Institutions and Politics in the European Union: The Design of the European Medicinal Evaluation Agency

Charles Lyon
Department of Political Science
4L01 Posvar Hall
University of Pittsburgh
Pittsburgh, PA 15260

email: cwlst6@yahoo.com

Prepared for delivery at the Biannual Meeting of the European Community Studies Association, Madison, May 31 – June 2, 2001.

Abstract

Institutions are constructed in institutional environments, which partially structure the process of institutional design, and ultimately help determine the shape of these institutions. The recently created European Medicinal Evaluation Agency (EMEA) in the European Union is an excellent example of this process, and as such, will be the subject of this study. Of specific empirical interest is how European-level pharmaceutical policy evolved from the first European legislation on medicinal drugs in the 1960s to the formation of a European pharmaceutical agency in the 1990s. Of broader theoretical interest is how the interaction between supranational authorities and the member states, and the relative strengths of these sets actors, determined how pharmaceutical legislation developed, and ultimately how the medicinal agency would be designed.

The evolution of pharmaceutical policy also provides an excellent opportunity to study how actors and environments interact over time. Actors make decisions that help structure the environment, but only in a limited sense, since the environment in turn helps shape the perceptions of actors. Consequently, the choices that led to the EMEA will be analyzed as one of many potential rational solutions to the problems encountered in the realm of pharmaceutical policy. This agency was a solution that was only partially constructed through intentional behavior, since it was equally a product of the historical evolution and institutional context of the EU. This paper will relate the story of the EMEA in a manner that demonstrates not only how member states and EU institutions interacted to create the agency, but also how rational decisions were constrained by the evolutionary processes of European integration.

Introduction

The European Union (EU) is a product of agreements among national governments.[1] These governments always have been – and continue to be – the most influential actors in the European arena. But the EU is not composed solely of national governments. Other EU institutions, the European Commission and the European Court of Justice, for example, have used the powers delegated to them by national governments to influence the balance of power in Europe. The supranational institutions of the EU have helped shape the political, economic, and social arenas in which European states operate. In many policy areas – particularly those related to the Single European Market (SEM) – these institutions possess privileged access to both national and European policy-making processes. In fact, some argue that the nation states of Western Europe are now better viewed as member states of the EU, in large part because they have become so entangled in the web that is the EU (Sbragia 1994). As a result, sovereignty is increasingly dispersed among various national and European actors (Krasner 1995/1996, 1988). It is this trend that will be examined in this paper.

This paper focuses upon the European market in pharmaceuticals. Of particular interest is market authorization – the process by which drug manufacturers are granted approval to sell new medicinal products in a particular market. Empirically, this study examines the evolution of European-level market authorization from the first European legislation on medicinal drugs in the 1960s to the formation of a European pharmaceutical agency in the 1990s. Theoretically, it evaluates the interaction between the supranational institutions and the member states, as well as their relative strengths, and how these factors affected the development of pharmaceutical

[1] The EU as such has moved through several name changes. This paper covers a period prior to the adoption of its current name, but in order to maintain consistency, the current name will be

legislation. Like many other policy areas, integration of the pharmaceutical sector proceeded haphazardly, with spurts of activity balanced by enduring periods of inactivity. This process reflected continuing tension between the Commission and the member states over the extent to which the Commission would formulate pharmaceutical policy. Together, the Commission and the member states eventually fashioned an institutional framework for a European market, but this framework mirrored the thirty-year conflict that preceded its completion.

The source of this conflict extends beyond the pharmaceutical sector and is framed in the Treaty of Rome. Article 30 of the Treaty requires member states to eliminate all non-tariff barriers to trade, but Article 36 of the Treaty grants exemptions to this clause in questions of public health. In practice, this has meant that the welfare state, its attendant structures, and its cultural foundations remain the preserve of the member states – and the member states have used this distinction to their benefit. As long as a member state could argue that a pharmaceutical authorized in another member state could have hazardous repercussions for its citizens, it could block any European measure in this sector. For decades this position remained the status quo in the pharmaceuticals market. Individual member states did not trust the regulatory procedures or health safeguards used by other member states. Consequently, the Commission was limited in the means that it could pursue to create a single market in pharmaceuticals. This has meant that the Commission, by necessity, relied upon the member states as the primary means through which it created pharmaceutical policy. This does not mean that the Commission was completely dependent upon the will of the member states, but, rather, that it was severely constrained by them.

This paper is divided into several sections. The first section is theoretical in nature. It

---

used throughout.

summarizes the extant theoretical work on European integration, focusing specifically upon the dominant theories, and then uses the new institutionalism to outline a broader perspective in which these theories can be grounded. The next three sections are empirical in nature. These sections describe the development of pharmaceuticals policy from the 1960s, after the Thalidomide scare, through the creation of the Single European Act (SEA) in the 1980s, and end with the creation of the European Medicinal Evaluation Agency (EMEA) in the 1990s. The final section places the empirical developments within a theoretical context, and discusses how the various decision-making processes affected the development of pharmaceutical policy. This story is an extremely complex one, which was dictated as much by the rational behavior of actors as it was by the environment in which they existed. Consequently, this paper is not only a story about policy-making, but it is also a story about the constraints on policy-making within the broader environment of the European arena.

European Integration and Institutional Design

Empirically, this paper analyzes the pharmaceutical sector; theoretically, it cuts a broader swathe. Policy-making is not the sole locus of decision-making in the EU. In order to tell this story properly, one must examine, first, how actors at several levels of decision-making interact to create policy, and second, how temporal conditions affect this process. In order to accomplish this task, this paper incorporates some of the lessons learned from the intergovernmental-supranational debate into a theoretical framework that analyzes both institutional actors and their relationships, i.e., the new institutionalism (see Knight 1992; March and Olsen 1989; North 1990; Scharpf 1997; and Steinmo *et al.* 1992 for general discussions; see Pierson 1996 and Pollack 1997, 1996 as it pertains to policy-making in the EU). It is also assumed that the EU is

best understood as a regulatory state (Majone 1991, 1992, 1994, 1996), and that the context in which decision-making occurs has been conducive, over time, to the creation of such a state. Finally, actors are assumed to be boundedly rational (March 1978), so decisions are framed by the evolutionary and multi-level nature of European integration, not by the omniscience of fully rational behavior.

Contemporary theories of European integration derive primarily from analyses of the Single European Act (SEA) (see Caporaso and Keeler 1995 for a summary). Intergovernmental theories draw from the neorealist school of international relations, and emphasize the resiliency of the state. These theories do not recognize the transfer of state authority to supranational (or other) actors. Instead, the member states are not only the primary, but also the determinant actors in the European arena (Garrett 1992; Moravcsik 1991, 1993, 1998; Scharpf 1988). The influence of supranational actors is at best only reactive. Supranational theories derive from neofunctional theories of integration, and emphasize the gradual development of European-level competencies at the expense of those of the member states. This transformation occurs in an increasingly interdependent world, where groups or institutions can exercise power independently of the state (Cowles 1995; Sandholtz and Zysman 1989). Unlike intergovernmental theories, these theories emphasize the development of the SEA as a product of the action of non-governmental actors.

Theorists that advocate either supranational or intergovernmental perspectives too often ignore the broader context in which actors interact. The European arena is not a vacuum. It is an institutional environment, created by actors, that is the interactive sum of numerous decision-making processes. In such a context, the EU can be viewed as a set of nested rules (Ostrom 1990; Peterson 1995). At the highest level, the EU is structured around constitutional rules, such

as the Treaty of Rome, the SEA, and the Maastricht and Amsterdam Treaties, which are largely the result of intergovernmental bargaining. These treaties, the grand bargains of European integration, can be treated as a series of sequential equilibria. It is this level of rule-making that supranational and intergovernmental theories usually address (see Schmidt 1997 for an exception). Between intergovernmental conferences, the treaty framework remains constant, but is supplemented and interpreted through the interaction of governmental and non-governmental actors, both through the legislative processes and within the bureaucratic networks of the EU.

Because the repercussions of treaty-making are immense, even if the resulting institutions provide collective benefits, actors attempt to frame European institutions to their benefit (Knight 1992). Consequently, it is here that the member states will be least likely to delegate decision-making. Due to the complexity of the European project, however, constitutional rules can only establish the most basic framework for the European project, so the member states must delegate power to other institutions to achieve their stated aims. The member states have created a set of supranational institutions, i.e., the Commission, the Court of Justice, and the Parliament, and a set of intergovernmental institutions, i.e., the Council of Ministers and the European Council, whose primary mission is to elaborate upon the constitutional rules, and make this project a reality. Distributive battles exist at this level as well (Knight 1992), but they are less intense. Policy-making occurs in an established framework, so conflict arises as rules are interpreted, not as they are framed.

The policy-making institutions of the EU serve, in turn, as the foundation for bureaucratic networks. Just as policy-makers interpret the intent of treaty-makers, so bureaucrats interpret the intent of policy-makers. But bureaucratic behavior is fundamentally different from that which

occurs at the other decision-making levels. Administrators are concerned less with the fruits of battle than with the norms of behavior (March and Olsen 1984, 1989; Simon 1997). Policy-specific networks of national and European officials develop as officials attempt to implement policy. Patterns of behavior are then institutionalized within these networks, which often become the foundation for shifts in policy at higher decision-making levels (Peters 1992). In a parallel manner, the outcomes of policy-making processes subsequently become the foundation for shifts in the constitutional framework. Decision-making structures the future behavior of actors precisely because of the fluid nature of the EU governance. The EU is a developing polity, so the effects of decision-making are compounded. In this context, decision-making is often coterminous with rule-making – creating structure as events unfold (Arthur 1989; North 1990; Pierson 1996).

Yet the SEM can only be realized to the extent that the Commission can overcome the historical, cultural, and social foundations of national markets – which can be extremely difficult if the member states do not cooperate (North 1990). The Commission attempts to maximize its influence within the policy process and create a market, subject to a variety of political, constitutional, and bureaucratic constraints. The member states, on the other hand, attempt to retain sovereignty, subject to the same constraints. Since the Commission is weaker than any individual member state, it usually must accommodate the preferences of the member states, even if the will of the Commission represents the constitutionally mandated goals of the member states. Consequently, the supranational institutions of the EU have learned that the best way to move towards a European market is to adapt to the substantial presence of the member states. Majone (1991, 1992, 1994, 1996) argues that the very nature of the relationships in the European

arena is conducive to the creation of a European-level regulatory state; i.e., the EU can be understood as a corrective to the market failures that West European states are unable to address.

The EU can be viewed as an isomorphic institution (DiMaggio and Powell 1991): The institutional structures and decision-making processes at the European level complement those found within the member states. There has been considerable tension regarding the boundary between the EU and the member-states, and over time, the line that delimits the functions of the EU from those of member states has not only become more fluid, but the level at which the EU interferes in member state functions has increased as well. This development is evident in the area of pharmaceuticals. The pharmaceuticals market reflects both various cultural patterns of drug disbursement and a long history of segmentation along national lines. The regulatory structures of the member states represent significant sunk costs, which have hampered attempts to integrate this sector (Krasner 1984; Steinmo *et al.* 1992). Yet the Commission has successfully moved into this sector. The Commission has succeeded not through confrontation, but through subterfuge (Heritier 1997). It has packaged proposals with the member states in mind, using repetition and opportunism as means towards its legislative ends.

This paper examines how the Commission created a pharmaceutical market within the evolving context of European integration. This story will focus primarily upon the Commission and the member states (both independently and within the Council). It is first and foremost a history of policy-making. As the preceding paragraphs would indicate, a fully integrated pharmaceutical market could not have been created independent of events at both the constitutional and the bureaucratic levels. Changes that occurred at these levels cannot be ignored, but they will be treated as exogenous factors. The influence of other actors, such as

national regulators and various interest groups, is also important, but these actors will only be mentioned tangentially. Consequently, the question that this paper seeks to answer should be restated. This paper will show how the Commission and the member states shifted pharmaceutical policy from a preserve of member states to a concern of the EU. It will show this by examining how actors at multiple levels of decision-making influenced policy-making (Bulmer 1994; Marks 1993; Marks *et al.* 1996).

Setting the Stage: Policy-Making as Institutional Design

The Commission first broached the subject of a common European pharmaceuticals policy in the early 1960s – largely as a consequence of the Thalidomide scare. The Thalidomide tragedy provided an opening for the Commission – both (so the Commission argued) to prevent further catastrophes and to create a common market in pharmaceuticals (Kingdon 1984). There was considerable conflict over what approach to pursue, i.e., to gradually harmonize national administrative procedures, and move towards eventual mutual recognition of national authorizations, or to create a central European pharmaceuticals authority, which would issue authorizations for the entire European market (Seidel 1968). The first approach represented the lowest degree of centralization necessary to create a common market, while the second approach represented a significantly greater shift of power to the Community. Due largely to opposition from Germany and industry, the former approach was chosen (Hancher 1990). The Commission and the member states would focus initially upon harmonizing administrative procedures, so that authorizations could eventually be based upon common criteria.

The first directive in this area (65/65/EEC) recognized a need to completely harmonize marketing authorization procedures. Towards this end, the directive attempted to harmonize

some administrative regulations for placing pharmaceuticals on national markets while also acknowledging that public health protection as well as market authorization itself remained the preserve of the member states. The legislation required that a permit be issued for any new pharmaceutical to be sold on a national market, and that safety, efficacy, and quality serve as the basis for this authorization. This directive was envisaged as the first of several steps towards mutual recognition. Follow-up legislation was proposed in 1964 and again in 1967 (Seidel 1968). The latter proposals would have harmonized the remaining national legal and administrative procedures – providing for the mutual recognition of national pharmaceutical authorizations across all member states.

At the end of 1969, the Commission proposed a calendar for harmonizing the rest of the pharmaceutical sector (*Europe* 29 September 1969). Assuming that the current proposals would be adopted, the Commission suggested that additional directives be introduced in the early 1970s (relating to advertising, prices, patents, and delivery, among other issues). By 1975 the Commission would introduce proposals to establish a procedure for European authorizations, which would be valid throughout the Community. This goal would be difficult to reach. Germany, which only had a registration system for pharmaceuticals, wanted immediate mutual recognition. The remaining member states, which had full-fledged authorization bodies, desired eventual mutual recognition, but only after all administrative and regulatory practices had been harmonized. Germany would accept the proposals, but only if the other member states committed to eventual mutual recognition. Some member states suggested that a European committee of scientific experts be created to resolve any differences among national authorization bodies, while other member states desired a transition period, in which use of

Community procedures would initially be optional, but would eventually be required (*Europe* 14 January 1970). These proposals would eventually provide the foundation for mutual recognition of authorizations, but at the present, they only added more fuel to the debate.

The Commission had linked several issues on its agenda, and it was difficult to move on one issue as long as differences remained on others. The pharmaceutical industry and several member states felt that this linkage should be broken, so that questions like market authorization could be confronted immediately and more protracted problems could be tackled later (*Europe* 24 January 1973). However, some member states would not relinquish the right to regulate market authorization, since it would move the decision-making process beyond the national level. Through necessity, the Commission compromised. The member states developed an alternative set of proposals, which would permit authorization at the Community level to be optional. As initially developed, this proposal provided for a European-level scientific committee that would facilitate the authorization of medicinal products across member states. If one member state did not accept the market authorization of another member state, the committee could try to resolve any differences through its own non-binding recommendation (*Europe* 31 January 1973). Germany accepted this provision under two conditions: first, the other member states would have to accept a unanimous opinion of the committee, and second, the other member states would have to commit themselves to complete the pharmaceuticals market by a certain date (to be stipulated later).

In February of 1975, the Council agreed on the first steps towards the free movement of proprietary medicinal products. This legislation liberalized the pharmaceutical market in name only. Wherever a product was produced, it would subject to the same manufacture and control

provisions under the surveillance of people with equivalent qualifications (75/318/EEC and 75/319/EEC).[2] As a result, safety requirements, which had hindered the free movement of pharmaceuticals, would be identical. Denmark, France, and the United Kingdom had opposed the German push for mutual recognition, probably because these countries felt that it would lead to lower levels of scientific evaluation. Mutual recognition of authorizations, therefore, would not be automatic, and instead would be facilitated by a newly created Committee for Proprietary Medicinal Products (CPMP) (set up by Directive 75/319/EEC), composed of one representative from each of the member states and one representative from the Commission.[3]

Once a pharmaceutical was approved in one member state, that state could forward the dossier (on behalf of the pharmaceutical manufacturer) to the CPMP, which would then submit it to at least five other member states.[4] In theory, if the five member states agreed with the recommendations of the submitting state, then the pharmaceutical would be admitted to the markets of these states as well. In reality, rather than rely upon the reports of the original member state, national regulators continued to perform their own quality tests (Orzack *et al.* 1992). The CPMP could also issue opinions if member states reached different conclusions regarding the authorization of a pharmaceutical, but contrary to German wishes, these opinions would not be binding. At least one member state objected to each of the 41 applications

---

[2] This directive was directed more towards trade than authorization. If a pharmaceutical was manufactured in one member state and sent to another member state, safety checks would not have to be repeated. Trade could only occur after the pharmaceutical had been authorized in the receiving country.

[3] A Pharmaceutical Committee would also be established (75/320/EEC). This committee would operate at a higher level than the CPMP, and would consider general questions regarding pharmaceutical policy and legislation. The Commission was to consult the Committee when drafting legislation.

[4] In order to lessen the administrative load on the CPMP, the directive was later amended so that the member state that initiated the process would submit the dossier directly to the other member

submitted through this procedure – effectively ending attempts at mutual recognition (Commission 1988). Because the member states retained a veto over those pharmaceuticals that could enter its market, a segmented market continued to exist.

By now, it was assumed that a single pharmaceuticals market could only be realized incrementally. To the Commission's benefit, the 1975 directives required the Commission to present new proposals within four years of their implementation. In the intervening period, the Commission consulted various industry and consumer groups. Industry argued that a system of mutual recognition should be created, but industry also noted that the lack of trust among member states prevented it from using any system effectively (*Europe* 1 March 1979). Industry argued for a system constructed upon the current one, where the authorization agencies of the member states continued to function, but the CPMP facilitated greater cooperation (*Europe* 6 June 1980). Consumer groups, on the other hand, complained that the Commission focused too much on the needs of industry and too little on questions of safety. They desired an institution along the lines of a European registration agency, which would overlap with the competencies of the member states (*Europe* 8 January 1981).

The Commission explicitly excluded a European agency as a solution to this problem, stating that the needs of such an agency were beyond its financial and administrative means.[5] To push for such an institution would also use too much political capital for a project that the member states almost certainly would not accept. But the Commission did request greater authority for the CPMP (within the current system of proposed mutual recognition). To buttress this system, the Commission also wished to update existing regulations, taking into account

---

states, rather than via the CPMP (78/420/EEC).

[5] In 1958, the Court of Justice ruled in *Meroni vs. High Authority* that the institutions of the EU

scientific and technical changes. Despite objections from consumer groups, who argued that mutual recognition would not improve regulatory procedures, and might even provoke regulatory competition, Parliament supported the Commission proposals.[6] When Parliament later questioned the Commission about potential national regulatory competition, the Commission stated that nothing in the proposed legislation would prevent member states from stipulating additional conditions regarding pharmaceutical use (*European Report* 17 March 1982; also see European Parliament 1982). In other words, the member states would still retain the upper hand, and the proposed legislation would probably not move the pharmaceuticals market beyond its current status.

Neither industry nor the Commission received all they desired. A recommendation (83/571/EEC), while not binding, suggested that testing procedures performed by national authorities be further harmonized – both so that they could be more easily compared but also so that technical advances could be included. Applications for market authorization would also be comparable, since the information included in each dossier would now be standardized (83/570/EEC). The latter directive also reduced to two the number of additional member state authorizations required for mutual recognition, since many manufacturers had complained that they often did not desire entry to five additional markets. A manufacturer that could apply to two rather than five additional member states might use this procedure more frequently (now called the "multi-state" procedure). But the directive did not grant the CPMP any additional powers. Member states could still deny access to their markets for any pharmaceutical product, although

---

could not delegate powers. Since that time, this decision has been interpreted more loosely.

[6] The Economic and Social Committee came to the same conclusion as consumer groups, but since its opinions were (and remain) non-binding, its suggestions had little effect (OJ C 189/45, 30 July 1981).

they were now required to take account of the opinions of the first authorizing agency, as well as the opinions of the CPMP. The Commission and industry also gained additional rights, since the former could now influence the agenda of CPMP meetings and the latter could now approach the CPMP directly (rather than via the member states).

Debate over the legislation had been mixed. Denmark, Greece, and the Netherlands had opposed any form of mutual recognition while Germany had continued to support it. Many northern states, where the procedures for scientific evaluation were more fully developed, remained suspicious of mutual recognition. In the end, mutual recognition was not achieved, but a provision in these directives directed the Commission to introduce new proposals within four years (leading, theoretically, towards the elimination of any remaining barriers – but this had already been tried once before). Germany also included a note in the minutes that stated its desire for further progress towards mutual recognition (*European Report* 29 October 1983). Reactions to the legislation were equally strong. The Commission issued a statement saying that mutual recognition had still not been achieved, and that progress was still too slow. European industry immediately denounced the directive, arguing that the proposal should have been adopted in its original form. Despite the opportunity to create new proposals, it seemed that the Commission was reaching the limit to which it could push integration in the pharmaceuticals sector. Policy-making in isolation could not provide the foundation for a single market in pharmaceuticals.

Constitutional Crisis: Building a Pharmaceuticals Market from the Top Down

The Commission was confronted with a serious problem: The mission defined for it by the founding treaties could not be realized. Some sort of equilibrium had been reached – not only in the pharmaceuticals sector, but in the EU as well. These were the years of Eurosclerosis.

The treaty framework was structured so that what little slack existed in the system had already been used (March 1981). If change did continue, then it would probably proceed at an increasingly diminishing rate. The much-vaunted agenda-setting power of the Commission mattered little when its alliances with one or several member states in the Council of Ministers could be annulled by any other member state. While it was difficult for the Commission to use its powers to further European integration, it had served as a source of ideas, and thus framed the debate (Peters 1994; Pollack 1997). In the pharmaceuticals sector, the Commission had begun a slow, haphazard, almost exploratory, movement towards mutual recognition of market authorizations (March 1988; Simon 1983). The Commission would doggedly push this idea until its eventual realization. But under the then current institutional and constitutional arrangements, the Commission could not move any further. Mutual recognition of market authorizations based upon the harmonization of scientific and procedural rules required too much effort.

In the 1980s, a policy window appeared that provided the Commission with an opportunity to move in numerous sectors. The economies of Europe were stagnant. European governments, industry, and the Commission began to search for a solution. They settled upon an old idea: the common market. The foundation already existed in the Treaty of Rome, but for the last thirty years the member states had had little real incentive to move in this area. The Second World War had ended, the United States had provided stability, and national economies had flourished. There was no real need for a common market. Now there was, or so it appeared. The segmented national markets had prevented industry from taking advantage of economies of scale. A rejuvenated European market would permit European industry to compete with the United States and Japan. While there was general agreement that something needed to be done,

and that the common market would be a good solution, someone or something had to provide direction. If the member states agreed that the common market was the solution, then the Commission, as the think tank of the integration process, was in a position to frame the debate.

The Commission achieved this in the form of its *White Paper on Completing the Internal Market* (COM (85)310). This document was a collection of almost 300 proposals, many of them stalled in the legislative process, that the Commission moved to the fore. The White Paper became a focal point (Garrett and Weingast 1993; Kingdon 1984) in a garbage can of problems and solutions (Cohen *et al.* 1972). The White Paper included twelve proposals in the area of pharmaceuticals, in which the Commission pushed for action in areas ranging from pricing transparency and veterinary medicine to high technology medicines and technical standards.[7] This document not only supplied the agenda upon which the new SEM would be built, but it also provided the mechanism through which the regulatory process could be furthered. Based upon the *Cassis de Dijon* case, the Commission suggested that mutual recognition of national regulations rather than complete harmonization of national regulations be the rule.[8] It would no longer be necessary for the Commission and the member states to quibble over minutiae. In the area of pharmaceuticals and other health matters, Article 100A(3) of the SEA would require higher levels of protection, but many of the earlier obstacles could still be overcome. In this sense, the White Paper was part of an evolutionary process. It was an opportunistic attempt on the part of the Commission to use an institutional crisis in order to further policy-making

[7] Of greatest potential interest was a proposal (scheduled to be delivered after 1987) that would complete the market in pharmaceuticals. How this would be done was not discussed.

[8] In 1979, the Court of Justice had ruled in the *Cassis de Dijon* case that member states needed good reason (beyond those dictated by culture or tradition, such as health) to ban the import of goods into their countries. The Court did not explicitly mention mutual recognition, but the Commission used the ruling for its own purposes (See Alter and Meunier-Aitsahalia (1994) for

processes (March 1988; Simon 1983; Zhou 1993).

As part of the SEA, significant institutional changes were also adopted. Until the SEA, Parliament lacked any power to amend legislation. Since the Council only needed to consult Parliament, the legislative process primarily involved negotiations between the Commission and the Council, and more significantly, among the member states. Now, under the new cooperation procedure, the powers of Parliament were expanded, so under certain circumstances, Parliament could amend legislation. Furthermore, within the Council, the unanimity rule would be abandoned in favor of qualified majority. For the Commission, this change could provide significant leeway in the decision-making process. Although member states still preferred to find some sort of consensus in the Council, recalcitrant states could now be marginalized via a majority vote. The Commission had always been a relatively fluid organization – appealing to various interest groups as sources of support (Peters 1994). Theoretically, the Commission could now use this support beyond the agenda-setting stage. Member states would continue to dominate the European arena, but the Commission could exploit the new decision rules in its alliances with the member states (i.e., in the Council) and Parliament. How these constitutional changes would affect policy-making in the pharmaceuticals sector remained to be seen.

Significant changes in the pharmaceutical industry bracketed the systemic changes incorporated within the SEA. Since the early 1980s, not only had the number of applications for market authorization doubled, but the applications had become increasingly complex (Commission 1988). In the mid-1980s high technology and biotechnology drugs also began to enter the market in greater numbers. The Commission wished to postpone national authorizations of these pharmaceuticals, at least to the extent that the CPMP could coordinate

---

an extended discussion).

work before national decisions were made. The Commission argued, probably correctly, that the member states lacked expertise in these areas, and that only through a concerted effort could the necessary expertise be collected.[9] The Commission also requested the power to alter technical standards, so that they would not have to be altered via Council Directives, which often took years to accomplish. The Commission argued that with these powers it could preempt national action in the area of technical requirements, preventing the fragmentation of the market in area of high technology and biotechnology drugs. Proposals to this effect were incorporated in the White Paper, even though they had been formally introduced a year or so earlier (COM (84)437).

Both the Commission and industry viewed the aforementioned proposals as a means not only to create a European market but also to compete with U.S. and Japanese firms. Industry supported these proposals – as long as they were limited to pharmaceuticals derived from biotechnology and the role of the CPMP was limited to a forum for information exchange (*European Report* 22 February 1986). Consumer groups continued to view attempts at mutual recognition as unacceptable. They felt that the Commission was ignoring questions of quality, and that only a European level authorization body could provide the necessary reinforcement to prevent regulatory competition. They also argued that the Commission was emphasizing the market at the expense of safety, and wanted to align safety standards at the highest level before creating a unified market. More importantly, it was difficult to convince countries with large pharmaceutical industries, like Germany and France, to adopt a centralized procedure (*Europe* 10 December 1986). Germany, among other countries, had also questioned whether powers to

[9] Since firms had no access to the CPMP until after they received a marketing authorization, the Commission also thought that this procedure would facilitate cooperation between the member states and pharmaceutical firms.

update technical standards should be delegated to the Commission.[10] Yet the Council approved these proposals in a ten month period, so it appears that both the SEA and the urgency of the issue, as framed by the Commission, had an effect on the legislative process.

The Council agreed to three directives in December 1986 and a recommendation in February 1987. The first directive (87/22/EEC) required member state regulators to consult the CPMP before authorizing a pharmaceutical derived via biotechnology (this procedure was optional for high technology drugs).[11] All member states could then become involved in the assessment, prior to the initial authorization. Similar to the multi-state procedure, however, the recommendations that accompanied this procedure (called the concertation procedure) were non-binding. The second directive (87/19/EEC) enabled the Commission to update testing procedures for pharmaceuticals without going through the traditional legislative process.[12] The Commission could submit proposals to a committee established to review changes in technical standards, which would decide via qualified majority vote. If the committee supported the proposed change, then the Commission could amend the original directive; if the committee rejected the proposed change, then the Commission would have to submit the proposal to the Council, which would also decide via qualified majority vote. As with the CPMP, the member states appointed members to the committee, and thus retained some control over its decisions (Vos 1997). The other directive simply updated some of the informational and testing requirements for authorization (87/21/EEC), while the recommendation continued the work

[10] These positions would have been congruent with its desire for mutual recognition.
[11] Member states were also now required to submit to the Commission any draft technical standards. The Commission would now be aware of any changes in member state procedures.
[12] The Commission first used this procedure in 1991 (91/507/EEC).

begun in the previous recommendation (87/176/EEC).[13]

By the end of the decade, the process of drug review had been harmonized, yet the procedures for mutual recognition were still ineffective (Kaufer 1989). Different cultural approaches to pharmaceutical regulation appeared insurmountable. Without some means of enforcement or a better way to encourage trust, it seemed that cooperation was impossible (see Axelrod 1986, 1981 and Ostrom 1990 for discussions of exceptions). In the end, the SEA had not provided the incentives necessary to create a unified pharmaceutical market. The equilibrium point that had been reached several decades earlier had only been surpassed to the extent that it was now more refined. The constitutional changes enshrined in the SEA did not significantly alter the behavior of the member states. Parliament generally supported the Commission, so its position did not alter the legislative outcome, and the Commission lacked the political (as opposed to legal) strength to enforce its constitutional mandate. The legal structure for a single market in pharmaceuticals was present, and the bureaucratic organization and constitutional rules necessary to facilitate this process were present as well, yet this project could not be completed. A market should have existed, but the political will was lacking.

The multi-state procedure had been established as a mechanism to facilitate mutual recognition of authorizations. Since the 1960s, mutual recognition had been predicated upon the assumption that harmonized provisions for authorizations would sustain it. The procedure functioned effectively, but not for the reasons that it was designed. It was not the provisions for mutual recognition for which the system was noted, but the provisions for dealing with

[13] Until this point, several pharmaceutical products had been excluded from the European authorization process. In 1989, the Council agreed to proposals that expanded the scope of the pharmaceutical regime to include immunological medicinal products (89/342/EEC), radiopharmaceuticals (89/343/EEC), and medicines derived from human blood (89/381/EEC). In

objections from member states (Commission 1991). This clause had been intended for exceptional cases, where real health risks accompanied the introduction of pharmaceuticals. Yet one hundred and twenty two of the 142 applications that were submitted via the multi-state procedure were accompanied by member state objections (Commission 1991).[14] The concertation procedure fared slightly better. Since the member states had already agreed that a single the rapporteur would be chosen from among the member states, some measure of cooperation was built into the procedure. Applicants under both the multi-state and concertation procedures tended to use the more scientifically advanced regulatory authorities, such as those in France and the UK, so one would expect some measure of success (Commission 1991). But it was not here where the procedures broke down. It was where the authority of the CPMP ended, prior to any binding agreement. Since member states were left to resolve their own problems, a fully effective system could not be created.

Bureaucratic Foundations: Building a Pharmaceutical Market from the Bottom Up

The lack of success at the policy level hid modest success at the bureaucratic level. Early in its development, members of the CPMP had recognized that they needed specialized support, and began to incorporate expertise from the national level into the activities of the Committee (Commission 1991). A network of several hundred national experts developed, which included not only participation in the multi-state procedure, but involvement in numerous working parties (including working parties on the quality of medicines, biotechnology and pharmacy, safety of medicines, and efficacy of medicines) (Commission 1988, 1991). The CPMP also met several times a year, and over time, a dialogue developed among those officials that attended the

---

1992, it agreed to expand coverage to homeopathic products as well (92/73/EEC).

[14] Applications in the remaining cases were withdrawn – usually for fear of a member state

meetings. This process did not eliminate the reticence of national regulators to cooperate, but it did create a foundation upon which greater integration of this sector could develop (Axelrod 1986, 1981). The Commission was already responsible for updating technical requirements for testing medicines, and the CPMP had already become a focal point for industry and consumer groups. It was evident that some sort of structure existed, but how the Commission could use it remained unknown.

Despite the example of the pharmaceuticals sector, the boundary between the EU and the member states had evolved extensively. In the end, the SEA proved to be a necessary, but insufficient criterion for change in the pharmaceutical sector. An additional systemic shock was necessary if the member states were going to move in this area (Eckstein 1988; Krasner 1984). The real move towards an enforceable European procedure came towards the end of the 1980s, as the increasing number of applications for market authorization overwhelmed the national authorities. In some cases, pharmaceutical companies had to wait years for market approval. The CPMP obviously lacked the necessary staff to deal with this crisis, but some of the tangential benefits derived from the multi-state and concertation procedures gave the Commission an opportunity to move once again. It was, one might argue, a second policy window (Garrett and Weingast 1993; Kingdon 1984), but this time it was specific to this sector. As mentioned previously, a network of experts had developed at the European level. It was upon this foundation that the Commission would eventually build a proposal for a European pharmaceutical agency. Surprisingly, the process that had ineffectively complemented the member state regulatory procedures would enable the Commission to complete the pharmaceuticals market.

---

objection.

As early as 1988 the Commission stated that it would submit proposals for community level authorization procedures to the Council (IP/88/190). The Commission argued that not only was the current system was ineffective, but that the existing disparities between national systems constituted a handicap for European pharmaceutical firms trying to compete with American and Japanese firms. The Commission also emphasized that the new proposals would be based upon the principle of subsidiarity; in other words, they would be framed so that control remained largely with the member states (*European Report* 27 June 1990). In October of 1990, the Commission floated a proposal for a European agency that would be based upon two procedures, one derived from the multi-state procedure and the other derived from the concertation procedure. This proposal was part of a package of four proposals. Two other directives would establish the procedures for reviewing medicinal and veterinary drugs, while the final directive would eliminate some of the optional procedures currently in existence. The new agency would consist of an administrative structure (composed of a secretariat and a management board) that housed two committees, the CPMP and the CVMP (for veterinary products). These committees would continue to perform the substantive scientific work. The new agency would not possess direct decision powers (for constitutional reasons), but would issue opinions, upon which the Commission would act.

As usual, there was a certain amount of disagreement among the member states. The Commission initially proposed that all relevant legislation be based on Article 100A, while Germany, at the other extreme, desired that all legislation be based upon Article 235 (*European Report* 23 September 1992). The Commission (later supported by Denmark) argued that the agency was only a means towards creating the SEM, and as such, was provided for in the Treaty

of Rome. Germany and France (as well as the legal services of the Council and the Commission) recommended the use of Article 235, which required unanimity rather than qualified majority in the Council. Contrary to the Commission, they argued that since the agency would be a new legal entity, it was not provided for in the Treaty. Germany and France also wanted the role of the agency restricted to scientific matters (in the case of Germany) and coordinating evaluations (in the case of France). The Commission had also desired a more independent CPMP run by independent scientific experts, while some member states, such as France and Spain, wanted the scientific committees to be composed of member state representatives, as they had been previously (*European Report* 17 June 1992). In the end, the committees would be composed of member state experts, who would not be able to act on the instructions of the member states, while the agency was created via Article 235 and the enabling legislation via Article 100A.

Despite the rancor, these proposals were not as extreme as it might seem. The expansion of EU powers into areas traditionally occupied by the member states was usually permitted only if the member states were compensated through representation in the EU (Dehousse 1992). If the member states were to grant authority to the new agency, then they expected something in return. The move towards an agency model was an attempt to create a network of national authorization agencies (Dehousse 1997). The agency would be designed so that it complemented rather than replaced the existing national regulatory bodies, and this is how it was presented to the member states. The agency itself was to be governed by a management board composed of two representatives from each member state, two representatives from the Commission, and two representatives from Parliament. Finally, the agency would be small, and would have no independent experts of its own. The idea for a European agency did not meet with greater

resistance precisely because it was built upon a preexisting framework of national authorities and expertise.

The Regulation (2309/93/EEC) that created the agency was agreed in July 1993. It was based upon several procedures. The centralized procedure (also established under 2309/93/EEC) was to be mandatory for biotechnology drugs and optional for high technology drugs.[15] When an application was submitted to the CPMP, the Committee would make a recommendation, which would be forwarded to the Commission for a final decision.[16] Before reaching a conclusion, the Commission would consult the Standing Committee on Medicinal Products for Human Use, which would consist of representatives of the member states (a further check on Commission prerogatives). If there were disagreements (e.g., the Commission reached a conclusion different from the CPMP), then the application would be referred to the Council of Ministers. The decentralized procedure was to be used for all other pharmaceuticals (93/39/EEC). Here, the manufacturer would submit its application to a member state, which would decide whether to authorize the product. If another member state refused to recognize the original authorization, then the matter would be referred to the CPMP, which would deliver an opinion that would be enforced by means of a Commission decision. Until 1998, there would be some flexibility in how the latter procedure was used. There would also be a national authorization procedure that, after 1998, could only be used by those manufacturers that wished to provide a pharmaceutical in one member state.

The EMEA was established as a structural complement to past policies. Its role would be

---

[15] Another directive (93/41/EEC) repealed the directive that established the concertation procedure (87/22/EEC).

[16] This is done because the institutions of the EU are constitutionally unable to delegate decision-making power to outside bodies.

to coordinate the evaluation procedures in tandem with expertise drawn from the member states. As the relationship between the member states and the Commission currently stands, the agency is probably the best solution that the Commission could have found. The process of institutional design almost always entails some form of distributional conflict, but the Commission was able to optimize with the least possible damage to its interests (Knight 1992). The member states had resisted ceding sovereignty in this sector for almost thirty years, but the Commission achieved its goals by presenting a solution that also minimized the costs to the member states.[17] The European bureaucracy would remain almost the same and would only be supplemented by an administrative structure, comprised primarily of experts from the member states. The agency represents a saddle point, albeit one that it took decades to find (Sharpf 1994; Simon 1983). It is a position in Cartesian space where the desires of numerous entities – one bent on creating a European market and the others bent on retaining some sort of sovereignty – intersect, while simultaneously maximizing the interests of both sides.

Conclusion

The proposals with which the Commission initiated this process were virtually identical to those with which it completed it, but the results could not have been more different. The program that the Commission created in the late 1960s eventually culminated in a European-level authorization procedure, yet it took almost thirty years to realize this outcome. How the Commission initially framed these proposals became a legacy that it confronted at almost every juncture – i.e., choosing between a decentralized and centralized solution, between mutual recognition and an agency. But if the Commission was to be a leader in the policy-making process

[17] In fact, in the discussions over the medicinal agency, the decision rule to be used and the location of the agency were more highly disputed than the question of the agency itself.

– and if it was to succeed – it could not move too far from the positions held by the member states. For this reason, the Commission did not seriously considered a centralized solution in the intervening years. The Commission discovered that it could only construct the pharmaceuticals market incrementally – literally one procedure at a time (Lanzara 1998). The agency could not be created *de novo*; it could only develop as a function of time, influence, and circumstances (Moe 1987).

How did the Commission overcome the interests of the member states? In reality, it did not – it could only manipulate them. When decision-making is characterized by bargaining, i.e., zero-sum behavior, then absent extremely strong alliances, the Commission rarely wins. When decision-making is characterized by problem-solving, i.e., positive-sum games, the Commission can profit (Heritier 1999; Peters 1997; Scharpf 1994). For years, bargaining behavior was endemic in this sector. Despite its constitutional mandate, the Commission could not alter these conditions. The Commission could only play the game – repeatedly – and wait. The Commission tried at least once in each decade from the 1960s to the 1980s, but it did not succeed until the 1990s. The Commission, as an entity with legal power to build the SEM, but lacking the political power to create it, could only manufacture the conditions under which a pharmaceutical market should exist. The Commission had to wait for the member states in order to realize its goal.

What turned the tide? Exogenous shocks propelled the Commission proposals to the fore (Eckstein 1988; Krasner 1984). Almost every shift in the legal structure of the European pharmaceuticals market was foreshadowed by an external event. These events were largely random, and were not predicted by any actors, but when they occurred, they altered the decision-

making framework significantly. The Thalidomide scare initiated the process; then, after a two decade hiatus, biotechnology, the SEA, and the national regulatory crisis appeared in quick succession. The regulatory inertia of the member states was only overcome when it became evident that the member states could not control their own fate (Eckstein 1988; Krasner 1984; Steinmo *et al.* 1992). But the changes that followed were much more subtle than either intergovernmental or supranational theories would have predicted. The solution, the EMEA, reflected not only the power struggles that preceded its creation, but the historical circumstances under which these struggles occurred as well (Knight 1992; Steinmo *et al.* 1992). As a result, the EMEA complemented the regulatory structures of the member states – assuming only those regulatory functions that the member states were unable to perform (Majone 1991, 1992, 1994, 1996).

The EMEA is the product of thirty years of constitutional, policy, and bureaucratic decision-making. The political development of the pharmaceutical market was structured by both constitutional inertia and institutional crisis (Eckstein 1988; Krasner 1984; Shepsle 1989). At this level, the member states dictated when and how changes would proceed, so the Commission could only use random opportunities to generate change. The legal and bureaucratic structures of the agency developed in a radically different manner. Policy-making was subject to conflict, but using its powers of initiation, the Commission was able to frame the legislative debate. Here, the Commission used a much more methodical approach. Conflict was largely absent at the bureaucratic level. Actors at this level were more interested in creating functioning procedures than in competing for spoils. The outcome of these developments was a surprise to many. Several decades ago, few would have predicted that the member states would delegate policy

responsibility to a European-level agency. The Commission had placed pharmaceuticals policy on the agenda because it interpreted its mandate to require this action, but it took thirty years of decision-making to construct the agency.

References

Alter, Karen J., and Sophie Meunier-Aitsahalia. 1994. "Judicial Politics in the European Community." *Comparative Political Studies* 26: 535-561.

Arthur, Brian. 1989. "Competing Technologies, Increasing Returns, and Lock-In by Historical Events." *Economic Journal* 99: 116-131.

Axelrod, Robert. 1986. "An Evolutionary Approach to Norms." *American Political Science Review* 80: 1095-1111.

_____. 1981. "The Emergence of Cooperation among Egoists." *American Political Science Review* 75: 306-318.

Bulmer, Simon J. 1994. "The Governance of the European Union: A New Institutionalist Approach." *Journal of Public Policy* 13: 351-380.

Burstall, Michael. 1990. *1992 and the Regulation of the Pharmaceutical Industry.* IEA Health Series 9. London: Institute of Economic Affairs.

Cameron, David R. 1992. "The 1992 Initiative: Causes and Consequences." In Alberta Sbragia (Ed.) *Europolitics: Institutions and Policymaking in the 'New' European Community.* Washington, D.C.: The Brookings Institution.

Caporaso, James A., and John T.S. Keeler. 1995. "The European Union and Regional Integration Theory." In Carolyn Rhodes and Sonia Mazey (Eds.), *The State of the European Union.* Boulder, CO: Lynne Rienner.

Cecchini, Paolo. 1988. *The 'Cost of Non-Europe' in the Pharmaceutical Industry.* Luxembourg: European Community.

Cohen, Michael, James March, and Johan Olsen. 1972. "A Garbage Can Model of Organizational Choice." *Administrative Science Quarterly* 17: 1-25.

Cowles, Maria Green. 1995. "Setting the Agenda for a New Europe: The ERT and EC 1992" *Journal of Common Market Studies* 33: 501-526.

Dehousse, Renaud. 1997. "Regulation by Networks in the European Community: The Role of European Agencies." *Journal of European Public Policy* 4: 246-261.

_____. 1992. "Integration v. Regulation? On the Dynamics of Regulation in the European Community." *Journal of Common Market Studies* 30: 383-402.

DiMaggio, Paul, and Walter Powell. 1991. "The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields." In Walter Powell and Paul DiMaggio (Eds.), *The New Institutionalism in Organizational Analysis*. Chicago: University of Chicago Press.

Eckstein, Harry. 1988. "A Culturalist Theory of Political Change." *American Political Science Review* 82: 789-804.

European Commission. 1991. *Report on the Activities of the Committee for Proprietary Medicinal Products COM (91/39)*. Luxembourg: European Community.

_____. 1988. *Report on the Activities of the Committee for Proprietary Medicinal Products COM (88/143)*. Luxembourg: European Community.

European Parliament. Committee on Economic and Monetary Affairs. 1982. *Report on the Production and Use of Pharmaceuticals in the Community*. Luxembourg: European Parliament.

_____. Committee on Institutional Affairs. 1992. *Report on the Setting Up and Operation of Specialized Bodies and Agencies*. Luxembourg: European Parliament.

Gardner, John. 1996. "The European Agency for the Evaluation of Medicines and European Regulation of Pharmaceuticals." *European Law Journal* 2: 48-82.

Garrett, Geoffrey. 1992. "International Cooperation and Institutional Choice: The European Community's Internal Market." *International Organization* 46: 533-560.

Garrett, Geoffrey, and George Tsebelis. 1996. "An Institutional Critique of Intergovernmentalism." *International Organization* 50: 269-299.

Garrett, Geoffrey, and Barry R. Weingast. 1993. "Ideas, Interests, and Institutions: Constructing the European Community's Internal Market. In Judith Goldstein and Robert O. Keohane (Eds.), *Ideas and Foreign Policy*. Ithaca, NY: Cornell University Press.

Hancher, Leigh. 1992. "1992 and the Creation of a Single European Market." *Antitrust Bulletin* 37(2): 387-428.

_____. 1991. "Creating the Internal Market for Pharmaceutical Medicines – An Echternach Jumping Procession?" *Common Market Law Review* 28: 821-853.

_____. 1990. "The European Pharmaceutical Market: Problems of Partial Harmonization." *European Law Review* 15: 9-33.

Hankin, Robert. 1996. *Integrating Scientific Expertise into Regulatory Decision-Making: The Cases of Food and Pharmaceuticals*. EUI Working Paper RSC 96/7. Florence: European University Institute.

Heritier, Adrienne. 1999. *Policy-Making and Diversity in Europe: Escaping Deadlock.* New York: Cambridge University Press.

_____. 1997. "Policy-Making by Subterfuge: Interest Accommodation, Innovation and Substitute Democratic Legitimation in Europe." *Journal of European Public Policy* 4(2): 171-189.

Kaufer, Erich. 1989. *The Regulation of Drug Development: In Search of a Common European Approach.* EUI Working Paper 411. Florence: European University Institute.

Kingdon, Jon. 1984. *Agendas, Alternatives, and Public Policies.* Boston: Little, Brown, and Company.

Knight, Jack. 1992. *Institutions and Social Conflict.* New York: Cambridge University Press.

Krasner, Stephen. 1995/1996. "Compromising Westphalia" *International Security* 20 (3): 115-151.

_____. 1988. "Sovereignty: An Institutional Perspective." *Comparative Political Studies* 21: 66-94.

_____. 1984. "Approaches to the State: Alternative Conceptions and Historical Dynamics." *Comparative Politics* 16: 223-246

Lenaerts, Koen. 1993 . "Regulating the Regulatory Process: 'Delegation of Powers' in the European Community." *European Law Review* 19: 23-49.

Lanzara, Giovan. 1998. "Self-Destructive Processes in Institution Building and Some Modest Countervailing Mechanisms." *European Journal of Political Research* 33: 1-39.

Majone, Giandomenico. 1996. *Regulating Europe.* London: Routledge.

_____. 1994. "The Rise of the Regulatory State in Europe." *West European Politics* 17 (3): 77-101.

_____. 1992. Regulatory Federalism in the European Community. *Environment and Planning C* 10: 299-316.

_____. 1991. Cross-National Sources of Regulatory Policy-Making in Europe and the United States. *Journal of Public Policy* 11: 79-106.

March, James. 1988. "The Technology of Foolishness." In James March (Ed.) *Decisions and Organizations.* Cambridge, MA: Basil Blackwell.

_____. 1981. "Footnotes to Organizational Change." *Administrative Science Quarterly* 26: 563-577.

_____. 1978. "Bounded Rationality, Ambiguity, and the Engineering of Choice." *Bell Journal of Economics* 9: 587-608.

March, James, and Johan Olsen. 1989. *Rediscovering Institutions*. New York: Free Press.

_____. 1984. "The New Institutionalism: Organizational Factors in Political Life." *American Political Science Review* 78: 734-749.

Marks, Gary. 1993. "Structural Policy and Multilevel Governance in the EC." In Alan Cafruny and Glenda Rosenthal (Eds.) *The State of the European Community: The Maastricht Debates and Beyond.* New York: Lynne Rienner.

Marks, Gary, Liesbet Hooghe, and Kermit Blank. 1996. "European Integration from the 1980s: State-Centric v. Multi-Level Governance." *Journal of Common Market Studies* 34: 342-378.

Moe, Terry. 1987. "Interests, Institutions, and Positive Theory: The Politics of the NLRB." *Studies in American Political Development* 2: 236-299.

Moravcsik, Andrew. 1998. *The Choice for Europe: Social Purpose and State Power from Messina to Maastricht.* Ithaca, NY: Cornell University Press.

_____. 1993. "Preferences and Power in the European Community: A Liberal Intergovernmentalist Approach." *Journal of Common Market Studies* 31: 473-524.

_____. 1991. "Negotiating the Single European Act: National Interests and Conventional Statecraft in the European Community." *International Organization* 45: 19-56.

Mossialos, Elias, and Brian Abel-Smith. 1997. "The Regulation of the European Pharmaceutical Industry." In Stelios Stavridis, Elias Mossialos, Roger Morgan, and Howard Machin (Eds.), *New Challenges to the European Union: Policies and Policy-Making*. Brookfield: Dartmouth.

North, Douglass. 1990. *Institutions, Institutional Change, and Economic Performance.* New York: Cambridge University Press.

Orzack, Louis, Kenneth Kaitin, and Louis Lasagna. 1992. "Pharmaceutical Regulation in the European Community: Barriers to Single Market Integration." *Journal of Health Politics, Policy, and Law* 17: 847-868.

Ostrom, Elinor. 1990. *Governing the Commons: The Evolution of Institutions for Collective Action.* New York: Cambridge University Press.

_____. 1986. "An Agenda for the Study of Institutions." *Public Choice* 48: 3-25.

Peters, B. Guy. 1997. "Escaping the Joint-Decision Trap: Repetition and Sectoral Politics in the European Union." *West European Politics* 20(2): 22-36.

_____. 1994. "Agenda-Setting in the European Community." *Journal of European Public Policy* 1: 9-26.

_____. 1992. "Bureaucratic Politics and the Institutions of the European Community." In Alberta Sbragia (Ed.) *Europolitics: Institutions and Policymaking in the 'New' European Community.* Washington, D.C.: The Brookings Institution.

Peterson, John. 1995. "Decision-Making in the European Union: Towards a Framework for Analysis." *Journal of European Public Policy* 2: 69-93.

Pierson, Paul. 1996. "The Path to European Integration: A Historical Institutionalist Analysis." *Comparative Political Studies* 29: 123-163.

Pollack, Mark. 1997. "Delegation, Agency, and Agenda Setting in the European Community." *International Organization* 51: 99-134.

_____. 1996. "The New Institutionalism and EC Governance: The Promise and Limits of Institutional Analysis." *Governance* 9: 429-458.

Sandholtz, Wayne. 1996. "Institutions and Collective Action: The New Telecommunications in Western Europe." *World Politics* 45: 242-270.

Sandholtz, Wayne, and John Zysman. 1989. "1992: Recasting the European Bargain." *World Politics* 42: 95-128.

Sbragia, Alberta. 1994. "From 'Nation-State' to 'Member-State': The Evolution of the European Community." In Paul Michael Lutzeler (Ed.), *Europe After Maastricht: American and European Perspectives*. Providence, RI: Berghahn Books.

Scharpf, Fritz. 1997. *Games Real Actors Play*. Boulder, CO: Westview Press.

_____. 1994. "Community and Autonomy: Multi-Level Policy Making in the European Union." *Journal of European Public Policy* 1: 219-242.

_____. 1988. "The Joint-Decision Trap: Lessons from German Federalism and European Integration." *Public Administration* 66: 239-278.

Schmidt, Susanne. 1997. "Sterile Debates and Dubious Generalizations: European Integration Theory Tested by Telecommunications and Electricity." *Journal of Public Policy* 16: 233-271.

Shepsle, Kenneth A. 1989. "Studying Institutions: Some Lessons from the Rational Choice Approach." *Journal of Theoretical Politics* 1: 131-147.

Simon, Herbert. 1997. *Administrative Behavior*. New York: The MacMillan Company.

_____. 1983. *Reason in Human Affairs*. Stanford, CA: Stanford University Press.

Steinmo, Sven, Kathleen Thelen, and Frank Longstreth, eds. 1992. *Structuring Politics: Historical Institutionalism in Comparative Analysis*. New York: Cambridge University Press.

Thelen, Kathleen, and Sven Steinmo. 1992. "Historical Institutionalism in Comparative Politics." In Sven Steinmo, Kathleen Thelen, and Frank Longstreth (Eds.) *Structuring Politics: Historical Institutionalism in Comparative Analysis*. New York: Cambridge University Press.

Vos, Ellen. 1997. "The Rise of Committees." *European Law Review* 3: 210-229.

Zhou, Xueguang. 1993. "The Dynamics of Organizational Rules." *American Journal of Sociology* 98: 1134-1166.