four. Germany enjoys the strongest trade balance of the four. For one indicator, foreign penetration, we find outcomes that appear to contradict expectations based on the VOC model. British and US firms have moved a lot of their production to other countries. British firms appear to have concentrated in the US. But US firms have also moved production to a surprising extent into continental Europe. Indeed the negative trade balance of the United States in pharmaceuticals is due to an important degree to this trend towards overseas production. From the VOC perspective, this trend appears unusual, since the United States should offer comparative advantages in drug development. I will argue below that these apparent contradictions of the VOC approach can readily be explained by incorporating demand institutions, especially product market regulation, into the VOC analysis.

We can also aggregate the performance indicators in order to compare broad national experiences of pharmaceutical production. By tallying the rankings in Figure 15 above, we can construct an admittedly blunt set of indicators of industry and government perceptions of success. Plotting cumulative rankings for each country, we depict graphically the success of governments and of industry in achieving their productivity objectives. See Figure 16 below. It should be noted that the plotted points represent only relative and not absolute values, and that they are highly skewed, since we are considering some of the most successful countries in terms of pharmaceutical production. With these caveats, however, the findings are interesting in two respects.

Figure 16. Plot of government and industry indicators of success.



First, they offer an criticism of the French and US pharmaceutical industries. Not only has the French industry failed to excel by reasonable industrial standards of performance, it has also failed to excel by reasonable government standards of performance. Perhaps more surprising is the performance of the US pharmaceutical industry, which surpasses the French by only a small margin. Measured according to government criteria, US performance is nearly as poor as French performance. The British pharmaceutical industry is the overwhelming success story. Not only does it score well from industry's perspective, it also scores extremely well from the government's perspective. Germany, finally, is a mitigated success. Seen from the government's perspective, pharmaceutical performance is good, if not as good as in Britain. But from industry's perspective, performance is poor.

Second, we see that pharmaceutical producers in liberal market economies (Britain and United States) do perform better than producers in coordinated market economies (Germany and France) when we look at performance from the perspective of industry. This is an important confirmation of the VOC hypothesis. Seen from the government's perspective, however, the results are again ambiguous. Germany and Britain sit on opposite sides of all VOC classifications, yet both do far better than the United States and France in satisfying government goals for the pharmaceutical industry. This finding is not surprising in the case of Germany, where the coordinated market has built-in rules that help to protect broader social interests. But the finding is surprising for

Britain, where the liberal market economy might be expected to undermine collective social goals. France offers another surprise, as its tradition of state intervention in industry has done little to help achieve the government's performance goals. Finally, in the United States, where the Food and Drug Administration has exerted extraordinary regulatory control over product quality in the pharmaceutical industry, government goals have similarly not been served.

Before proceeding to an explanation of these differences, I want to address a common set of arguments about industrial success in the pharmaceutical sector that focuses on drug testing and intellectual property. Given the strong differences in performance of pharmaceuticals in France, Germany, Britain, and the United States, we see a surprising uniformity in the regulation of testing and intellectual property.

Figure 17. Average effective patent life of 100 main drugs by country.

	1980	1988
France	13.6	10.2
Germany	11.8	10.5
Britain	13.1	11.9
US	15.1	10.7

Source: Tarabusi and Vickery 1996, 84.

First, and despite extended debates on national differences in the treatment of intellectual property (Tarabusi 1996, 129), all four countries now endorse a 20 year patent protection for new drugs. For France and Germany this standard was established by the European Patent Convention, which created a unified patent system in 1972 (OECD 1985, 44). In Britain, patent life was extended in 1986 from 16 to 20 years (Earl-Slater and Bradley 1996, 397). Moreover, the drug evaluation process, which takes longer today than in the past, appears nonetheless to take roughly the same amount of time in each of the countries. See Figure 17 above. France has the shortest effective patent life, at just over ten years, while Britain has the longest, at just under twelve years. Some countries have offered the possibility of patent extension. In the United States, the Waxman-Hatch Act of 1984 has permitted patent extensions for up to 5 years in case of regulatory delays so as to provide a total effective protection of up to 14 years (Scherer 1993, 100). France legislated a similar provision for 5 year patent extensions in 1991 (Hancher 1992, 392). It remains unclear, however, what an optimal patent life might be for pharmaceutical products, and in any case the average effective patent life appears not to vary strongly among the four countries in this study.

Second, the process of clinical testing has been nearly standardized across these countries. In Europe, the results of clinical tests have been accepted by member countries since 1977 (OECD 1985, 39). And despite considerable debate about the time required to apply for marketing licenses, a

recent study by the European Commission (1997, 31) shows that license applications in France, Germany, Britain, and the US all required an average of approximately 2 years. Finally, standards of drug manufacturing across these countries are, while not identical, very similar. France, Germany, and Britain rely on World Health Organization (WHO) manufacturing guidelines for drugs. The United States relies on FDA manufacturing guidelines, which are essentially the same as the WHO guidelines (Balance et al. 1992, 142).

If the regulations that govern testing and intellectual property are similar in each of the countries studied, strong differences persist in regulation that focuses on the qualities of the products themselves and the markets into which they are sold. Despite ongoing efforts at the European level to standardize these divergent product market regulations,¹⁰ nonetheless "...existing member state regulations and concerns regarding the safety and efficacy of pharmaceuticals have consistently thwarted legislation focused on removing barriers in the pharmaceutical market" (Smith 1995, 471-472). In the following section I explore the historical development of distinctive national product market regulations governing pharmaceutical products and the impact that these regulations have had on production strategies.

III. Government Regulation of Drug Quality and Price

Pharmaceutical product regulation in the advanced industrial countries has proceeded in two waves. The first wave, stimulated primarily by the Thalidomide (Contergan) tragedies, began in the 1960s and focused on drug safety, efficacy, and testing. The second wave of regulation emerged mainly in the late 1980s around pharmaceutical pricing and the rapidly increasing cost of drugs. The way in which different countries have addressed these issues has depended in turn upon national traditions of competition and business regulation, as well as on the organization and political strength of pharmaceutical producers and drug consumers. These distinctive national political and institutional traditions have shaped the way in which domestic markets for drugs have been regulated in each country. Differences in market regulation have, in turn, had an impact on the product strategies of domestic producers.

Drug safety and efficacy regulation has in most countries proceeded in two steps. The first step has generally required all drug producers to register their products with an administering authority. The second step has required a positive marketing license for product sale. By the early 1970s most countries had moved from passive drug registration scheme to mandatory drug licensing through which all new drugs were required to pass. Within this general trend, however, there has been a great deal of room for national variation in treatment. In France, safety and efficacy oversight by the government has long depended upon the expertise and information of industry. The result has been a system of industry

¹⁰ The European Union has endorsed three approaches to pharmaceutical certification: existing national certification, a new centralized European certification, and a decentralized multi-state approach that requires that producers gain certification in at least two member states. Most manufacturers continue to use existing national certification procedures (Juès 1998, 73).

capture that has granted the French pharmaceutical industry a broad leeway to determine the level of efficacy of their products. At the opposite extreme, the United States in the 1962 Keffauver-Harris amendments to the Food and Drug Act imposed extremely stringent safety, quality, and efficacy requirements on drug manufacturers, and they have shown extraordinary resistance to industry lobbying. They have created the most stringent drug standards of any country.

If France and the United States sit at the extremes of drug quality enforcement, Germany and Britain have taken up an intermediate position. Both were relatively late to regulate drug safety and efficacy, and both have relied heavily on industry to police itself. In Britain, safety measures were imposed by the 1968 Medicine Act, as well as through an industry code of conduct negotiated between the Association of the British Pharmaceutical Industry (ABPI) and the Health Ministry. The German pharmaceutical industry has been politically powerful and has managed to create for itself a favorable regulatory climate. Germany first required positive drug certification in 1976, but administrative oversight is less exacting than in the United States and mandatory efficacy thresholds are correspondingly lower.

A second wave of pharmaceutical regulation has focused on reducing the overall drug bill in each country. For some countries, especially Germany and the United States, which have traditionally had no drug price regulation, this represents an entirely new demand condition for industry. For France and Britain, recent reforms come in the wake of a long tradition of price regulation that has shaped pharmaceutical demand for most of the postwar period. From the Varieties of Capitalism perspective this pairing looks unfamiliar, grouping as it does France with Britain on one side and Germany with the United States on the other. However, it follows directly from the organization of health care in the two countries. In France and Britain, the government is in effect a drug monopsonist. In Germany and even more in the United States, a plurality of private health insurance companies share the national drug bill.

Two broad strategies have been adopted for restraining the domestic cost of pharmaceuticals. The first focuses on restraining the price level of individual drugs. In this approach, pharmaceutical firms are seen as monopoly producers driven by profit concerns toward higher pricing. The second strategy for reducing the domestic cost of pharmaceuticals has focused on lowering overall demand for drugs in the health marketplace. This approach includes incentives for consumers to purchase fewer drugs, incentives for doctors to prescribe fewer drugs, and a limitation on the kinds of drugs that can be reimbursed through health insurance. Each of the countries in this study has resorted to some combination of these strategies. The historical trend of per capita spending on pharmaceutical products (see Figure 8 on page 13) shows that Britain has consistently enjoyed the greatest purchasing restraint. The French experience shows that price controls alone may fail to restrain overall domestic *per capita* drug spending.

France and Britain represent cases in which price regulation by the government has been intensive for most of the postwar period. In Britain, however, industry has enjoyed a strong bargaining position in price-setting

negotiations, and the government has acceded to high levels of return on capital in exchange for a combination of export emphasis and a moderate domestic drug bill. Largely as a consequence of this approach, British pharmaceutical firms are among the most profitable in the world. In France, by contrast, pharmaceutical producers have exercised little control over drug pricing. This had kept pharmaceutical profits low. It has also pushed French producers to emphasize a strategy of low cost production, low innovation, and high volume sales. By contrast, Germany and the United States represent cases of minimal government intervention in pharmaceutical price setting, at least up until the past decade.

National approaches to pharmaceutical product market regulation have emerged at the intersection of distinctive national institutions of production (liberal versus coordinated) and of distinctive institutions of consumption (single buyer versus multiple buyer). See Figure 18 below. National production institutions have a strong impact on national approaches to the regulation of drug quality. In coordinated economies, product quality is assumed to emerge from the highly regulated institutions of production. Thus France and Germany have not enacted very strict drug efficacy requirements. But national consumption institutions also play a central role. In countries with multiple purchasers, such as the United States and Germany, the government faces little pressure to enact strict price regulation. Taking the impact of production and consumption institutions together, we observe in France for example a strategy of strict price regulation combined with industry dominance in setting drug quality. In the United States, by contrast, we observe a strategy of strict quality regulation combined with a liberal set of price provisions.

		<i>consumption</i>	
		many buyers	single buyer
<i>production</i>	liberal	US (quality regulation)	Britain (regulation via negotiation)
	coordinated	Germany (regulatory laxity)	France (price regulation)

Figure 18. National institutions of drug production and consumption, and the resulting regulatory strategy (in parentheses).

Interestingly, the deployment of these regulatory strategies has often led to unexpected or contradictory outcomes. France's strict price regulations, for example, have caused industry to pursue a high-volume, low-margin sales strategy that has generated an extremely high per capita drug bill. In the United States, stringent product efficacy requirements had the unintended effect of driving many producers out of the country in order to compete in less regulated foreign markets. Pharmaceutical companies have proved particularly savvy in locating production so as to take advantage of differences in national regulatory approaches (Braithwaite 1993, 16).

In Germany, where the institutions of the coordinated market economy confront multiple demand-side actors, pharmaceutical product regulation has tended to be lax. The assumption is that a skilled labor force and long-term capital create their own pressures towards quality production. Moreover, Germany's multiple medical insurers (*Kassen*) have not until recently been able to coordinate their efforts in order to achieve price restraint. In Britain, by contrast, the combination of a liberal production regime and a unified buyer has created concern about both quality and price. The result has been a set of unusually-broad negotiations among pharmaceutical producers and the government that has generated a regulatory strategy that meets the goals of both.

This account of national regulatory traditions is of course stylized. Each country has a distinctive history and regulatory tradition that has conditioned its response to the dual threats of drug safety and drug price. In the remainder of this section I lay out in more detail the historical evolution of quality and price regulation of the pharmaceutical industry in these countries. Each country description presents first safety and efficacy regulation, then price regulation.

Germany: Regulatory Laxity

Pharmaceutical regulation in Germany has intervened in only a minimal way to set safety and efficacy requirements for drugs. Regulatory intervention began in 1961 in response to the Contergan (Thalidomide) tragedies. The first Drug Law (Arzneimittelgesetz, or AMG) of 1961 required only that all drugs in circulation be registered. This weak requirement was reinforced in May 1976 by a new AMG, instigated by the Social Democratic-Liberal Democratic coalition, that imposed a system of mandatory certification for all drugs (Borchert 1983, 195). All drugs had to be certified by the Bundesgesundheitsamt (BGA) in Berlin, not merely registered as under the previous law, although companies were given until 1990 to have all of their drugs registered. The staff and funding of the BGA were increased to take on the extra responsibility; staff grew from 116 to 138, funding grew by 22m DM. The new AMG also called for mandatory labeling of drugs (including instructions for use and side-effects), restrictions on drug advertising, and the requirement that patients give consent to all clinical drug tests. Furthermore, the law imposed a strict standard of product liability on drug companies, and required that they purchase liability insurance from a private insurer of their choice (Arzneimittelrecht 1976, 147). Insurers were grouped into

the Pharma-Pool (Jaeger and Kaukewitsch 1998, 9). Section 84 of the 1976 AMG is the first case in which strict product liability was applied in Germany. But damages are limited to 500,000 DM for single cases and to a total of 200 million DM for total damages resulting from a single drug (Rambow 1977, 163). Germany has resisted a formal system for reporting the harm caused by drugs (*Test* 1983, 2).

The new AMG, which remains the foundation of drug safety in Germany, represented a clear victory of the SPD, which favored a regulatory strategy based on administrative regulation. The CDU had sided with the peak employers' association (BDA) in favoring industry self-regulation. Instead of government certification, they had proposed a collaboration between drug manufacturers and the medical profession to establish a system of drug labeling that would help to increase market transparency. The SPD position also did not reflect the view of trade unions, which, as expressed by the peak German trade union association (DGB), favored a collaboration among drug companies, doctors, and insurers to evaluate the price-performance, quality and usefulness of drugs and to set standards for how that information should be included on the drug packaging (Bruck 1974, 136-139). One impact of the regulatory solution, however, was to increase the overall quality and usefulness of drugs in Germany, and the pharmaceutical industry appears to have felt that this would improve the marketability of their drugs overseas (Schatz 1983, 386). Moreover, as the registration requirement did not have to be met for all drugs until 1990, the cost of transition was spread over a period of ten years.

Germany's relatively late move to regulate drug quality was mirrored by a late effort at restraining drug costs. Until 1989, German pharmaceutical prices as well as pharmaceutical demand conditions were largely unregulated. Since the mid-1970s, the German government had attempted to restrain the cost of pharmaceuticals. Germany's 1977 Federal Law on Cost Containment established a Concerted Action Committee (KAG) to set spending ceilings on the Sickness Funds (*Kassen*) for drugs paid for by the National Health Insurance Fund (GKV), and granted a joint committee of doctors and *Kassen* the right to make a negative list of drugs to be excluded from reimbursement (Hancher 1989, 90). Moreover, the 1976 Medicines Act created a Transparency Commission of industry, *Kassen*, and health professional representatives, to publish 'transparency lists' comparing drugs based on safety, efficacy, and treatment cost. Questions of efficacy, however, fell exclusively under the 1976 law to the Health Department (Bundesgesundheitsamt). Thus industry was able to object successfully to the use of many comparative criteria by the Transparency Commission. In 1985 the Supreme Court found that publishing a transparency list infringed on the right of entrepreneurial activity, and the negative list idea was set aside. Only an amendment to the Medicines Act of 1986 rendered the use of a negative list legal (Hancher 1989, 90-91).

In the wake of this change, and under growing cost pressure, the Health Care Reform Act of 1988 put in place a combination of four separate regulatory mechanisms to manage the drug bill in Germany. A first provision, reference pricing, uses drug reimbursement levels to control the level of drug pricing. Three

other mechanisms focus not on price but instead on restraining the volume of demand for drugs. A black list eliminates certain drugs altogether from reimbursement. Indicative volume controls set target spending levels for doctors. Mandatory prescription co-payments also give consuming patients an incentive to use fewer drugs. Together these four mechanisms constitute a formidable new regulatory nexus that may seem surprising in an age of deregulation and in a country for which market competition has been a dominant ideology.

The first mechanism, reference pricing (*Festbeträge*), sets a single level of reimbursement for all drugs that fall within common pools defined in terms of specific common therapeutic qualities. These price levels are set by the organization of doctors and medical insurers after discussion with industry and pharmacists. Producers are not bound to this price, but patients are required to pay any amount by which drugs exceed the reference price for their pool. In practice manufacturers rarely exceed these reference prices. Because these government price levels have encouraged oligopolistic collusion, they have worked to eliminate price competition below the reference price (Danzon 1997, 19-20). Generic drug sales in Germany, for example, remain the lowest of all of the countries studied. Only 30 percent of reimbursed drugs fall within the reference pricing system, with the result that some firms have simply stopped developing new drugs in these therapeutic categories (Finkelstein and Bittinger 1993, 18). To remedy this problem, the government in 1993 imposed a price freeze on all drugs not covered by reference pricing, and set the frozen level at 95% of the March 1992 level (Jaeger and Kaukewitsch 1998, 11). Thus all prescription drugs were covered either by reference pricing or by the price freeze. By 1997, 64 percent of all prescription drugs were covered by reference pricing.

In addition to price controls, three other regulatory mechanisms have worked to hold down demand for drugs. The first of these demand-management efforts was a negative, or black, list that eliminates certain drugs thought to be of "questionable therapeutic value" from reimbursement. This list is drawn up by the Ministry of Labor (Jaeger and Kaukewitsch 1998, 10). About 2,500 drugs have been blacklisted in this way. But this is a relatively small part of the total market, and leaves an additional 13,000 kinds of drugs that are still available for reimbursement (Finkelstein and Bittinger 1993, 17). For the pharmaceutical industry this black list has the effect of concentrating competition in core therapeutic categories that have in any case been the focus of traditional German success.

The 1988 Health Care Reform Act also imposed a set of volume controls (*Richtgrößen*) on physicians that set a recommended drug budget for different categories of medical practice. The system is monitored by physician associations. Doctors who exceed their recommended level facing an audit (Wertheimer et al. 1996, 166). To compliment these volume controls, intended to reduce physician demand, Germany also imposed in 1994 a co-payment fee intended to make patients more conscious of the cost of drugs they consumed. The co-payment was set first at 3.5 DM or 7 DM, depending on the price of the drug. In 1997 the co-payment was raised to 9 DM, 11 DM, or 13 DM, depending

again on the expense of the drug. Pharmacists strongly opposed this measure, and indeed experienced a 10 percent drop in profit when the co-payment system was put in place (Jaeger and Kaukewitsch 1998, 11).

What impact have these regulations had on the pharmaceutical industry? The final effect will be unclear for some time, but initially at least they have received support from industry for the benefits that they convey. The reference pricing system has helped the industry to create oligopolistic prices that have, among other things, repressed the market for generic drugs (Danzon 1997, 19-20). It has also forestalled a significant threat from inexpensive French drugs. The black list helps to set a high standard of competition, by eliminating reimbursement for more frivolous kinds of drugs, even if they have passed regulatory safety and efficacy requirements.

The system of volume controls for doctors also represents a mild victory for the drug industry. First, it emphasizes demand rather than price restraint. Second, the burden of restraint falls on the medical profession rather than on the pharmaceutical industry itself. Moreover, by forcing doctors, who are arguably most capable of deciding rationally about drug consumption, to make hard decisions about where limited drug spending must go, the regulation creates the conditions for a strong competition focused on quality and usefulness. In any case, the impact of domestic regulations on industry in Germany is likely to be less than in other countries, as only 37 percent of sales serve the domestic market (Finkelstein and Bittinger 1993, 18).

Britain: Regulation via Negotiation

Drug quality regulation in Britain is relatively rigorous, although British drug reviews tend to emphasize safety more than efficiency. Basic safety and efficacy requirements were set first by the 1969 and 1971 British Medicines Acts. As in other European countries, Britain requires that drugs receive a market license certifying their safety, efficacy and quality (Earl-Slater 1996, 396). These evaluations are sub-contracted to expert committees. Britain has been more accepting of foreign trials than have other countries (Grabowski 1981, 9). But Britain also relies on export and research incentives to induce pharmaceutical companies to self-police the safety of their products. And it relies more heavily than other countries on a post-marketing evaluation of how drugs are performing in everyday use (Tarabusi 1993, 129).

Most importantly, the way in which pharmaceutical pricing is set in Britain creates incentives to pursue safe and innovative drugs. Britain, like France, has a long tradition of government regulation of pharmaceutical pricing. This high level of regulation is perhaps surprising in the VOC framework, but it reflects the reality that the British National Health Service pays for 90 percent of all drugs purchased, the highest government share of any of the countries studied. Since 1958, British pharmaceutical manufacturers have negotiated directly with the government in order to set the sales price of drugs. But the British system does not focus either on individual product prices, nor on company revenues, but instead on return on capital. Britain is the only country in Europe to focus controls on pharmaceutical profits (Commission 1997, 70). This approach requires an

extremely high level of government oversight, and intervention in areas of basic producer strategy. But it offers the advantage of permitting British firms to pursue more risky products that could also be more lucrative (Danzon 1997, 53). More recently, Britain has also begun regulating the demand conditions of pharmaceutical production.

The history of postwar British pharmaceutical regulation can usefully be divided into two periods. From 1958 to 1978, the pharmaceutical industry negotiated with the government over voluntary price restraint. Until 1960, negotiations were carried out by the Association of British Pharmaceutical Industries (ABPI). After that the government negotiated directly with many of the larger producers. This approach was called the Voluntary Price Regulation Scheme (VPRS). By 1969 prices were based explicitly on return on capital for drugs purchased by the National Health Service (Sargent 1985, 112-117)

A second period, beginning in 1977, was marked by the end of voluntary negotiations. The election of the Labour Party in 1974 carried with it the threat of nationalization, which put the pharmaceutical industry in a difficult negotiating position. The shift was made decisive when the 1977 Health Act granted the Secretary of State for Social Services the right to impose drug prices (Greenwood 1991, 340). While Britain has never fallen back on this provision, the explicit right to intervene changed the nature of government-industry negotiations. Indeed, in recognition of the non-voluntary character of later agreements, the new price setting scheme was renamed the Pharmaceutical Price Regulation Scheme (PPRS). The PPRS lies at the core of British drug pricing today.

Under the PPRS, companies are compensated for higher investments and export success (Sargent 1985, 120-121). Agreements are negotiated annually between the Medicines Control Agency (MCA) of the Department of Health and individual manufacturers (Earl-Slater 1996, 398). The price that the National Health Service (NHS) pays for drug products is set in these negotiations, based on the return on capital employed (ROCE) for those drugs that the NHS buys. (OECD 1985, p 40). In the 1993-98 period, allowed ROCE was between 17 and 21%. These levels are not guaranteed, but producers are permitted to increase drug prices in order to achieve their negotiated range (Earl-Slater 1996, 399). In the case of excessive profits, producers are required to offer rebates directly to the government (Sargent 1985, 122). What level of ROCE a producer may claim depends in turn upon the level of their investment in research and development, and upon the export success of their products. This means that the profit of any British pharmaceutical company is determined almost entirely by their innovation and upon their level of export.

Apart from controls on the profit of pharmaceutical manufacturers, Britain has also implemented four projects to lower the demand for pharmaceuticals. Many of these are similar to German efforts to keep down demand for drugs. First, in 1985, the British government published a black list of 600 drugs not to be prescribed by NHS doctors. Beginning in 1993 the list was extended (Earl-Slater 1996, 400-401). Second, since April 1991, doctors have been given indicative drug budgets. Prescription levels of different categories of doctors are compared

through the nation-wide computerized Prescribing Analysis and Costs (PACT) system. As in Germany, doctors who over-prescribe are audited, in Britain by the Health Commissioner. Starting in 1991, in an effort to introduce market mechanism among prescribing doctors, some general practitioners have become “fund holders,” able to make their own decisions about dispensing a pool of funds for their patients. Third, Britain has long imposed patient co-payments on pharmaceutical prescriptions. These have been increased from 0.45 pounds in 1979 to 5.50 pounds in 1996. However 50 percent of the population is exempted from these fines, accounting for 80 percent of drug use (Earl-Slater, 1996, 403-405).

Finally, beginning under the Labour government of 1974-1979, a 14% ceiling was set on promotional activities by the drug industry. This level dropped to 9% in 1983-1984. About half of this promotional spending goes to paying medical representatives who visit individual practitioners to push specific products (Greenwood 1991, 344-345). Indeed the high percentage of sales spent on R&D in Britain is due in part to the relatively low promotional spending mandated by national regulations (Finkelstein 1993, 5). But because the government has kept permissible profit margins relatively high (between 18 and 21 percent of revenue), and because these profit margins are not related to domestic sales levels, the drug industry has accepted lower promotional spending.

Given the profound influence of Britain’s Pharmaceutical Price Regulation Scheme (PPRS) on industry profit, innovation, and sales, it seems unlikely that British pharmaceutical success can be attributed solely to the benefits of a liberal market economy. Contrary to the notion of a liberal market economy, industry and the government have long negotiated a set of industry targets that were mutually acceptable. This does not mean that the VOC model was irrelevant. The goals of industry — high profit and high investment in R&D — were exactly those envisioned by the VOC model. Yet the means by which they were achieved suggests that industry success may depend as much on the configuration of consumption as on the configuration of production.

France: Price Regulation

The French regulatory approach to the pharmaceutical industry is unusual in that it emerged directly from the regulation of apothecaries (Plat 1970, 7). It has been characterized by a long history of industry self-regulation of product quality combined with government oversight of product pricing. Drug safety and efficacy evaluations have, until very recently, been carried out by industry experts paid for by pharmaceutical companies and employing data from the applying firm. Patricia Danzon estimates that only half of all drugs sold in France would meet US Food and Drug Administration efficacy requirements (Danzon 1997, 44). Drug pricing, by contrast, has been the focus of intensive government intervention since the 1950s.

Drug quality regulation in France began under the Vichy government in 1942, with the creation of the Service Central de la Pharmacie. Its primary emphasis was not on drug safety but instead on ensuring the quality and novelty

of drug production, much of which occurred at individual pharmacies (Hancher 1990, 107; Buisson and Giorgi 1997, 20). Drug producers applied for a visa that was granted based on the recommendation of experts from the industry. The visa required that any drug be both useful, and also new (Brudon and Viala 1995, 215). This novelty requirement permitted the visa system to function as a kind of patent system before patents were applied to drugs. Under the visa system, newly registered drugs were granted a 6 year window of monopoly sales. In 1959 a special patent was introduced for medicines and the novelty requirement was removed from the visa application process (Buisson and Giorgi 1997, 19). The visa system also required a manufacturing authorization (*autorization de débit*) from the French pharmaceutical inspectorate. This requirement effectively blocked the import of finished drugs into France (Hancher 1990, 115).

In the wake of the Thalidomide disaster, and under the guidance of EEC Pharmaceutical Directive 65/65, France enacted the ordinance of 1967 which replaced the visa system with a new marketing authorization (*autorization de mise sur le marché*, or AMM) and drug test protocols. The system was overseen by a new Commission on Marketing Authorizations (*Commission d'autorisation de mise sur le marché des médicaments*) with 28 members. These were primarily doctors, but also included two representatives from industry and one consumer representative (Hancher 1990, 124-125). As under the visa system, the expert remained central to the new approach. Experts were paid by the company requesting an evaluation. Moreover all information about the drug came from the company itself (Hancher 1990, 126-127).

In 1977 the Commission of Marketing Authorizations was replaced again by the *Direction de la pharmacie et du médicament* (DPHM) of the Health Ministry (Buisson and Giorgi 1997, 20-21). This new centralized body was responsible for all aspects of drug regulation, but had a staff of only 30! Hence, as before, drug applications were assessed out of house by experts paid by the applying firm (Hancher 1990, 124). In 1978, France imposed a set of guidelines for good manufacturing practice (*bonnes pratiques de fabrication*, or BPF) that drew on a common European standard (Buisson and Giorgi 1997, 26). In addition to the formal approval process for drugs, the Ministry of family health in 1976 created a *Commission technique de pharmaco-vigilance*. Its mission was to collect and compile information about drug-related accidents. Its members were eminent professors. Consumer groups and the *Commission technique de pharmaco-vigilance* worked together in the *Liaison avec les organisations de consommateurs* (Pujol 1978).

In 4 January 1993, the DPHM was restructured and renamed the *Agence française du médicament* (AFM). The new agency was given responsibility for setting safety standards, for setting manufacturing policy, for deciding on product information and risk, and for assisting industry to further research and innovation. Unlike the previous DPHM, the AFM has its own internal experts that evaluate industry applications for AMM (*Agrément de Mise sur le Marché*). The AFM sets the labeling and instructions for new drugs. The AFM also sets the medical classification of the drug, i.e., prescription of over-the-counter (Buisson and Giorgi 1997, 20-21). Like the US FDA, the *Agence Française du médicament*

enjoys a high level of insulation from political interference, although there is provision for an emergency procedure in case of a “serious menace to the public health” (Viala and Vion 1994, 246-248).

In the regulation of drug pricing, France combines the lowest prices for individual drugs with the highest per capita spending on drug purchases. This pattern has arisen from a set of regulatory policies that have effectively restrained drug prices but have been much less effective at holding down demand. Price regulation has been the primary means of restraining monopoly pricing in the drug industry for most of the postwar period. Only in the past ten years have French regulators acknowledged that these price restraints have had a negative impact on the French pharmaceutical industry, at least from the perspective of the government. First, they have failed to keep down the overall drug bill in France compared to other countries. Second, they have kept industry investment in research and development low. These are problems for the government but not necessarily for the pharmaceutical industry itself. Operating in what Hancher (1990, 229-230) has called a gilded cage, French drug producers have responded by focusing their production efforts on a strategy of low price and low innovation combined with high promotional spending.

Price fixing is a revered tradition of French product markets, dating back at least to the ordinances of 1945 (45-1483, 45-1484) which granted the government the right to intervene to set prices for any kind of product. Price setting in the pharmaceutical industry began in 1948 and can be usefully separated into four periods. Between 1948 and 1968, drug prices were set by the state based on a pricing framework (*cadre de prix*) calculated on a cost-plus basis from a combination of production costs and a pre-determined margin of profit (Hancher 1990, 76). In 1968, drug pricing fell under the dual control of the old pricing administration and the new *Commission de remboursement de la securite sociale* (the Coudrier Commission) created in 1967. While drug prices were still set by the state pricing administration, the new social security commission worked with them to determine reimbursement levels for prescription drugs, and to decide which drugs should be included on the reimbursement list (Hancher 1990, 92-3).

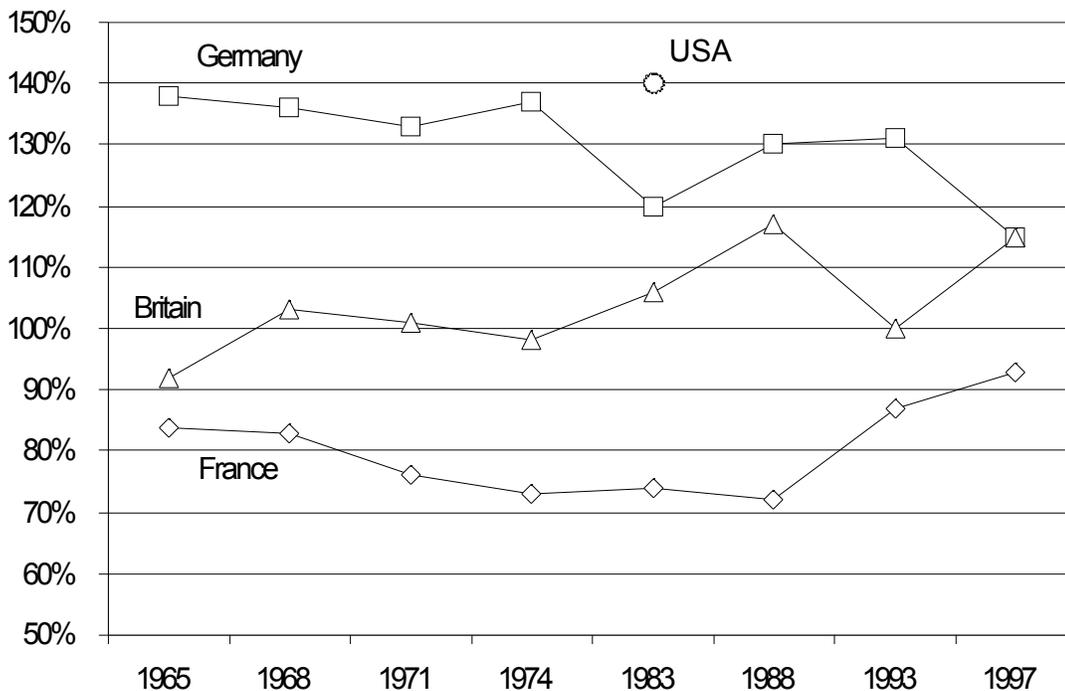
In 1980, drug prices for prescription drugs were liberalized. This meant in practice that drug prices would be determined entirely by reimbursement levels set by the Social Security code. In order to decide an appropriate reimbursement level a new *Commission de transparence*, created in 1980, evaluated price applications from drug producers. They assessed production costs and compared applicant drugs with others on the market (Juès 1998, 70). Under this system, a separate price was set by the government for each individual drug. The 1986 *Plan Seguin* to reduce the cost of health care included among its cost-cutting efforts a reduction in state reimbursement for drugs and a cap on drug price increases to about 1 percent per year.

Concerned that this approach reduced industry incentives to innovate, and in particular that it was leading French drug companies to create false-innovations in order to elude the cap on price increases for existing drugs, France created in 1994 a pricing system based on a so-called global envelope

(*enveloppe globale*). The idea, first proposed in 1991, allowed the state to negotiate with each pharmaceutical producer an upper and lower level for their expected sales level for the year. Any sales exceeding the target level would have to be offset by a lower unit price on drugs so that the overall cost to the government would remain the same. The goal was to give producers the freedom to set prices as they wished among their portfolio of products. So as not to impede major innovations, breakthrough drugs were treated separately under the old price-setting scheme (Finkelstein 1993, 12-3; Danzon 1997, 18-19). By mid-1995, 96 conventions had been signed under the *enveloppe globale* system, covering 81 percent of drug sales (Hofstetter 1996, 15).

While France's primary effort at reducing medical spending was focused on price control, it has also more recently attempted to create incentives on the demand side in order to keep down spending. Since 1980, drugs have been reimbursed under social security at different levels depending on effectiveness and need. Reimbursement is set at 100 percent for cases of severe sickness, 65 percent for regular drugs, and 35 percent for drugs with "modest therapeutic value" (Juès 1998, 77). Most patients, however, have a private insurance plan that covers the non-reimbursed cost of drugs. Only 10 percent of French patients are not covered in this way (Wertheimer 1996, 162-3). More recent efforts have focused on restraining doctor prescription levels. A 1990 *controle medicale* set non-binding, indicative levels for doctors in order to keep them from over-prescribing (Finkelstein 1993, 12). In January 1994 a new set of negotiated good medical practice guidelines has attempted to standardize prescription activities of doctors. (Wertheimer 1996, 162-3) The impact of the system, also voluntary, remains uncertain.

France has also acted to reduce the level of drug advertising. As in the other European countries, advertising to the public for drugs covered by social security is prohibited in France (Juès 1998, 70). Nearly 80 percent of promotional spending by French firms has therefore focused on informational visits to medical practitioners (SNIP 1996). As part of the 1994 framework agreement that implemented the global envelope pricing system, the peak association of the drug industry, SNIP, agreed to voluntary restraint on advertising spending in exchange for more liberal prices for innovative products ("L'Industrie pharmaceutique" 1995, 4; Danzon 1997, 18-19). French firms nonetheless spend almost 13 percent of revenue on advertising and marketing, compared to only about 7 percent on research and development (SNIP 1996).



Sources: EC 1997, p. 71; Faibis 1984, p. 22; Möbius et al. 1976, p. 75; SNIP.

Figure 19. Index of relative drug prices in France, Germany, and Britain, 1965-1997.

Peculiarities of the French pricing scheme have pushed companies to evade the effects of regulation. Two side-effects were particularly formative for the drug industry. First, research costs were fixed at 7%, so that in effect companies that did less research enjoyed higher profits. Because the prices of existing products were not systematically reviewed, producers commonly reintroduced existing drugs under new names in order to receive a higher price. Useful inexpensive drugs disappeared from the market and were replaced by a large number of copy drugs (Hancher 1990, 89-90). Alan Afuad (1993, 9-10) writes, "price controls contribute to an increase in drug expenditure...because research and development is re-oriented towards developing non-innovative new products with contemporary price tags to replace older drugs with low controlled prices." Second, because prices were calculated based on production costs, many French firms moved component production into their own subsidiary companies located in foreign countries. Through exclusive contracting with these subsidiaries, the firms could artificially elevate the prices of imported chemical components while extracting higher profits from their foreign firms (Faibis 1984, 23; Hancher 1990, 94).

French price restraints have indeed been effective at keeping down the unit cost of drugs. See Figure 20 above. French firms have adjusted by skimping on R&D and advertising their products heavily. The combination of ineffective and inexpensive drugs, pushed by a strong advertising campaign, has created a surge in consumer demand. This is why France combines the lowest unit drug prices with the highest per capita drug spending. Furthermore, these low prices, publicized by the government, have made French pharmaceutical firms quite successful in exporting conventional kinds of medicines. Low prices have made France a particularly strong exporter of antibiotics and vaccines, for example, especially to developing countries. In sum, a regulatory practice that has been a major failure from the perspective of the French government, has, by contrast, carved out a low-innovation business niche for French pharmaceutical manufacturers.

United States: Quality Regulation

Drug safety regulation in the United States has proceeded in two stages. A first stage, beginning with the Food and Drug Act of 1938, was characterized by a high degree of industry control over drug markets. A second period of strict government oversight, initiated under the 1962 Keffauver-Harris Drug Amendments, continues to characterize drug regulation today. The United States today is generally considered to impose the highest drug quality and efficacy standards of the advanced industrialized countries. After a decade of strong opposition to this policy, the pharmaceutical industry has come to accept the principle of strict regulatory oversight by the FDA as a source of comparative advantage for the US industry, as well as an impediment to foreign imports.

The FDA, created in 1906 in response to Upton Sinclair's fictional account of the Chicago meat packing industry in *The Jungle*, gained significant regulatory control over drugs only in 1938, following the death of 107 people from consuming an elixir of sulphanilamide (Davis 1997, 15). The 1938 Drug Act imposed drug labeling standards, or alternatively permitted drug companies to evade the labeling standards if they sold their drugs by prescription only. Under this early set of regulations, producers were required to register new drugs with the FDA, after which the FDA had ninety days in which to raise objections to commercializing the drug. In the absence of FDA notification, the company could proceed with marketing the drug. The process of drug testing was largely unregulated. Amendments to the Drug Act in 1951 instituted a mandatory prescription-only class of drugs (Bogner 1996, 76).

This move set the stage for an extraordinary consolidation of power by pharmaceutical manufacturers in the United States. The primary focus of this effort was on eliminating the generic drug industry, which amounted to nearly one third of the drug market in 1950. The new National Pharmaceutical Council (NPC), created 1954 by the large pharmaceutical manufacturers, proved so successful that generic sales fell to less than 5 percent by 1959. Their strategy involved co-opting pharmaceutical service providers, namely drug stores and doctors.

Drug stores in the United States, having received a boost during prohibition (as the only stores that could legally sell alcohol, and thanks to the soda fountain), had by the early 1950s become large and powerful retail chains (Mobley 1990). Lively competition among drug stores was exerting strong downward price pressure on pharmaceutical producers. Through intensive state-level lobbying, the NPC was able to block drug stores in most states from advertising prices for prescription drugs. In many states a standard mark-up was provided for drug stores, typically 33% of the wholesale price, which helped to reduce competition over drug prices (Bogner 1976, 77-78). Finally, and critically, the NPC succeeded in making it illegal for pharmacies to substitute generic drugs for branded prescriptions. They managed this by petitioning individual states' Boards of Pharmacy to change the legal definition of drug substitution (Hirsch 1975, 333).

The NPC launched a similarly effective campaign to promote branded drugs in the medical profession. In what appears to have been a *quid pro quo* agreement, the American Medical Association (AMA) shifted their support away from generic drugs and towards branded drugs in exchange for greater advertising revenues in journals published by the AMA (Bogner 1976, 77). The AMA-administered pharmacopoeia *Useful Drugs*, in which drugs were evaluated and categorized by generic name, was superseded by the *Physician's Desk Reference*, compiled from manufacturer data by the newly created Pharmaceutical Manufacturers Association (Pharma), created in 1958. The AMA began encouraging physicians to prescribe branded rather than generic drugs. Second, when the drug industry came under increased government scrutiny in the 1960s, the AMA argued *against* requiring a higher level of drug efficacy. As Paul Hirsch has written, "it is clear that the medical profession was effectively co-opted by the drug industry" (Hirsch 1975, 338-339).

Strict government oversight of pharmaceuticals, which began with the 1962 Kefauver-Harris amendments, arose largely as a backlash against this growing power of the drug industry. It also followed the revelation of birth defects caused by Thalidomide, a drug which the FDA had warned against but was at the time unable to block for experimentation. In 1960, Senator Kefauver charged the pharmaceutical industry with monopolistic exploitation of consumers (Schwartzman 1976, 325). The 1962 amendments required a positive approval from the FDA for a new drug to be marketed, and called on the FDA to establish good manufacturing practice (Edwards and Glenn Thomas 1983, 58-59). They set high standards not only for drug safety but also effectiveness. They also required a preliminary FDA approval before undertaking clinical testing (Grabowski 1981, 7).

This legislation fundamentally changed the industry. The cost of creating a new chemical entity (NCE) rose by a factor of 2 over the decade following its enactment (Grabowski et al. 1978, 157). Development times grew from 3-4 years on average for each NCE before 1962, to 7-10 years after that date (Grabowski 1981, 8). Moreover, a lag in US pharmaceutical performance in the 1970s was taken to indicate that the more stringent FDA approval process called for in the 1962 amendments had hurt innovation in pharmaceuticals (Grabowski et al.

1978, 137). Critics argued that the increased cost of innovation had pushed companies to lower their investments levels (Edwards and Glenn Thomas 1983, 66-67).

Subsequent congressional opposition to the increased power of the FDA was extremely vociferous. In the years 1969 and 1970 alone, Congressional hearings were held on 38 FDA decisions not to approve the marketing of specific drugs. Congress in other words was putting heavy pressure on the FDA to approve drugs (Edwards and Glenn Thomas 1983, 62), but the FDA was and remains insulated from such political pressures. Today, strict FDA oversight is seen as an important comparative advantage for US drug manufacturers. The standard of safety and efficacy set by the FDA remains unusually high by international standards. Japan's top-selling drug in 1986, for example, an anti-cancer agent called Krestin, has never been submitted for US approval in the understanding that it would not be likely to pass the FDA review (Reich 1990, 140). This means that drugs originating in the US market meet a particularly high standard of safety and efficacy and are strong competitors for foreign sales. It also means that many foreign drugs of questionable effectiveness are kept out of the US market.

But this high domestic standard of safety and efficacy, in conjunction with idiosyncratic drug licensing requirements in foreign countries, had the unexpected effect of encouraging US firms to move production overseas. Under the strict US standards, drugs could not be exported if they had not yet received FDA approval, even if they would be acceptable in the receiving country. US companies thus established foreign subsidiaries, operating under foreign safety and efficacy rules, to produce products for foreign consumption. In this way, the high safety and efficacy requirements of the United States exerted a strong pressure for globalization of company ownership, and a corresponding reduction in export of drugs produced in the United States. The US prohibition against exporting unlicensed drugs was rescinded in the 1986 Drug Export Amendment Act, but by that time the strategy of overseas production by US firms had been firmly established (Tarabusi and Vickery 1996, 101-102). This regulatory side-effect must be considered the primary reason for the continued low export emphasis of domestic drug producers.

In contrast to the strict treatment of drug quality, the United States has imposed by far the lowest level of regulatory control of drug pricing and demand. This is due primarily to the low level of government spending in the national drug bill. In 1996, 43 percent of the cost of drugs was paid by the US government, via Medicare, Medicaid, or through the Veterans Administration. Individual insurance companies pay slightly less, at 39 percent, with the remainder paid by consumers themselves (Wertheimer et al. 1996, 169). The most significant incursion into free pricing has been the 1990 Medicaid Prudent Pharmaceutical Purchasing Act (Pryor Bill, Public Law 101-508), which imposed a rebate on government purchases at least 5 percent below standard volume rebates offered by drug companies (Scherer 1993). The bill was imposed to permit the government to take advantage of rebates that drug companies were offering to large private insurance companies. One unexpected result has been to lower volume

discounts to all large purchasers in order to reduce the level of rebate to the government. Moreover, because the Veterans Administration itself has in the past benefited from large negotiated rebates, it is unclear whether the Pryor Bill has actually decreased the total government drug bill (Finkelstein and Bittinger 1993, 19).

Despite the Pryor Bill, the United States remains, viewed in terms of price, the most deregulated market for pharmaceutical products. The relatively low level of government participation in drug payment has accompanied relatively higher drug prices than in other European countries. In 1983, for example, a standard basket of drugs cost nearly twice as much in the United States as in France (See Figure 20 above). These high prices have helped to drive up pharmaceutical industry profits. In part because of the high cost of drugs, the Clinton administration has suggested that the government should take on the cost of pharmaceuticals for many elderly. This move, which would increase the government share of the drug burden significantly, would also be likely to create pressures for greater price regulation. The French example stands as a warning of the potential negative impact of pharmaceutical price regulations in the absence of more extensive negotiations between government and industry.

IV. Conclusions

From the Varieties of Capitalism literature, we have derived two general hypotheses about comparative national industrial performance in the pharmaceutical sector. First, because coordinated market economies such as Germany and France are oriented towards high quality but incremental innovation strategies, we should expect poor performance in the innovation-intensive drug sector. Second, because institutional setting confers comparative advantage in what is a highly globalized industry, we should expect to see greater trade success among the liberal market economies. We should also expect to see pharmaceutical producers moving production out of France and Germany and into Britain and the United States.

Evidence from the pharmaceutical sector offers strong confirmation of the first hypothesis, especially in areas of employment, profitability, and innovation. Coordinated market economies have promoted a high level of employment in the pharmaceutical industry. This is consistent with restrictive labor laws that increase the cost to employers of pursuing layoffs. Hence French and German pharmaceutical sectors account for a greater percentage of employment than do British and US sectors. Profitability in the drug sector in France and Germany has been significantly lower than in Britain and the United States. This finding is consistent both with rigid labor laws in coordinated market economies and with the availability of risk-accepting capital markets in liberal market economies. Innovation echoes national patterns of profitability. Consistent with the VOC model, France and Germany invest relatively little in new drug development compared to Britain and the United States. Thus in many important aspects of industry performance, experience in the pharmaceutical industry confirms the insights of the VOC model.

The second hypothesis generated from the VOC model, the expectation that liberal market economies should enjoy a comparative international advantage in the innovation-intensive pharmaceutical industry, finds less support in industry performance indicators. While Britain is the most successful drug exporter, as the VOC model predicts, France and Germany have also enjoyed strong export success. More surprisingly, the United States has not. The reasons for this export pattern have less to do with the organization of domestic production than with the regulation of domestic product markets. French firms have enjoyed strong exports because stringent government price regulation has made them price-competitive in low-technology areas of pharmaceutical production such as vaccines and antibiotics. US firms have shown weak export performance, primarily because they have decided to locate production for foreign markets in foreign countries. Even in Britain, where exports are expected to be high, pharmaceutical companies have been encouraged to export by means of drug pricing regulations that reward greater export intensity with higher prices.

Moreover, patterns of company ownership appear directly to contradict VOC expectations about comparative institutional advantage. The United States and Britain, which should enjoy the most salubrious production environment, engage in the most overseas production. France and Germany, which should have the greatest interest in moving product development and production to Britain and the United States, do not. Why? France and Germany may be restrained by strict labor market rules that keep French and German companies from firing locally and hiring globally. The high cost of moving thus makes an export strategy more attractive for these countries. The United States and Britain appear to have been driven by product market conditions to move production abroad. Britain's interest has primarily been to capture a share of the large US market. In the United States, however, stringent domestic efficacy requirements imposed by the 1962 Kefauver-Harris amendments pushed companies to set up overseas production sites. Although these restrictions have been eased, overseas production remains extremely high. The trend was aggravated by countries such as France, which until the early 1970s placed an effective ban on imported drugs, thereby encouraging foreign firms to buy domestic production sites. Finally, the high profit and equity level of British and US firms has undoubtedly made it easier for them to acquire foreign companies. In sum, patterns of ownership and export have been dictated by a combination of production and product market conditions that have interacted in often unexpected ways.

Given the importance of domestic product market regulations to industry strategy, what kinds of regulations are best? This research suggests that, as in production, a coordinated approach to product market regulation generates strong benefits both for industry and for society. Britain's Pharmaceutical Price Regulation Scheme offers a good example of coordinated regulation, in which industry and the government have come to a regulatory solution that respects the fundamental goals of both actors. France and the United States, by contrast, offer examples of uncoordinated product market regulation. In France, where the

state has imposed strict price restrictions, companies have responded by pursuing a high-volume, low quality product strategy that has had the unexpected result of pushing domestic drug consumption extremely high. In the United States, where the state has imposed strict efficacy restrictions, companies have responded by moving production for foreign markets overseas. In these cases, uncoordinated approaches to product market regulation have hurt performance both as it is perceived by the government *and* as it is perceived by industry. In Britain, where product market regulations have been negotiated, both the government and industry enjoy superior outcomes. This suggests that product market regulation does not take the form of a zero-sum trade-off between private benefits and public externalities. Instead, a coordinated approach to regulation appears to combine industrial and social benefits.

Beyond these theoretical points, three empirical findings from the pharmaceutical industry should be highlighted. First, the US pharmaceutical industry, measured across a broad range of industry performance indicators, ranks close to the bottom. It lags behind Germany in its social benefits and behind Britain both in social benefits and in industry-relevant performance indicators. Second, the pharmaceutical industry is a highly globalized industry that is also highly regulated, with different countries employing very different regulatory strategies. At least in this industry, global trade and ownership appears to be compatible with a very high level of domestic regulation. Indeed, a rapid increase in drug trade over the course of the 1990s accompanied a rapid increase in specialized, nationally distinctive drug pricing regulation. Finally, the strong export success of German pharmaceutical manufacturers, despite the innovation challenges posed by new technologies, suggests that viable strategies exist for coordinated market economies even in industries characterized by high risk and rapid innovation.

Reference List

1. L'industrie pharmaceutique. 1995. *Economie Géographie* 321-322, no. 1-2: 1-24.
2. World OTC Retailing. 1995. *Retail Monitor International* February: 133-45.
3. Abel-Smith, B., and P. Grandjeat. 1978. *Pharmaceutical Consumption: Trends in Expenditure, Main Measures Taken and Underlying Objectives of Public Intervention in this Field.*, Vol. 38. Public Policy Series. Brussels: Commission of the European Communities.
4. Afuad, Alan N. 1993. Public Policy and Pharmaceutical Innovation: A Literature Review and Critique. Sloan School of Management, Program on the Pharmaceutical Industry, Working Paper 14-96.
5. Albach, Horst. 1994. *Culture and Technical Innovation: A Cross-Cultural Analysis and Policy Recommendations*. Berlin: Walter de Gruyter.
6. Albert, Michel. 1993. *Capitalism Against Capitalism*. Translated by Paul Haviland. London: Whurr.
7. Ballance, Robert, János Pogány, and Helmut Forstner. 1992. *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy*. Hants: Edward Elgar Publishing.
8. Ballance, Robert H. 1996. Market and Industrial Structure. *Contested Ground: Public Purpose and Private Interest in the Regulation of Prescription Drugs*. Edited by P. Davis. New York: Oxford University Press.
9. Bogner, William C. 1996. *Drugs to Market: Creating Value and Advantage in the Pharmaceutical Industry*. Oxford: Pergamon.
10. Borchert, Günter. 1983. Arzneimittelgesetz und Verbraucherschutz. *Zeitschrift Für Rechtspolitik* 8: 194-96.
11. Braithwaite, John. 1993. Transnational Regulation of the Pharmaceutical Industry. *Annals of the AAPSS* 525: 12-30.
12. Bruck, Gerhard Wilhelm. 1974. *Perspektiven der Sozialpolitik : Synopse sozialpolitischer Vorstellung der Bundesregierung, SPD, FDP, CDU, CSU, DAG, des DGB und der Bundesvereinigung der Deutschen Arbeitgeberverbände*. Goettingen: Otto Schwartz.
13. Brudon, Jean, and Georges Viala. 1992. France. *International Pharmaceutical Services: The Drug Industry and Pharmacy Practice in Twenty-Three Major Countries of the World*. Edited by Richard N. Spivey, Albert I. Wertheimer, and T. Donald Rucker. New York: Pharmaceutical Products Press.
14. Buisson, Jean-Philippe, and Dominique Giorgi. 1997. *La Politique du médicament*. Paris: Montchrestien.
15. Burstall, M. L. 1985. *The Community's Pharmaceutical Industry*. Luxembourg: Commission of the EC.
16. Burstall, M. L., and B. G. Reuben. 1987. *The Cost of Non-Europe in the Pharmaceutical Industry*. London: Economists Advisory Group.
17. Casper, Steven, and Catherine Matraves. 1997. Corporate Governance and Firm Strategy in the Pharmaceutical Industry. Discussion Paper FS

- IV 97-20, Wissenschaftszentrum Berlin.
18. DAFSA, Eurostaf. 1989. *Les laboratoires pharmaceutiques*. Paris: Eurostaf DAFSA.
 19. Danzon, Patricia M. 1997. *Pharmaceutical Price Regulation: National Policies versus Global Interests*. Washington, DC: American Enterprise Institute Press.
 20. Davis, Peter. 1997. *Managing Medicines: Public Policy and Therapeutic Drugs*. Buckingham: Open University Press.
 21. Earl-Slater, Alan, and Colin Bradley. 1996. The Inexorable Rise in the UK NHS Drugs Bill: Recent Policies, Future Prospects. *Public Administration* 74: 393-411.
 22. Edwards, Charles C., and Lacy Glenn Thomas. 1983. *The Competitive Status of the U.S. Pharmaceutical Industry: The Influences of Technology in Determining International Industrial Competitive Advantage*. Washington, DC: National Academy Press.
 23. Elgar, Edward, Robert Ballance, János pogány, and Helmut Forstner. 1992. *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy*. Paris: UNIDO.
 24. Estevez-Abe, Margarita, Torben Iversen, and David Soskice. 1999. Social Protection and the Formation of Skills: A Reinterpretation of the Welfare State.
 25. European Commission. 1997. *Impact on Manufacturing: Pharmaceutical Products.*, Vol. 2. The Single Market Review. Luxembourg: European Communities.
Notes: Label: drugs
 26. F&C, Towers-Perrin. 1992. *L'industrie phramaceutique*. Paris: Syndicat national de l'industrie pharmaceutique.
 27. Faibis, Laurent. 1984. *Les laboratoires pharmaceutiques*. Paris: DAFSA Kompass.
 28. Finkelstein, Stan N., and Peter G. Bittinger. 1993. Price Controls and the Competitiveness of Pharmaceutical Firms: A Preliminary Look at the Experience of Five Countries. Sloan School of Management, Program on the Pharmaceutical Industry, Working Paper 8-93.
 29. Geddes, Andrew. 1991. Free Movement of Pharmaceuticals within the Community: The Remaining Barriers. *European Law Review* 16, no. 4: 295-306.
 30. Gholz, Eugene. 1999. Getting Subsidies Right: Government Support to High-Tech Industries. MIT Department of Political Science PhD Dissertation.
 31. Grabowski, Henry, and John Vernon. 1994. Innovation and Structural Change in Pharmaceuticals and Biotechnology. *Industrial and Corporate Change* 3, no. 2: 435-49.
 32. Grabowski, Henry G. 1981. Regulation and the International Diffusion of Pharmaceuticals. *The International Supply of Medicines: Implications of U.S. Regulatory Reform*. Edited by Robert B. Helms Washington, DC: American Enterprise Institute.

33. Grabowski, Henry G., John M. Vernon, and Lacy Glenn Thomas. 1978. Estimating the Effects of Regulation on Innovation: An International Comparative Analysis of the Pharmaceutical Industry. *Journal of Law and Economics* 21, no. 1: 133-63.
34. Greenwood, Justin, and Karsten Ronit. 1991. Pharmaceutical Regulation in Denmark and the UK: Reformulating Interest Representation to the Transnational Level. *European Journal of Political Research* 19: 327-59.
35. Hall, Peter A., and David Soskice. 1999. An Introduction to Varieties of Capitalism. *Varieties of Capitalism: The Institutional Foundations of Comparative Advantage*. Edited by Peter A. Hall, and David Soskice. Draft.
36. Hancher, Leigh. 1992. Competition and the European Pharmaceutical Market. *The Antitrust Bulletin*: 387-428.
37. ———. 1989. Regulating Drug Prices: The West German and British Experiences. *Capitalism, Culture, and Economic Regulation*. Edited by Leigh Hancher, and Michael Moran, 79-108. Oxford: Clarendon Press.
38. ———. 1990. *Regulating for Competition: Government, Law, and the Pharmaceutical Industry in the United Kingdom and France*. Oxford: Clarendon Press.
39. Hancké, Bob. 1999. Revisiting the French Model: Coordination and restructuring in French industry in the 1980s. working paper FS I 99-301, Wissenschaftszentrum Berlin.
40. Hirsch, Paul. 1975. Organizational Effectiveness in the Institutional Environment. *Administrative Science Quarterly* 20: 327-38.
41. Hofstetter, Sandrine. 1996. "Les restructurations dans l'industrie pharmaceutique dans les années 1990." Dissertation, Pantheon Sorbonne.
Notes: Academic Department: University of Paris 1
42. Hollingsworth, J. Rogers. 1997. Continuities and Changes in Social Systems of Production: The Cases of Japan, Germany, and the United States. *Contemporary Capitalism: The Embeddedness of Institutions*. Edited by J. Rogers Hollingsworth, and Robert Boyer, 265-310. Cambridge: Cambridge University Press.
43. Hollingsworth, Rogers, and Robert Boyer. 1997. *Contemporary Capitalism: The Embeddedness of Institutions*. Cambridge: Cambridge University Press.
44. Howells, Jeremy, and Ian Neary. 1995. *Intervention and Technology Innovation: Government and the Pharmaceutical Industry in the UK and Japan*. London: Macmillan Press.
45. Jaeger, H., and R. Kaukewitsch. 1998. Le droit pharmaceutique en République fédérale d'Allemagne. *Droit Pharmaceutique*. Edited by Jean-Marie Auby, and Frank Coustou. Paris: Litec.
46. Juès, Jean-Paul. 1998. *L'Industrie Pharmaceutique*. Paris: Presses Universitaires de France.

47. Kaitin, Kenneth. 1996. Pharmaceutical Innovation in a Changing Environment. *Contested Ground: Public Purpose and Private Interest in the Regulation of Prescription Drugs*. Edited by P. Davis. New York: Oxford University Press.
48. Kidd, Dan. 1996. The International Conference on Harmonization of Pharmaceutical Regulations, the European Medicines Evaluation Agency, and the FDA: Who's Zooming Who? *Indiana Journal of Global Studies* 4, no. 1: 183-206.
49. Kitschelt, Herbert, Peter Lange, Gary Marks, and John D. Stephens. 1999. *Continuity and Change in Contemporary Capitalism*. Cambridge: Cambridge University Press.
50. Koekijk, Kees, Zhen Kun Wang, and L. Alan Winters. 1996. Market Opening, Regulation, and Growth in Europe. *Economic Policy* 23: 443-67.
51. Kogut, Bruce. 1991. Country Capabilities and the Permeability of Borders. *Strategic Management Journal* 12: 33-47.
52. Levy, Jonah D. 1999. *Tocqueville's Revenge: State, Society, and Economy in Contemporary France*. Cambridge, Massachusetts: Harvard University Press.
53. Mataves, Catherine. 1998. Market Structure, R&D and Advertising in the Pharmaceutical Industry. WZB Working Paper FS IV 98-17.
54. Milner, Helen. 1988. *Resisting Protectionism: Global Industries and the Politics of Global Trade*. Princeton, New Jersey: Princeton University Press.
55. Mintzes, Barbara, and Catherine Hodgkin. 1996. The Consumer Movement: From Single-Issue Campaigns to Long-Term Reform. *Contested Ground: Public Purpose and Private Interest in the Regulation of Prescription Drugs*. Edited by P. Davis. New York: Oxford University Press.
56. Möbius, Klaus, Ekkehart Seusing, and Adolf Ahnefeld. 1976. *Die Pharmazeutische Industrie in der Bundesrepublik Deutschland: Struktur und Wettbewerb*. Tübingen: J. C. B. Mohr.
57. Mobley, Jane. 1990. *Prescription for Success: The Chain Drug Store*. Kansas City: Lowell Press.
58. OECD. 1985. *L'Industrie pharmaceutique: Questions liées aux échanges*. Paris: OECD.
59. Orzack, Louis H., Kenneth I. Kaitin, and Louis Lasagna. 1992. Pharmaceutical Regulation in the European Community: Barriers to Single Market Integration. *Journal of Health Politics, Policy and Law* 17, no. 4: 847-68.
60. Plat, Monique. 1970. *Droit Pharmaceutique industriel.*, Vol. 1. Paris: Centre de documentation universitaire.
61. Polanyi, Karl. 1944. *The Great Transformation*.
62. Porter, Michael. 1990. *The Competitive Advantage of Nations*. New York: The Free Press.
63. Pujol, Rosemonde. 1978. Une antenne pour les consommateurs au

- ministère de la Santé. *Le Figaro*.
64. Reich, Michael R. 1990. Why the Japanese Don't Export More Pharmaceuticals: Health Policy as Industrial Policy. *California Management Review*: 124-50.
 65. Sargent, Jane A. 1985. The Politics of the Pharmaceutical Price Regulation Scheme. *Private Interest Government: Beyond Market and State*. Edited by Wolfgang Streeck, and Philippe C. Schmitter, 105-27. London: Sage Publications.
 66. Saura Estapa, Eduard. 1994. "L'accord-cadre de l'industrie pharmaceutique de janvier 1994: une *event study*." Thesis, Institut d'Etudes Politiques de Paris.
 67. Schatz, Heribert. 1983. Consumer Interests in the Process of Political Decision-Making: A Study of Some Consumer Policy Decisions in the Federal Republic of Germany. *Journal of Consumer Policy* 6: 381-95.
 68. Scherer, F. M. 1993. Pricing, Profits, and Technological Progress in the Pharmaceutical Industry. *Journal of Economic Perspectives* 7, no. 3: 97-115.
 69. Schwartzman, David. 1976. *Innovation in the Pharmaceutical Industry*. Baltimore: Johns Hopkins Press.
 70. Seillier, M. Bernard. 1991. Rapport fait au nom de la commission des Affaires sociales sur le projet de loi relatif à la pharmacie d'officine. *Raport 257 d la séconde session ordinaire, 1990-1991*. Paris: Sénat.
 71. Shoheit, Simon, and Martha Prevezer. 1996. UK Biotechnology: Institutional Linkages, Technology Transfer and the Role of Intermediaries. *R & D Management* 26, no. 3: 283-98.
 72. Shonfield, Andrew. 1969. *Modern Capitalism: The Changing Balance of Public and Private Power*. London: Oxford University Press.
 73. Sitzius-Zehender, Hannelore, Bertram Dervenilch, Frank Diener, and Gerd M. Foh. 1992. Federal Republic of Germany. *International Pharmaceutical Services: The Drug Industry and Pharmacy Practice in Twenty-Three Major Countries of the World*. Edited by Richard N. Spivey, 227-50. New York: Pharmaceutical Products Press.
 74. Smith, Christopher R. 1995. Pharmaceuticals, Intransigent Member States and a Single Market. *Boston College International and Comparative Law Review* 18, no. 2: 471-83.
 75. Soskice, David. 1999. Divergent Production Regimes: Coordinated and Uncoordinated Market Economies in the 1980s and 1990s. *Continuity and Change in Contemporary Capitalism*. Edited by Herbert Kitschelt, Peter Lange, Gary Marks, and John D. Stephens, 101-34. Cambridge: Cambridge University Press.
 76. ———. 1996. German Technology Policy, Innovation, and National Institutional Frameworks. Wissenschaftszentrum Berlin, Discussion Paper FS I 96-319.
 77. Storper, Michael, and Robert Salais. 1997. *Worlds of Production: The Action Frameworks of the Economy*. Cambridge, Massachusetts: Harvard University Press.

78. Streeck, Wolfgang. 1996. Lean Production in the German Automobile Industry? A Test for Convergence Theory. *National Diversity and Global Capitalism*. Edited by Suzanne Berger, and Ronald Dore, 138-70. Ithaca: Cornell University Press.
79. ———. 1992. *Social Institutions and Economic Performance: Studies of Industrial Relations in Advanced Capitalist Economies*. London: Sage Publications.
80. Syndicat national de l'industrie pharmaceutique. *L'industrie pharmaceutique: Ces réalités*. Paris: SNIP.
81. Tarabusi, Claudio Casadio. 1993. Globalization in the Pharmaceutical Industry: Technological Change and Competition in a Triad Perspective. *STI Review* 13: 123-61.
82. Tarabusi, Claudio Casadio, and Graham Vickery. 1996. La mondialisation de l'industrie pharmaceutique. *La Mondialisation de l'industrie: vue d'ensemble et rapports sectoriels*. Paris: OECD.
83. Tortajada, Stéphane. 1996. "Impact des réglementations publiques sur la valeur des entreprises pharmaceutiques: le cas français." Thesis, Institut d'études politiques de Paris.
84. Viala, Georges, and Daniel Vion. 1994. La loi n° 94-43 du janvier 1994 et la pharmacie. *Revue De Droit Sanitaire Et Social* 30, no. 2: 239-60.
85. Wertheimer, Albert, W. Michael Dickson, and Becky A. Briesacher. 1996. Pharmacy in the Western World Health Care Systems. *Contested Ground: Public Purpose and Private Interest in the Regulation of Prescription Drugs*. Edited by P. Davis, 159-76. New York: Oxford University Press.
86. Wieviorka, Michel. 1977. *L'Etat, le Patronat, et les Consommateurs: Etude des mouvements de consommateurs*. Paris: Presses Universitaires de France.
87. Ziegler, J. Nicholas. 1997. *Governing Ideas: Strategies for Innovation in France and Germany*. Ithaca, New York: Cornell University Press.