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**Diagnosing Policy Dynamics:
The Birth & Evolution of the Pharmaceutical Subsystem**

Katie R. Stores

Dissertation submitted to the Eberly College of Arts and Sciences at West Virginia University in
partial fulfillment of the requirements for the degree of

Doctor of Philosophy
in
Public Policy

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Morgantown, West Virginia
2009

**Keywords: Agenda-Setting; Congress; Subsystems; Pharmaceutical Regulation; Policy
Process; Policy Equilibrium
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Abstract

Diagnosing Policy Dynamics: The Birth & Evolution of the Pharmaceutical Subsystem

Katie R. Stores

The rising cost of prescription drugs in the United States has led patients—older populations and the disabled especially, to seek relief through foreign nations, and internet mail-order sites, which are often hosted and condoned by state and local governments. Patients are traveling to Canada and Mexico to purchase affordable prescription drugs. According to the Congressional Budget Office, “American seniors alone will spend 1.8 trillion dollars on pharmaceuticals over the next ten years” (U.S. Senate 2007, S 251). This research examines the agenda status and change of pharmaceutical regulation by tracing the evolution of the pharmaceuticals subsystem. By employing a punctuated equilibrium approach, I seek to understand if periods of agenda access and issue definition have corresponded to changes in the institutional structure of policymaking.

As such, this study is motivated by three questions: *(1) how has Congress governed the pharmaceutical policy agenda over the post World War II era, (2) have periods of agenda access led to venue changes in pharmaceutical regulation, (3) has the image of pharmaceutical policies led to positive or negative feedback, and if so, what factors precipitated such change.* Understanding how image and agenda access can impact the institutional structure of policymaking will illustrate how ideas influence the strength and weakness of the pharmaceutical policy monopoly. The results of this study are important because they highlight the institutional factors influencing the cost and availability of prescription drugs. Moreover, this research provides insight concerning federal involvement in regulatory policy.

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Prescription Drug Importation as a Matter of Policy

“Due to the ever increasing prices of pharmaceuticals in the United States, compared to those in many other countries, consumers and innovative entrepreneurs have devised various means of obtaining cheaper pharmaceuticals...” Wertheimer and Santella 2007, 303

According to the Congressional Budget Office, “American seniors alone will spend 1.8 trillion dollars on pharmaceuticals over the next ten years” (U.S. Senate 2007, S 251). The rising cost of prescription drugs in the United States has led state and local governments to openly develop prescription drug importation mail-order sites to combat their increasing deficits and offer affordable prescription drug benefits to state employees and retirees despite its illegality. In addition, patients are traveling to Canada and Mexico to purchase affordable prescription drugs. Despite the prohibition against prescription drug importation, the Food and Drug Administration (FDA) has presently taken a lax approach to enforcement. But, the FDA has threatened to pursue more serious ramifications if the states continue to pursue drug importation from foreign non-approved FDA facilities.

A range of actors from local, state, federal government, industry, as well as professional societies and organizations have become active in the area of prescription drug importation policy. Despite coalition efforts, legislative progress to allow the importation of prescription drugs by pharmacists, wholesalers, and consumers has been stymied. Prescription drug importation is presented in this introduction as an illustration of subsystem resistance to change-- a concept explored more broadly throughout the analysis. I seek to understand the dynamic governing the evolution of pharmaceutical policy as a case study in how positive and negative feedback shape policy subsystems. Specifically, this research examines how Congress governs the multidimensional nature of pharmaceutical policy.

Prescription Drug Importation: An Example of Subsystem Resistance

Drug importation, occurs when prescription drugs are imported into the U.S. from other countries. According to the U.S. Department of Health and Human Services (HHS), imported drugs can be classified as either personal imports (internet sales or purchases by customers who travel across the border) or commercial imports (pharmaceuticals purchased by pharmacies and wholesalers for resale) (HHS Task Force on Drug Importation 2004). *Re-importation*, on the other hand, occurs when FDA approved drugs manufactured in the U.S. and exported to foreign countries are brought back into the United States (Ornes and Hendrix 2006, 15). Imported drugs can be classified by the following *types* according to Wertheimer and Santella: (1) legally imported drugs, “which include those manufactured in foreign but FDA—inspected facilities meeting U.S. standards and those that were manufactured in an FDA—approved U.S. facility, sent abroad, then reimported by the manufacturer under the requisite conditions,” (2) imported drugs manufactured in a foreign facility that also produces the FDA—approved U.S. version, and (3) a drug imported from a non-approved FDA facility (2007, 304; HHS Task Force on Drug Importation 2004).

Currently, the Federal Food Drug and Cosmetic Act (FFDCA) prohibits individual or commercial importation of prescription drugs by anyone other than the manufacturer. During the mid-1980s unsafe prescription drugs were being reimported back into the United States, which prompted Congress to pass the 1987 Prescription Drug Marketing Act (PDMA) (as detailed in chapter 3). The PDMA “included a provision... [making] it illegal for anyone other than drug manufacturers to import pharmaceuticals into the United States” (Congressional Research Service 2002, 1). Section 801 (d)(1) of the FFDCA states no “drug...which is manufactured in a

state and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug” (Congressional Research Service 2002, 1).

Pharmaceutical manufacturers may import prescription drugs if: 1) the pharmaceuticals have been manufactured for or by them in the foreign country and 2) guidelines prescribed by the Food and Drug Administration concerning manufacture and distribution are enforced (Benjamin and Levinson 2004, 55). As stipulated in section 804 (j)(3) of the FFDCA, the Food and Drug Administration (FDA) has implemented a “personal use” policy, at the discretion of U.S. customs, in order to allow citizens to purchase a 90 day supply of non-FDA approved drugs from foreign countries for “compassionate use” (Congressional Digest 2003; Ornes and Hendrix 2006, 16). The compassionate use policy was initially adopted to facilitate treatment for life-threatening diseases, such as cancer and AIDS and illustrates the pharmaceutical monopoly was not complete. These disease based interest groups end up forming part of the advocacy coalition that creates the opportunity for subsystem arrangements to be broken up or maintained.

Advocacy Coalitions

As noted by Sabatier and Jenkins-Smith, the policy process operates within policy subsystems, which are composed of coalitions (1993, 150). Coalitions include business representatives, interest groups, trade associations, federal agencies, legislative committees, as well as elected officials, scholars, and members of the press (Sabatier and Jenkins-Smith 1993, 150). Following an examination of the prescription drug importation debate, I have identified three coalitions. The *safety* coalition members primarily include a select group of government officials, the FDA, the Health Care Distribution Management Association (HDMA), representing distributors, and the Pharmaceutical Research and Manufacturers Association (PhRMA) (Ornes and Hendrix 2006, 18; Stearn 2004, 538; Wertheimer and Santella 2007, 310). This coalition

believes imported pharmaceuticals create a public health risk that far outweighs any cost benefit. These importation opponents suggest policies to allow legal importation will result in an influx of unsafe and counterfeit drugs.

According to Stearn, Congress can address international counterfeit pharmaceutical imports based on the following legislative jurisdiction: territorial, national, protective, passive personality and universal jurisdiction (2004, 541). Although practical matters of gathering evidence, ethical rules, and jurisdiction and extradition present major difficulties in prosecution. Therefore, to protect the U.S. public from fake pharmaceuticals, Stearn suggests, foremost, the FDCA should explicitly apply to foreign companies and individuals who are involved in the distribution of drugs and devices in the United States (2004, 550).

Critics of drug importation, including the Bush Administration, cite safety risks as cause for abandoning this possible cost cutting approach (Guglielmo 2005; Melnitzer 2005). The safety coalition suggests risks include counterfeiting and a lack of notification procedures when a drug has to be recalled in another country (Young 2004, 874). Recent focusing moments such as the halting of clinical trials by the National Institutes of Health (NIH), adverse long term trials on popular medications, and Congressional support to expand adverse drug event requirements in the pharmaceutical industry have contributed to raising safety concerns associated with prescription drug importation (Wechsler 2005, 26). The Bush administration suggests Americans should look to generic medications and prescription drug discount cards for lower-cost solutions (Young 2005, 233).

According to the FDA, as much as 8% of the drug supply is counterfeit, which is defined as products “without the active ingredient, with an insufficient quantity of the active ingredient, with the wrong active ingredient or with fake packaging” (FDA 2004). The FDA has submitted

letters to governors and state health officials to warn them of the liabilities incurred by promoting the purchase of imported drugs (Davolt 2005, 65). States have countered the FDA by assuring they have thoroughly reviewed the prescribing practices of state approved foreign pharmacies. Supporters of drug importation suggest calls over safety concerns are merely scare tactics, because drugs bought in developed countries have stringent pharmaceutical safety regulations similar to the U.S. (Guglielmo 2005, 44).

These proponents of drug importation form the *affordability* coalition. Of the varied stakeholders, consumer advocates such as the American Association of Retired Persons (AARP) and the National Community Pharmacists Association (NCPA) support prescription drug importation albeit under different stipulations. The AARP view importation as a way to increase access, while the NCPA support legislation that would allow only pharmacists and wholesalers to import prescription drugs (Ornes and Hendrix 2006, 17). Thus, cost and safety concerns are at odds when current policy proposals are examined.

The level of activity by state and local governments is evidence of the wide-spread public attention the issue of importation has received. State and local governments have openly developed internet mail-order sites in order to combat their increasing deficits and offer affordable prescription drug benefits to state employees and retirees despite its illegality. Illinois' I-Save Rx and Minnesota's RxConnect Online are web based programs designed to facilitate prescription drug purchases from Canada, Ireland, or the United Kingdom and Canada respectively (Guglielmo 2005, 44). California, Illinois, Minnesota, New Hampshire, Oregon, Rhode Island, Vermont, Wisconsin, and the local jurisdictions of Montgomery, Alabama, Washington, D.C., Montgomery County, Maryland, Boston, Massachusetts, Springfield, Massachusetts, and Caldwell County, North Carolina, are all facilitating or subsidizing the

importation of prescription drugs for personal use (Davolt 2005; Guglielmo 2005; Teufel 2006). Connecticut, Mississippi, and West Virginia have also passed pro-importation bills (Guglielmo 2005, 46).

Minnesota's Department of Human Services has stated they have secured agreements with Canadian pharmacies to require Canadian International Pharmacy Association membership, a prescription from a U.S. physician, and exclusion of non-FDA approved medicines among other requirements (Guglielmo 2005, 65). Not all states have welcomed drug importation legislation. For example, Nevada passed a bill in 2003 barring illegally imported prescription drugs. States who have championed the legalization of drug importation, suggest citizens are already participating in drug importation; therefore, they have an obligation to maintain safety standards for their residents.

When policy proposals are considered for legislation, the issue definition of importation significantly influences the players involved and the policy beliefs that are accommodated. Several pieces of legislation aim to modify the FDCA to allow qualifying individuals, in addition to pharmacist and wholesalers, to import prescription drugs. According to David Kessler, former FDA commissioner, "the choice before [Congress] is not the choice of imports or no imports. We already have a system of importation of drugs that jeopardizes public health. Congress has the responsibility to fix this serious problem" (Mamudi 2005, 8). The U.S. Department of Health and Human Services (HHS) released a report examining prescription drug importation, which states the safety concerns of importing prescription drugs far outweigh any cost savings. The report was required under the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

The pharmaceutical industry, the *profit* coalition, suggests paying less for prescription drugs will lead to less drug development, but factual evidence concerning the exact reduction in research and development is scant (Mamudi 2005; Young 2005). The profit coalition includes large firms whose activities involve basic and applied research, biotechnology, and generic, non-research based companies, distributors, trade associations, and affiliated organizations with a profit motive. GlaxoSmithKline, Pfizer, AstraZeneca and Wyeth have made concerted efforts to limit the importation of prescription drugs from Canada by stifling supplies to traditional and internet pharmacies (Melnitzer 2005, 56).

As part of the Medicare Modernization Act of 2003, Congress instructed the Secretary of Commerce to conduct a study on The Organization for Economic Co-Operation and Development (OECD) drug price controls and the implications for U.S. consumers. The Commerce study found “top foreign brand-name drugs cost 18-67% less than in the United States, a factor that reduces manufacturer revenues by more than \$20 billion annually and curbs industry research and development” (Wechsler 2005, 27). Based on the reaction of the pharmaceutical industry and current drug cost differentials, advocates suggest the HHS report simply reflects pharmaceutical interests (Krisberg 2005, 1). The Pharmaceutical Research and Manufacturers Association (PhRMA) supports the purchase of generic drugs and utilizing the Medicare prescription drug benefit as alternatives to importation (Parekh 2005, 2).

The impact of legalized importation on manufacturer revenue and research and development investment is inconclusive. According to Pecorino, when a good subjected to negotiated prices and sold in a foreign country is legalized, the foreign country price becomes the domestic price, because the barriers to market segmentation are removed (2002, 700). “Allowing reimports always raises consumer surplus in the home country. Thus, in all of the

cases analyzed, home welfare is higher under the reimport regime” (2002, 700). Further, profits to the monopolist rise, because as prices in the foreign markets rise and prices in the United States market decrease the differential would be indeterminate (Pecorino 2002, 707). Pecorino’s findings would suggest pharmaceutical manufacturers would not experience revenue loss and therefore should not have justification for decreased research and development investment.

In contrast, Scherer suggests regulation of pharmaceutical pricing will lead to substantial hampering of research and development (1993, 113). According to Scherer, price controls would inherently lead to insufficient profits, which would discourage technological progress. Thereby, penalizing consumers, drug companies, and sacrificing the welfare of citizens in developing countries (Scherer 1993, 113-14). Drug companies suggest high prescription drug prices in the United States allows significant research and development, which would be impossible if importation or price controls were implemented (Choudhry and Detsky 2005; Teufel 2006). Economic theory does assert that fixed cost of drug development is most efficient when buyer price differentials are exploited (Choudhry and Detsky 2005, 360).

However, according to Choudhry and Detsky drug development costs are likely exaggerated. Drug companies earn profits on pharmaceuticals that utilize current delivery mechanisms, and research is often funded by taxpayer research (2005, 360). Finally, “the pharmaceutical industry spends twice as much on marketing, advertising, and administration than on research and development” (Teufel 2006, 389). Therefore, drug company profits could arguably be reduced without affecting innovation. Regardless of the exact price point-research and development trade off, Teufel concludes while Congressional efforts to increase the affordability of prescription drugs is admirable, the current solutions simply place an undue burden on the FDA, which will inevitably sacrifice the “gold standard” assurance of drug safety

and efficacy and simply pass on increased costs to manufacturers and pharmacies (Teufel 2006, 392-93).

In short, the debate surrounding drug importation centers on the cost savings available from foreign price-controlled nations, and whether these cost benefits outweigh the safety and profit concerns of importing pharmaceuticals. Prescription drug prices continue to rise with no foreseeable end to the increasing profits garnered by the pharmaceutical industry or cost relief to those most in need –the elderly, disabled, and the indigent. It appears alternative policy solutions to deter or control the costs of prescription drugs have been superseded by the call for prescription drug importation, despite questions of safety.

When the U.S. House of Representatives passed the Pharmaceutical Access Act of 2003 (H.R. 2427), which opened the door for the re-importation of prescription drugs, lobbyist waged a battle to protect their estimated \$1.8 trillion dollar industry at stake (Gokcekus, et al. 2006; U.S. Senate 2007, S 251). Yet, despite the undisputed influence of the pharmaceutical lobbying machine the bill passed the House. Consumer advocates, pharmaceutical manufacturers, insurers, state health plans, citizens, and employers all have cause to monitor the actions of Congress concerning pharmaceutical policy. The policy players dominating the debate will have serious implications on the outcome of pharmaceutical pricing and regulation.

Purpose and Organization

The first aim of my study is to describe the evolution of pharmaceutical policy. Despite the numerous economic debates concerning the costs and benefits of pharmaceuticals, there has not been an effort to summarize the policy progression. The second aim is to apply the agenda setting and policy equilibrium literature to the area of pharmaceutical policy in order to understand how positive and negative feedback shape the policy subsystem. As different

dimensions of pharmaceutical regulation have taken center stage, I am interested in examining how alternative coalitions have influenced the agenda setting process. The third, and final, aim of this study is to generalize my findings to the broader understanding of agenda setting.

Thus, my research is motivated by three questions: (1) *how has Congress governed the pharmaceutical policy agenda over the post World War II era*, (2) *have periods of agenda access led to venue changes in pharmaceutical regulation*, (3) *has the image of pharmaceutical policies led to positive or negative feedback, and if so, what factors precipitated such change*. The results of this study are important because they highlight the institutional factors influencing the cost and availability of prescription drugs. Moreover, this research provides insight concerning federal involvement in regulatory policy.

The second chapter will focus on the agenda setting literature, specifically prior research concerning punctuated equilibrium theory and punctuated equilibrium applications. The goal of chapter two is to provide a synopsis of the most relevant literature and highlight the significance of the current study. Chapter three provides a brief evolution of pharmaceutical policy in the United States. Chapter four includes my tracking of the pharmaceuticals agenda based on data collected on bill introductions from 1947 to 2007 garnered from the Congressional Bills Project and the Library of Congress's THOMAS website. The bill's sponsor, committee, referral information, subject, and progress are provided in combination with an analysis including descriptive charts and graphs. Chapter five assesses the dynamics of the pharmaceuticals agenda based on legislative hearings data collected from the *Congressional Information Service Index to Committee hearings and Abstracts to Committee Hearings*. The overall pattern of these data will reflect the issues that rise and fall from the political agenda. Finally, chapter six includes a summary of my findings, the research contribution, and ideas for further analysis.

Agenda Setting and Punctuated Equilibrium

There is no such thing as a fixed policy, because policy like all organic entities is always in the making. - Attributed to Lord Salisbury

Agenda Setting

Any attempt to understand the course of public policy, must inevitably, consider why a set of issues is addressed through policy while perhaps an equally important set of alternative issues are not. The study of agenda setting is thus inherently “the study of social change and of social stability” (Dearing and Rogers 1996, 2). Agenda setting can be conceptualized as the study of issue salience—or the relative importance of an issue on the agenda. It is also the study of the rise and fall of issue salience over a period of time (Soroka 2002, 5). During the agenda setting stage of the policy process individuals and groups compete as they define their problem and mobilize support for government attention to their issue (Ripley 1985, 51).

Specifically, an *issue* arises when a group perceives they have a problem that requires governmental action, and there is public disagreement over the best solution to the perceived problem (Eyestone 1978, 3). Problem definitions are constructed by policy actors who either dramatize the policy alternatives in order to push an issue onto the agenda, or they downplay the problem in an effort to encourage inaction (Rocheffort and Cobb 1994, 3). In some instances, an issue can be manufactured by those who manipulate the image of the issue for their own gain, and sometimes, issues are generated by those who are simply interested in the public good (Cobb and Elder 1972, 82-84). In either case, in order for the issue to be translated onto the decision making agenda, “lobbyists, bureaucrats, elected politicians, and other political entrepreneurs must be engaged to stoke the political fires” (Eyestone 1978, 2).

Public policy scholars have developed a useful distinction between the systemic agenda and the institutional agenda in order to clarify those issues that may receive attention by the public, but have not yet moved onto the decision agenda of governmental officials. The systemic agenda “consists of all issues that are commonly perceived by members of the political community as meriting public attention” (Cobb and Elder 1972, 85). In essence, the systemic agenda is the collective list of what the public considers ought to be done by government (Jones 1984, 58). Whereas, the institutional or governmental agenda is “that set of items explicitly up for the active and serious consideration of authoritative decision makers” (Cobb and Elder 1972, 86). Contemporary “public policy analysts consider how and why governments enact and implement policies to address public needs and demands” (Adolino and Blake 2001, 10). Similarly, the current study is an analysis of the pharmaceutical public policies Congress has enacted since World War II and a consideration of what actors and events, inside and outside of government, have influenced their policy decisions.

As suggested by Kingdon, a logical distinction between the players of the agenda setting process are those inside of government, including the administration, civil servants, and Congress and those actors outside of government—interest groups, academics, media, and public opinion (1995, 21). This simple, but effective method of explanation will be used to organize the set of policy players relevant to the current study. This chapter will begin by discussing the actors inside and outside of government, focusing on their relative impact on setting the governmental agenda. I will then turn my attention to the role of subsystems and how these subgovernments or issue networks work to restrict the number and variety of interests involved in policymaking in a particular policy area. Finally, I will present the policy change models that guide my theoretical perspective.

The Inside-Outside Distinction

Participants on the *inside* of government include the administration, civil servants, and Congress. Although the administration can be thought of as the president, the staff in the Executive Office, and the political appointees in departments and bureaus, I will focus my attention on the ability of the president himself to affect the agenda and alternative issue definitions. It probably comes as no surprise that the president can often dominate and even determine the policy agenda, but he or she cannot dictate the alternatives that are considered (Kingdon 1995). The president naturally commands public attention, due to the ability of the president to veto and hire and fire. Thus, the position of the presidency comes with it authority and status that bestow advantages in persuading other actors inside and outside of government (Neustadt 1990). Despite these persuasive powers, presidents do face restrictions on their internal resources (Light 1999, 6).

Paul Light finds that presidents are constrained in influencing the agenda by the internal resources of time, information, expertise, and energy. In addition, Light finds external resources such as, congressional support, public approval, and electoral margin all influence the presidents ability to impact the domestic agenda (1999, 10). In our government of shared powers, a president depends upon others whom he must persuade to act (Neustadt 1990, 31). For example, despite President Kennedy's personal interest and focus on civil rights in his 1961 domestic agenda, Kennedy concluded that a major civil rights bill would not pass until a stronger majority existed in Congress (Light 1999, 104). In short, the president can often place issues on the policy agenda, but he or she can also be precluded from obtaining congressional action.

In contrast, career civil servants do not appear to be as influential in setting the agenda as some scholars may assume (Kingdon 1995). Kingdon finds that careerists are more involved in

the day to day management of government programs and are therefore, not involved in advocating for new ideas or programs (1995, 31). Interestingly, despite their lack of involvement in setting the agenda, career civil servants are participants in generating issue alternatives. Their longevity, expertise, and relationships with people in Congress and interest groups are valuable in formulating policy alternatives (Kingdon 1995, Golden 2000, Denhardt and Grubbs 2003). The relationship “between these three actors—bureaucrats, committees, and interest groups—is often called an iron triangle because their interests dovetail nicely because they are alleged to be impenetrable from the outside and uncontrollable by president, political appointees, or legislators not on the committees in question” (Kingdon 1995, 33).

Congress, the final participant on the inside of government, is a powerful institution and holds a central place in the political system due to its oversight, policymaking, and advise-and-consent powers stipulated in the U.S. Constitution (Ahuja and Dewhirst 2003, 1). Congress, “in contrast to most other actors, [has] the unusual ability to combine some impact on the agenda with some control over the alternatives” due to its constitutional authority to act as a “primary policy-maker” (Kingdon 1995, 35; Anderson 1997, 59). The committee and subcommittee structure has enhanced the capacity of Congress to engage in policymaking. According to Davidson and Oleszek, congressional committees within Congress serve two broad purposes, individual and institutional (2004, 193).

Individually, committees within Congress allow members to advertise (be perceived in a positive light), gain expertise, and secure reelection—due to credit claiming (Davidson and Oleszek 2004; Mayhew 2004; Rohde 2005). Institutionally, committees allow members to control the policy issues of most concern to their districts, garnering power, and creating good public policy (Davidson and Oleszek 2004, 193; Mayhew 1974). Undoubtedly, committees are

“one of the most important institutional structures through which members pursue their goals” (Rohde 2005, 207). Committee boundaries are made based on the interaction between policy entrepreneurs and the House and Senate parliamentarians. King identifies two types of committee jurisdictions – statutory and common law. Statutory jurisdictions are “coded into the House or Senate written rules,” whereas, common law jurisdictions are determined when jurisdictionally ambiguous bills are referred to a committee within 24 hours of introduction (King 1997, 34, 37).

Common law jurisdictions are where the turf wars are fought, “as new issues arise, the parliamentarians of the House and Senate make decisions about where bills relating to them should be referred, and those initial referrals tend to govern future ones.” Baumgartner and Jones assert that the hearings process allows committees to invest resources as a “means of claiming future jurisdiction so that new bills will be referred to a given committee” (1993, 200). Policy entrepreneurs, those who facilitate the issue translation process, carefully craft their plan to move into uncharted territory, because if the bill is too far from their committee’s statutory expertise they may lose the battle permanently (King 1997, 40-41; Eyestone 1978, 88). Policy entrepreneurs actively present bills for referral that are related to their committees’ jurisdiction in the hope that the amended law will not find a host law in the original committee; thereby establishing a foundation for future control of similar issues, establishing a “common law jurisdiction” (King 1997, 8). King suggests that formal jurisdictions are codified by this type of evolution (King 1997; Rohde 2005). In short, Congress is able to influence the agenda not only by its broad statutory powers, but by its jurisdictional battles as well.

Participants without formal statutory positions can also influence the agenda and the policy alternatives. These *outside* participants include interest groups, media, the mass public,

and academics, as well as others, such as consultants and researchers. Baumgartner and Jones note that how various interests are organized and mobilized for political action influences policy change (1993, 175). Interest group activity in particular does influence the agenda and agenda alternatives, in varying degrees. Interest groups consist of business and industry, professional, labor, public interest groups, and government officials as lobbyists (Kingdon 1995, 47; Olson 1971). The influence of each type of interest group is contingent on the ideology of the group, the importance of the interest group, and the visibility of the policy issue. As recognized by Baumgartner and Jones, interest groups can structure the choices available to policymakers and the way the public perceives or understands the policy debate (1993, 190).

Policy communities spring up around numerous public policy issues, attaching their preferred policy alternatives to the debate—sometimes their policy definitions have already been made prominent by other groups or entrepreneurs (Kingdon 1995, 50). For example, in the United States, AIDS and Cancer disease-based interest groups have had a significant impact on the legislation and regulation of pharmaceutical policy for many years (Daemmrich 2004). The influence of disease-based interest groups, such as those focusing on AIDS and Cancer patient access to pharmaceuticals, has been achieved by their ability to exhibit a united front and to control internal conflict. But, despite the influence of disease based interest groups in pharmaceutical policy, it is important to note that even well organized, cohesive interests groups will be defeated on occasion. In short, interest groups are effective in framing alternative problem definitions, but responsibility for the emergence of agenda items cannot be solely credited to them or their activities.

The final participants on the outside of government—media and the mass public—often interact to influence the systemic and the governmental agenda. As noted by Kingdon, the

public's attention to governmental issues often follow the topics reported on by the media, which in turn, is considered by vote-seeking politicians (1995, 57, 65). This media-policy change process is often the normative view of how public opinion and the media interact to influence policy change. According to Stimson et al., "most political decisions are about change or the prevention of change....Thus, when public policy drifts away from the public's demands for policy, the representation system acts as a control mechanism [or thermostat] to keep policy on course" (1995, 543-44). But, this process has been challenged.

Cook et al. conducted an experimental design around a single media event in order to explore the impact of the media on the general public, policy makers, interest group leaders, and public policy. They found that the media event did influence the views about issue importance among the general public and government policy makers, but the change in public opinion was not found to lead to *policy change*. Cook et al. suggest the subsequent policy change following the media event was a result of collaboration between journalists and high-level subcommittee staff members (1983, 31-32).

However, attention to a particular policy area can become heightened due to media priming, where media attention to an issue causes people to place emphasis on a particular topic (Miller and Krosnick 2000). According to Miller and Krosnick, agenda setting "occurs when extensive media attention to an issue increases its perceived national importance" (2000, 301; McCombs and Shaw 1972). Readers recognize newspaper and television stories receive attention because the editors consider them to be important topics even without explicit statements suggesting their relevance to the nation (Iyengar and Kinder 1987; Miller and Krosnick 2000). Therefore, news coverage may influence citizens' perception concerning the importance of a policy issue. Thus, public opinion tends to influence the agenda more than the

alternatives (Kingdon 1995; Rogers and Dearing 1996; Stimson et al. 1995). As previously discussed, actors on the inside and outside of government form relationships in an effort to influence the agenda—including policy alternatives. In order to further understand the dynamics involved in the agenda setting process, the following section describes the influence of subsystem politics and the policy change or stability that occurs as a result of such dynamics.

Subsystem Dynamics and Policy Change

Policy subsystems, also known as policy networks, advocacy coalitions and policy communities are structural arrangements supported by powerful ideas, with patterns of interactions of participants or actors involved in making decisions in special areas of public policy—formed by an executive bureau and congressional committees, with special interest groups intimately attached (Baumgartner and Jones 1993, 3; Freeman 1965, 11; McCool 1998, 552). Policy subsystems may want to broaden the issue definition of a policy or contract it, depending on their goals. Thus, emotional symbols or complicated terms may be utilized (Baumgartner and Jones 1993). Therefore, issue definitions, institutional arrangements, and venue access create the opportunity for subsystem arrangements to be broken up or maintained.

A number of scholars have developed subsystem typologies in order to provide an understanding of the environment where subsystems operate. James Thurber distinguished among dominant, competitive, and disintegrated subsystems. The aforementioned systems are based on the type of policy, issue, and event facing the subsystem actors. “Although the most comfortable state of a policy subsystem is closed, static, and dominant over a particular program, competition and even policy disintegration occurs in any policy area from time to time” (Thurber 1991, 327). According to Thurber’s typology, dominant policy subsystems are relatively stable

and consist of a small number of participants; as such, these subsystems are usually distributive in nature, and combat those who seek to intrude on their autonomy (1991, 327).

Competitive subsystems, those most closely associated with regulatory or redistributive policies are more open and the relationships among the subsystem players are unstable. Competition can often be a result of a redefinition of the issue or by attacks from outside actors (Thurber 1991, 330). Multiple legislative referrals tend to be indicative of a competitive subsystem and competition also results from external events that challenge the subsystem power brokers. Finally, disintegrated policy subsystems experience extensive conflict often resulting in jurisdictional change. The impact and nature of subsystem change is influenced by the scope and level of conflict. In essence, competition among subsystems can lead to intervention from outside interests or increase the visibility of the issue, leading to a higher volume of interested players.

Daniel McCool (1998) further develops a subsystem typology based on conflict control and behavior, specifically focusing on functional behaviors. McCool suggests the principal goal of subsystems is to control conflict with little political liability; therefore, each type of subsystem has a conflict preference. Based on this theory, a preference hierarchy is developed in order to identify four types of subsystems. The hierarchy of conflict includes, exclusionary politics, which occurs when the subsystem effectively excludes potential opponents. Second, cooptation through allocation also occurs when the opponent or opponents are too powerful to exclude; therefore, opponents are influenced or “bought” by sharing subsystem benefits. Third, turf balkanization occurs when two subsystems control various aspects of the policy area. Thus, the two subsystems co-exist, even if tenuously. Finally, there is competitive confrontation, which as

inferred, exists when there is active conflict among subsystems. Subsystem competitiveness and zero-sum largess influence movement from one level in the hierarchy to another.

Worsham (1998) developed a wavering equilibrium theory of subsystem politics to distinguish between three types of subsystems. His approach offers a more parsimonious and empirically useful typology by moving “beyond the traditional dichotomy of iron triangle vs. issue network” (McCool 1998, 557). Worsham’s dominant, transitory, and competing coalitions typology demonstrates how a subsystem’s ability to control the policy agenda varies with a change in subsystem politics (1998, 486). As a first step in tracking subsystem political variation, Worsham conducted a subject search of the Congressional Information Service, U.S. Congress and Committee Hearing Index to locate the relevant hearings dealing with civilian development of nuclear power, forestry policy, and Indian policy. Next, participation profiles for each two year session of congress were constructed based on a review of the abstracts of all hearings. Finally, concentration ratios were constructed by adding the number of interests appearing at hearings during a particular Congress and then dividing the total by the number of witnesses. In essence, he finds subsystems experience cycles over time, which then influence interest group participation, agenda control, and public policy (Worsham 1998, 508).

A second trend in agenda setting process studies examines subsystem change over time. The subsystem change studies provide the research design and methodological structure for the current study. Sabatier and Jenkins-Smith suggest policy change over time is a function of three sets of processes, including competing advocacy coalitions within a policy subsystem, changes external to the subsystem, and stable system parameters (1993, 5). Advocacy coalitions, which are individuals from various backgrounds who share a set of beliefs, are the major focus for understanding change.

Within the ACF framework public policies and programs are thought to exhibit characteristics similar to belief systems. The assumption is based on the premise that public policies and programs are ushered in with implicit theories concerning their objectives. Thus, the belief systems of advocacy coalitions involve value priorities, perceptions of causal relationships, and perceptions of effective policy instruments, among other beliefs. Through internal feedback loops advocacy coalitions experience policy-oriented learning. They try to better understand the external world around them, but they will resist information not in line with their beliefs (Sabatier and Jenkins-Smith 1993, 19).

The ACF framework distinguishes between those parameters that are relatively stable over time and those that are susceptible to significant change. Relatively stable parameters include: (1) the basic attributes of the problem area, (2) the basic distribution of natural resources, (3) fundamental cultural values and social structure, and the basic legal structure. Stable parameters constrain subsystem actors. Dynamic system events, on the other hand, can offer constraints or opportunities: (1) socioeconomic conditions and technology, (2) systemic governing coalitions or “critical elections,” (3) and policy decisions and impacts from other subsystems. In short, policy change over time is a function of the advocacy coalition’s response to learning, external events, and threats to the core beliefs of the subsystem (McCool 1998, 557).

An illustration of policy change due to external events and threats to the subsystem is evident in the construction and collapse of the nuclear policy monopoly studied by Baumgartner and Jones (1993). Baumgartner and Jones show a historically powerful monopoly existed in the 1940’s and 50’s, which framed how nuclear power was defined and effectively shut out competitive visions (i.e. regulatory agencies, atomic energy commission, congressional committees, state public utility commissions, federal and state courts, the mass media, private

investors, and the broader public) (Baumgartner and Jones 1993, 60). Images of protecting the country and maintaining an industrial edge, as well as additional positive uses of nuclear power assisted in constructing the policy monopoly—effectively linking image and venue.

As a measure of attention and tone, Baumgartner and Jones utilized previously coded positive and negative titles listed in the *Readers' Guide to Periodical Literature* for military and civilian uses of nuclear power (1993, 64). Based on the number of articles on civilian nuclear power and the percentage of articles coded positive, they conclude the nuclear power issue emerged once again on the public agenda during the 1960's and 70's. In 1968 the image became negative, as evidenced by the dominance of negative titles. The very image used to strengthen support for nuclear policies now began to undermine earlier successes. Segments of the media and previously uninterested parties became active and institutions that were favorable became opponents.

Government agencies had been created and organized to encourage the private sector to research and utilize nuclear options. In addition, special joint committees of Congress were also influential (Baumgartner and Jones 1993, 66). Negative images began to emerge after the issue definition or policy image was expanded to include previously neglected definitions. Policy venues began to open and the combination of changing policy image and institutions resulted in the destruction of the closed nuclear policy subsystem. The regulatory environment experienced an increase in oversight, as exhibited by Atomic Energy Commission (AEC) annual reports, the number of reactor inspections performed by the AEC, and the increase in Inspection and Enforcement Division staff.

In combination with increasing regulatory oversight, congressional activities also began to change. Based on a coding of all nuclear power hearings from 1945 to 1987 few committees

held hearings (an average of three per year) from 1945 to 1954. But during the period 1969 to 1986, 51 hearings per year were held. The increase in hearings were accompanied by more committees and subcommittees claiming jurisdiction over nuclear policy. Nuclear power opponents were thus able to penetrate the powerful subsystem by utilizing regulatory rules and participating in jurisdictional claims.

Valerie Hunt (2002) also explores the interplay between issue redefinition efforts and the congressional committee system. She examines congressional immigration activity in both chambers in order to observe when and how policy activity shifts to influence long-term policy change. Specifically, Hunt traces the influence of committee entrepreneurial activity on shifts in issue definition and agenda change. These dynamics are examined within and across institutions, because political entrepreneurs often shop a current issue in order to locate the most favorable venue. She utilizes data drawn from The Policy Agendas Project database, which “is a series of comprehensive data sets of U.S. Congressional hearings, public laws, *Congressional Quarterly Almanac* stories, and selected stories from the New York Times spanning over forty-five years of policy making in the United States” (Hunt 2002, 79). Keyword searches and the Policy Agendas Project topic-coding scheme were used in combination with qualitative immigration reform and statute data.

First, Hunt examined the level and intensity of hearing activity in both chambers in order to discern redefinition efforts by policy entrepreneurs and to track subcommittee jurisdiction changes. Second, she compared the level and intensity of legislative output to hearings activity. As an indicator of importance, public statutes were weighted by the amount of news coverage received in the *Congressional Quarterly Almanac*. Following an examination of issue redefinition efforts in hearings activity, Hunt concluded the multidimensional nature of U.S.

immigration policy created opportunities for policy punctuations (2002, 93). In addition, subissues and new emergent issues created opportunities for competing policy venues to challenge the dominant subsystem. Thus, as proposed by the punctuated equilibrium theory – the interplay of issues and venues lead to changes in policy outputs and policy venues.

John Hardin (2002) also relies on the punctuated equilibrium theory to examine how committee jurisdictions have changed over time and influenced the use of committee information. He utilized the area of health care reform to buttress his positive feedback study. Hardin notes how previous studies have acted as if institutions were exogenous to the policy process by assuming committees remain static, hold monopolistic control, and define the committee function (2002, 96). In order to explore the policy process in addition to the congressional structure, Hardin asserts three dimensions influence the nature and extent of information acquired at committee hearings. The *topic* of the hearing, the *target group(s)* providing the context of the hearing, and the type of *witnesses* testifying at the hearing. Information obtained along these three dimensions can differ greatly in each committee; therefore, (1) how many committees acquire information about the stated issue at any given time and (2) the nature and extent of the information committees acquire along each of the three dimensions was empirically examined (Hardin 2002, 100).

Hardin's analysis focused on five factors pertaining to each of the hearings from 1947 to 1993: (1) the committee holding the hearing, (2) the type of hearing, (3) the specific topic(s) of the hearing, (4) the target groups(s) of the hearing, and (5) the interest affiliation of witnesses testifying at the hearing (2002, 101). He utilized the Policy Agendas Project congressional hearings data set. In combination with the available variables, he addressed the specific topics of the hearing, and the target groups of hearings or witnesses testifying at hearings by reading

summaries of each hearing in the *Congressional Information Service Abstracts* (CIS) and using an extensive coding procedure (2002, 101).

His analysis showed between 1947 and 1970, a small number of committees held hearings on health care reform and they received most of their information from health care providers. Beginning in the 1970's various committees began to hold hearings, but the range of witnesses decreased. Further, three topics were the main focus of the hearings. In the 1980's and early 1990's the number and variety of committees holding hearings increased yet again. Herfindahl indexes were constructed to measure the jurisdictional overlap and Hardin found overlap increased for both types of hearings over time. Simultaneous and consistent increases in attention by various groups to health care reform themes were evident. He suggested the "patterns appear to reflect an overarching positive feedback process," due to the increased attention of Congress as measured by hearing activity (Hardin 2002, 120). Specifically, these findings link issues and institutions, and highlight the benefits of longitudinal analysis (Hardin 2002, 121).

Wilkerson, et al. (2002) take on the examination of bills and hearings in order to trace attention in Congress, they too utilize health care legislation. Special attention is given to the policy window concept, where policy images change and thus encourages new participants in the policy area. They highlight the difficulty of quantitatively studying policy windows, but conclude the effects of opening windows can be systematically studied (2002, 251). Due to the multidimensional nature of health care policy, it is an excellent arena to examine policy windows; a specific example is the enactment of Medicare (Wilkerson 2002, 252). According to Wilkerson et al., "the Democratic landslide election of 1964 and President Johnson's Great society program provided the policy window" (2002, 253). Despite the occurrence of a policy

window, external events can encourage or stymie policy outcomes. The lack of national health care reform appears to be a result of these external events.

Wilkerson et al., provide an example of how bill introductions can be used to trace policy dynamics. Hearings are often held to stake claim to a jurisdiction or to show support of an issue, but as suggested by Baumgartner and Jones (2005), institutions suffer from the same bottleneck of attention as individuals; therefore, Congress must set priorities. The approach utilized by Wilkerson et al., compares bill activity in catastrophic health care coverage to committee hearings activity. They use data on the introduction of bills and hearings over twenty years to illustrate the process of policy windows. Specifically, congressional bill introductions concerning catastrophic health care costs from 1973 to 1998 were analyzed.

The bill introductions were obtained by using the Library of Congress's THOMAS website to search for bills containing key words (Wilkerson et al. 2002, 260). Wilkerson et al. note this search approach can produce problems of over or under sampling, but suggest these limitations are less problematic if the interest is in relative interest. In order to account for the aforementioned limitations, bills clearly not health related were eliminated. Based on their analysis, interest in catastrophic health coverage has varied over time and across chambers with the House exhibiting more activity than the Senate (2002, 260).

In order to compare bill activity with hearings activity Wilkerson et al. examined hearings abstracts in the Policy Agendas Project database. Initially, they identified all hearings related to issues of patient costs and coverage in the Medicare program, but due to the over and under sampling limitations and to make bill activity and hearings activity more comparable they reported differences from average levels of activity across the entire time period. Two punctuations in hearings activity occurred—first, from 1979-1980 when hearings activity

increased but without an increase in bill introductions. And second, in the 100th Congress when hearings activity and bill introductions spiked. They state, after a period of softening up, a “series of exogenous events produced rapid increase in interest culminating in a major policy change” – the Medicare Catastrophic Coverage Act (2002, 262). Although, the Act was repealed because Medicare recipients objected to paying for the new benefit (Wilkerson et al. 2002, 263).

By comparing catastrophic bill activity to bill activity on long-term care services and long-term care insurance, Wilkerson et al. find evidence of a spillover effect. A spillover effect is when a window for one subject opens or increases and therefore the probability of a window opening for another policy increases (Wilkerson et al. 2002, 262). The authors show how constituency backlash negatively affected efforts to provide catastrophic health care coverage. Suggesting, policy entrepreneurs must have an arsenal of viable solutions in order to take advantage of various policy windows when they arrive.

Results from the subsystem typology and policy change research, make it apparent conflict and competition affect the stability of a subsystem. Multiple legislative referrals and external events often challenge subsystem power brokers and can result in a competitive subsystem. The power brokers then seek to control the conflict based on their conflict preferences, but the ability to control the policy agenda varies with a change in subsystem politics. In order to effectively hash out the dynamics of these policy changes, the subsystem must be reviewed over a decade or more to allow for at least one cycle of formulation, implementation, and evaluation.

Previous theories of pluralism have emphasized policy incrementalism, but due to insight provided by the policy typology and change research, it is apparent many policy areas experience

long periods of stability with short bursts of change (Baumgartner and Jones 1991, 1044). I seek to understand the dynamic governing the evolution of pharmaceutical policy, and drug importation in particular, as a case study in how positive and negative feedback shape policy subsystems. Specifically, this research examines how Congress governs the multidimensional nature of pharmaceutical policy, including prescription drug importation. The following section details the theoretical perspective underlying this analysis.

Punctuated Equilibrium and Subsystems

In an attempt to understand the nature of the pharmaceutical policy domain and the difficulty in altering the existing policy equilibrium, a promising line of inquiry is the examination of the interplay of positive and negative feedback mechanisms in the maintenance of institutionally induced policy equilibria (Baumgartner and Jones 1991, 1993, 2002).

Punctuated equilibrium theory seeks to explain not only the partial equilibrium or incremental norm of American politics, but also the large-scale disruptions (True et. al., policyagendas.org, 155).

Policy equilibrium occurs when institutional arrangements allow individuals to satisfy their desires. Therefore, in order to understand disequilibria, or policy change, we must understand how institutions satisfy individuals, as well as how individuals alter arrangements to pursue their desires. Thus, any examination of the course of public policy must consider the role of issue definitions, institutional arrangements, and venue access (Jones 2001; Stores and Worsham 2008; Worsham 1998). According to the punctuated equilibrium theory, stability and change are a result of the same institutional system and rules. As issues are defined in public discourse they rise and fall in the public agenda, which can lead to reinforcement of existing policies (negative feedback) or policy redefinitions can lead to the questioning of policies at the

most fundamental levels—creating opportunities for major reversals in policy outcomes (positive feedback) (True et. al., policyagendas.org, 156; Baumgartner and Jones 1991, 1993, 2002).

Instead of equilibrium balancing public preferences and public policies through a combination of elections (social theory) and the open struggle of interest groups (group theory), stability is enforced through a complex system of mutually non-interfering policy monopolies (Baumgartner and Jones 1993). Partial equilibria is therefore maintained through the allocation of governmental elite attention and apathy from others who are not interested in the policy area or issues (Baumgartner and Jones 1993, 18). Thus, although punctuations are possible, the policy system is stable in the way it processes information or ideas. The presence of policy equilibriums suggest that policy monopolies effectively limit access to the political process.

Negative feedback models are thus characterized by shocks in the system being resisted, which eventually settles back to the status quo. Furthermore, negative feedback is an indicator that institutional arrangements are allowing groups to achieve their desires (Baumgartner and Jones 1991, 1993, 2002, Worsham 1998). The subsystem creates barriers to policy participation by restricting the number of interests involved in a particular policy area. Therefore, if congressional committees fail to represent the interests of a particular group, then policy problems related to that group may be displaced (Baumgartner and Jones, 1993). In short, the presence of limited access in the pharmaceutical policy domain could realistically lead to less than optimal drug policy, as ideas and interests that challenge the status quo are displaced.

On the other hand, positive feedback occurs when shocks or changes introduced into the system lead to a new point of stability. Typically, a system experiencing equilibrium will not change significantly, and when a force does push the system away from its stable point, it will move back to equilibrium over time (Baumgartner and Jones 1993). If a system is not in a state

of equilibrium, minor shifts in inputs can lead to dramatic, cascading changes in policy outputs (Baumgartner and Jones 1993, 16). According to Kingdon, success in one policy area can lead to a spillover process, as politicians and winning coalitions transfer the formula to a similar area in hopes of continued success (Kingdon 1995, 203).

The agenda therefore experiences periods of volatility, even while the policy alternatives remain relatively stable. Thus, policymaking experiences periods of structure induced equilibrium and punctuated change. When new issues emerge on the agenda new institutional structures are often created and remain for a decade or more if the general principles of the current policy are not challenged. However, when a new principle or issue definition is considered, agenda access can destroy the previous institutional structure. Therefore, studying change in committee control of policy jurisdiction is central to studying policy subsystems to determine the variant of subsystem politics in play and what interests are represented (Stores and Worsham 2008; Worsham 1998).

Thus, my study continues the line of work already established by Baumgartner and Jones (1993), McCool (1990), Thurber (1991) and Worsham (1998, 2006). In addition to understanding the alteration, if any, of the pharmaceutical subsystem, the interaction between issue definition and congressional venue are examined in order to assess how prescription drug importation has emerged and evolved on the governmental agenda. Several scholars have focused on the economic merits for and against importation, but a systemic agenda-setting account has not been conducted. The question thus becomes how the multidimensional nature of prescription drug policy and the congressional committee system interact to allow the various dimensions to gain agenda access in different committees within Congress.

Based on the proposed theory, I expect to find periods of punctuations due to cue taking or mimicking characterized by negative feedback as shocks to the system and actions of policy entrepreneurs influence the agenda setting of pharmaceutical policy. In addition, as the subject matter of legislation introduced varies, I expect to see signs of increased competition due partly to the activities of policy entrepreneurs. The next chapter will provide a history of key pharmaceutical regulation in the United States as the first step in examining the ideas, interests, and institutions entrenched in the pharmaceutical policy domain.

Pharmaceutical Regulation in the United States: An Institutional History

“Drug regulation is a complex system in which physicians, government regulators, the pharmaceutical industry, and disease-based organizations fight about or, less frequently, collaborate on clinical trials, approval decisions, and the monitoring of side effects.”
Daemmrich 2004, X

The pharmaceutical policy subsystem is founded on relationships fostered among congressional actors, regulatory agencies, the pharmaceutical industry, the medical profession, disease-based organizations, and consumers. The historical evolution of the pharmacy subsystem is a textbook example of how an institutionally induced equilibrium works to foster a policy monopoly and at the same time illustrates how punctuating events upset such relationships. Given the diversity of interests that are active in the policy domain, the prescription drug subsystem is marked by intense periods of competition and conflict. The result is that U.S. drug policy has experienced regular and significant renegotiation of authority among the key players in medical policy (Wood 1986; Daemmrich 2004). So, for example, as the Food and Drug Administration (FDA) expanded its authority, physician authority to represent the patient was weakened. Similarly, when disease-based interest groups became major players, they worked to usurp regulatory and or physician authority to set policy. Quite simply, group-based efforts to set the agenda quite often move another group’s concerns off the stage. In the end, it is the competition and conflict among the various participants that sets the theme for the pharmaceutical policy realm.

As will be illustrated throughout this chapter, the role of policy entrepreneurs is essential to altering the dominant image (and reigning policy) associated with pharmaceutical regulation. Conflicts over the meaning of information leads to subsystem challenges as groups try to extend or preserve their authority to determine policy. In examining the issue salience of prescription

drug regulation and its rise and fall on the systemic and institutional agenda, my intention is not to provide an exhaustive historical account (see Bailey 1930; Anderson 1958; Temin 1980; Wood 1986, Young 1989 for such efforts), but rather an analysis of how the multidimensional nature of prescription drug policy and the congressional committee system have interacted to allow various dimensions of the issue to gain a foothold on the agenda at a particular moment in time.

Grabowski and Vernon (1983) have characterized three distinctive periods in the history of American drug regulation, an approach I adopt in this chapter. The period 1906-1937 was an era that concentrated on preventing misbranding and adulteration of drugs. Therefore, I refer to this era as *the era of patent medicine correction*. The *patent medicine correction* period is characterized by a predominantly market-oriented approach to drug regulation that sought to correct market failure by preventing misbranding and adulteration of drugs, using the 1906 Pure Food and Drug Act and subsequent amendments in 1912 as a guide (Ceccoli 2003, 166; 2004; Grabowski and Vernon 1983, 2).

The second major period, 1938-1961, is characterized by a mix of market mechanisms and *centralized control* on the part of the FDA (Ceccoli 2003; 2004). The 1938 Food, Drug, and Cosmetic Act sought to remedy some of the weaknesses in the 1906 Act by expanding regulation and requiring pre-market proof of safety by manufacturers.

The third major period, 1962-1991, ushered in an era of even more *stringent centralized controls*. Following the passage of the 1962 Kefauver Amendments pharmaceutical manufacturers were required to receive regulatory approval prior to clinical testing and to prove drug safety and efficacy prior to marketing the drug (Ceccoli 2003; Grabowski and Vernon 1983; Jackson 1970).

Ceccoli (2003, 167; 2004) suggests a fourth period of drug regulation beginning in 1992, when the FDA rebalanced their risk-benefit analysis with an emphasis on making new drugs available sooner through the Prescription Drug User Fee Act. As the FDA began to broaden their interpretation of consumer protection, centralized controls gave way to a period that focused on *accommodating public access* to new pharmaceuticals.

Finally, it appears we are in the midst of a fifth period, marked by the passage of the Medicare Modernization Act in 2003. The fundamental philosophy of the current period is characterized by *expanded entitlements and renewed attention to safety concerns*.

In this chapter, I examine the five periods of American drug regulation, highlighting the key pharmaceutical policies enacted in each period, as well as the institutions, actors, and events that led to the enactment of these policies. As will be seen, drug policy is a result of balancing the competing, and often contradictory, needs of the major players in the subsystem, with the desire to serve the public interest for access to safe and effective prescription drugs.

1906 – 1937: Patent Medicine Correction

The first period of drug regulation was ushered in by the policy entrepreneurship of Harvey Wiley, known as the “Crusading Chemist.” Wiley, director of the Division of Chemistry (the precursor to the FDA), was interested in protecting the consumer from wide spread misbranding of pharmaceuticals, and expanding the jurisdiction of his bureau. Following a twenty-year campaign for a national pure food and drug law, Wiley and the USDA were well known among Congress, women’s groups, and business organizations for their analytical expertise. By establishing multiple networks, the department avoided catering to one set of Progressive interests, an approach Wiley used to engage in coalition building (Carpenter 2001, 256). Despite opposition from Republican Congresses in the late 1890s and early 1900s, Wiley

and his coalition of more than 100 organizations spurred Theodore Roosevelt and Congress to action with the passage of the 1906 Pure Food and Drugs Act (PFDA) (Carpenter 2001, 2). The PFDA attempted to prevent misbranding and adulteration of drugs and its passage also established an institutional legacy for what would become the Food and Drug Administration.

While my account of pharmaceutical regulation takes the 1906 Pure Food and Drugs Act as its starting point, regulation of pharmaceuticals was a topic of discussion during the latter half of the 19th century. Between roughly the end of the Civil War and the turn of the century, more than 100 food and drug bills were introduced in Congress. All eventually died in committee, due in part to the lack of sustained public concern, as well as questions regarding the constitutional authority of Congress to regulate commerce (Temin 1980, 28). Between 1879 and 1882 several general anti-adulteration bills were introduced in Congress, two substitutes were reported favorably in the House, but none became law (Anderson 1958, 70). Instead, anti-adulteration laws were state level creations, which led to difficulties when it came to enforcement across state lines. As the economy became increasingly national, at least some commercial interests agreed that national regulation was needed. To be sure, not all business interests supported a national pure food and drug law—their support or opposition was based on how the law would influence their profits (Wood 1986, 109). Enter Harvey Wiley.

Harvey Washington Wiley began work with the Chemistry Division of the Department of Agriculture in 1883 (Carpenter 2001, 201). He came to the department after teaching nine years at Purdue University where he had established himself as an expert in the analysis of sugar (Carpenter 2001). The agricultural economy of the late 1800s was volatile and Wiley's sugar expertise spurred him to build alliances with the Louisiana Sugar Producers' Association, a powerful actor in Democratic politics, as well as Gulf State farmers (Carpenter 2001). Although

Wiley achieved limited success in campaigning to expand sugar production, due to costly technology, he had built a strong alliance among planters, investors, state chemists and college officials. Following the stagnated sugar campaign, Wiley took up an interest in pure food in an effort to expand the role of the Chemistry Division.

Wiley, acting as a policy entrepreneur, worked to secure support for national level regulation by working with the Association of Official Agricultural Chemists, the National Board of Trade, Farm Journal Editors, and the Senate Agriculture Committee, under Algernon S. Paddock (R-NE). For example, the National Board of Trade (NBT), an organization of civic trade groups and chambers of commerce, helped to promote state-level campaigns. New York, New Jersey, and Massachusetts established state health boards, but state level activity declined following their establishment. Nonetheless, state chemists had become empowered to establish and enforce health standards. Further, the NBT also endorsed and had several bills introduced in Congress in the 1880s. None passed due to the inability of the various conflicting interests to find some middle ground (Anderson 1958).

In 1883 Dr. Harvey Wiley, known as the “Father of the Pure Food and Drugs Act,” became chief chemist of the Division of Chemistry and expanded the Bureau of Chemistry’s food adulteration studies (Anderson 1958; FDA 1999). Working with Algernon S. Paddock (R-NE), chair of the Senate Agriculture and Forestry Committee, he fashioned a bill that was the direct predecessor of the Pure Food and Drugs Act. It passed the Senate but died in the House due to opposition from cottonseed oil producers, and other manufacturers who were afraid their industries would be affected negatively by the legislation (Anderson 1958, 80).

Because the more direct legislative route proved impossible, Paddock worked within established channels to encourage Wiley’s entrepreneurship. The result was a Bureau of

Chemistry study that focused on the health effects of chemical preservatives and coloration. Wiley's food adulteration studies and his "Poison Squad," aided by additional events, drew attention and support for a federal food and drug law (Carpenter 2001). In the words of James Harvey Young (1989, 4) the period leading up to the passage of the Pure Food and Drugs Act was characterized by "change, complexity, competition, crusading, coalescence, compromise, and catastrophe."

Change originated from the research revolution—scientific discovery during the last third of the nineteenth century resulted in new technology for identifying adulterants. The new technology allowed scientists to narrow down the number and type of adulterants present in various food, drink, and drugs. In addition to industry changes, the legislative process became complex due to the omnibus food, drink, and drug bills in Congress. Producing and processing units were located in essentially every congressional district, which led to a large number of interest groups becoming involved (Anderson 1958; Young 1989).

Competition further complicated the omnibus bills in Congress, because less reputable food, drink, and drug makers drove down market prices with their cheap goods, which led non-adulterating processors to seek assistance through Congress. Farmers, in addition to industry producers, also complained as oleomargarine, a new invention from France, threatened the butter market. Single subject legislative bills, such as the drug import and oleomargarine act, were successful because they received support from influential interest groups, physicians, pharmacists, and dairy farmers who attempted to protect their competitive interests (Young 1989, 5).

Wiley, seeing an opening despite the seeming policy chaos, made adulteration studies the cornerstone of the Division of Chemistry in the Department of Agriculture (Young 1989, 5). He

was able to bring together business, state agricultural chemists, state and local government associations, physicians, women's club members, and journalists—key economic, political, and social organizations of the Progressive Period because of the common concern with adulteration. As a successful political entrepreneur he was able to join these previous conflicting interests into an effective coalition that raised public awareness and pressured legislators to consider adulteration of food, drink, and drugs a regulatory responsibility of the federal government (Anderson 1958; Young 1989, 5; Temin 1980).

Wiley's numerous affiliations would end up being a requirement for passage of the 1906 act. Adulteration was placed on the public agenda by 1898 as a result of the National Food and Drug Congress. The congress, which met in Washington, DC that year, included representatives from state and federal government along with "trade, manufacturing, agricultural, scientific, and medical associations" intent on formulating national level regulation (Anderson 1958, 124; Carpenter 2001, 260). Due to the efforts of the congress, the National Grange, the Farmers' National Congress, wholesale grocers, the health officer of the District of Columbia, and the editor of the Washington Post all joined the call for a federal food law (Anderson 1958, 124). The 1898 Congress was the first national gathering to bring attention to the misbranding and adulteration of both food and drugs. Harvey Wiley delivered the central address to the Pure Food Congress, which focused on adulteration in scientific terms. Given the prevalent belief in the "invisible hand" of the market, Wiley was careful to express his opposition to any prohibition to the manufacturing of goods—he only wanted protection from deception for the innocent consumer (Anderson 1958; Wood 1986, 51).

The argument was focused on the importance of honesty in the market, but did not challenge the free-market ideals of the Progressive Period. Manufacturers managed to secure

exclusions for disclosing their trade formulas, the National Confectioners' Association secured a special definition of adulterated candy, and trade interests lobbied to narrow the definition of drugs "to include only cosmetics and products recognized as medicines in the United States Pharmacopoeia and the National Formulary"—thus excluding proprietary or patent drugs (Anderson 1958, 125). Wiley convinced the National Food and Drug Congress (NFDC) to endorse a regulatory measure written by the Association of Official Agricultural Chemists (AOAC). From 1898 to 1900 Wiley succeeded in encouraging Representative Marriott Brosius of Pennsylvania and others to introduce several bills based on the AOAC measure (Anderson 1958; Carpenter 2001, 261). None passed.

The National Food and Drug Congress met twice more, once in 1899 and once in 1900, in order to raise awareness regarding the anti-adulteration movement, but in 1900 the congress moved toward reducing the Chemistry Divisions power. Wiley lost interest and the institution eventually dissolved (Carpenter 2001, 262). Although the NFDC dissolved, the networks and coalitions forged during its development linked together farm organizations, the Women's Christian Temperance Union, civic leagues and business associations, in pursuit of a bill for pure food and drugs. Wiley came out of the experience with a reputation as an expert and champion of anti-adulteration measures. Therefore it was not a surprise when William E. Mason (R-IL), chairman of the Senate Committee on Manufactures, hired Wiley as an analyst to guide the committee during the fifty-one days of hearings on food adulteration in 1902.

Wiley analyzed food samples and interviewed witnesses. His daily interaction with the investigation committee over two months established him as an authority on adulteration (Anderson 1958, 129; Carpenter 2001, 262). The Mason hearings set the policy agenda, focusing congressional attention on the adulteration of food and drugs and raising public

awareness through press coverage. Momentum for legislation grew, and Wiley drafted the bill that Mason introduced in the Senate in 1902. If Wiley was able to get the topic on the Senate agenda, a coalition of baking powder, blended-whisky, and dairy interests managed to make sure it never came up for a vote.

Wiley inevitably helped to create opposition to the pure food legislation he ardently supported, by making statements and encouraging regulation that favored some companies' products over others (High and Coppin 1988, 294). In addition to protecting the consumer, Wiley was also interested in pure food legislation as a way to expand the importance and authority of the Chemistry Division in the Department of Agriculture (Carpenter 2001; High and Coppin 1988). Therefore, Wiley's bureau was threatened when the National Association of State Dairy and Food Departments suggested a separate bureau within the federal government be created to administer the law.

It was this threat that spurred Wiley to action—he went to work securing support from Robert M. Allen, secretary for the National Association of State Dairy and Food Departments, his superior, Melville A. Scovell, and Edmund Taylor, maker of Old Taylor brand straight whiskey for the McCumber-Hepburn bill (High and Coppin 1988, 294-95). Although he did not receive an official endorsement for the bill, Wiley was successful in garnering support from the group's executive committee (High and Coppin 1988, 295).

In December 1902, the House of Representatives passed a broad pure food and drug bill introduced by William P. Hepburn of Iowa. Porter McCumber, the new chair of the Senate Manufacturers Committee, attempted to introduce a similar bill, but due to opposition from the proprietary drug industry, the publishing industry, and the National Wholesale Liquor Dealers the Senate refused to consider the legislation (Carpenter 2001; High and Coppin 1988).

McCumber's Senate bill broadened the definition of drugs to "include any substance intended to cure, mitigate or prevent disease," which encompassed all proprietary medicines, and the publishing industry stood to lose substantial revenues from advertising patent medicines (High and Coppin 1988, 297). The whiskey rectifiers continued to oppose any pure food bill that would require them to label their product as an "imitation."

Frank Barrett, editor of the *American Grocer*, suggested to Wiley that the bill did not pass due to the lack of public support (Carpenter 2001; High and Coppin 1988). Wiley thus set out to broaden publicity of his cause against adulteration with research experiments using human subjects to test the health implications of various adulterants. Wiley's "Poison Squad" consisted of a dozen volunteers restricted to specific diets, including food additives such as boric acid, salicylic acid, and formaldehyde, which were all found to be harmful to the volunteers' digestion or health (Carpenter 2001; Temin 1980, 28). Wiley published his research results in Bulletin 84, in which he concluded even small doses of specific adulterants can cause digestive disturbances (Carpenter 2001, 264).

Wiley's experiments received wide-spread attention from the public and Congress. Partly due to increased public attention and concern, the 1902 and 1903 Appropriations Acts granted new discretion and authority to the Agriculture Secretary and the Association of Official Agricultural Chemists (AOAC) to set standards for food and drug purity. The drug market became a subject of study in 1902, following the drug tragedy of a contaminated diphtheria vaccine in children that resulted in the deaths of twenty-one children in Saint Louis, Missouri, and Camden, New Jersey (Carpenter 2001; Young 1982). The 1902 Biologics Act passed in response to this tragic event. Despite this advancement in regulation, Wiley's goal for pure food and drug legislation continued to face entrenched opposition by the Proprietary Association,

blended-whiskey manufacturers, dairy interests, and baking powder interests. Once again, the Fifty-Seventh Congress did not enact a pure-food law.

The Fifty-Eighth Congress considered the bill once more, and following a few modifications the bill passed the House. Hearings in the Senate were even more extended. The committee on Manufacturers took up the bill, and the definition of drugs was broadened to include patent medicines. The committee reported the bill favorably on January 15. In February, the Senate committee considered the measure that had passed the House. Attacks on patent medicines resulted in powerful new opposition by the *National Druggist*, an influential journal subsidized by proprietary interests, and the Proprietary Association of America (Anderson 1958, 157).

The Proprietary Association, a group of small patent medicine firms and their allied newspapers, formed in 1881 (Temin 1980). Doctors and drug firms that used only ingredients listed in the *United States Pharmacopoeia* and the *National Formulary* were in opposition to the Proprietary Association. In the 1900s patent medicines, which were bought without the aid of a doctor, were a threat to the profession. The Proprietary Association spent large sums of money to influence legislators. By their investment in advertising they effectively controlled a large portion of the nation's press—sponsoring protest meetings, radio propaganda, and memorials (Jackson 1970; Anderson 1958). In addition, the National Association of Wholesale Druggists and the National Association of Retail Druggists also opposed the broadened definition of drugs to include “any substance intended to be used for the cure, mitigation, or prevention of disease” (Anderson 1958, 162). Wiley tried to reassure a variety of interests, and many chose to support the bill before the Senate, including some food commissioners. Despite these positive

implications, the bill reported to the Senate was not considered due to the strong opposition from the drug trade (Anderson 1958, 163).

Prior to the convening of the Fifty-ninth Congress in December 1905, Wiley was able to get the two principal women's federations of the period, the Women's Christian Temperance Union and the General Federation of Women's Clubs (GFWC), behind the bill. Support of the women's groups was important due to their effectiveness at keeping a constant pressure on legislation (Anderson 1958). For example, the GFWC was the organizational backbone for the early development of child and women's welfare programs in the U.S. (Carpenter 2001, 265). New Jersey activist Alice Lakey was particularly influential in securing the endorsement of the New Jersey chapter and persuading the General Federation to create a pure-food committee. In addition, she garnered support from the National Consumer's League in support of Wiley's campaign (Carpenter 2001, 266). Finally, due to an alliance Wiley had with Charles A.L. Reed, a Cincinnati physician and president of the American Medical Association (AMA), he received support from the AMA as well.

Prior to 1900 pure food legislation was considered by the Agriculture Committee, which was favorable toward the USDA. Yet, in the Fifty-Ninth Congress, the House and Senate *Agriculture* Committees never saw the food and drug legislation. First, the bill was referred to the Agriculture and Forestry Committee, but Redfield Proctor (R-VT), the Senate Agriculture Committee chairman, requested the Agriculture Committee be excluded from considering any pure food bills. James Wilson, Secretary of the USDA, and Proctor were developing a close relationship and Secretary Wilson sought to restrict Wiley's enforcement power (Carpenter 2001). Therefore, beginning in 1902, the Senate *Committee on Manufacturers* took authority over the legislation. The House leadership referred the Hepburn bill to the *Interstate and*

Foreign Commerce Committee, chaired by Representative James R. Mann, an Illinois Republican (Carpenter 2001, 266).

Despite the committee assignment, Wiley's coalition building, increased public interest, and pressure from President Theodore Roosevelt to enact a food and drug law proved imperative in influencing congressional members. Public interest was raised in part by the publication of Upton Sinclair's *The Jungle*¹, and Samuel Hopkins Adams, *Collier's Weekly* series.

Specifically, *The Jungle* highlighted the horrendous details of the meatpacking houses and *Collier's Weekly* brought to light the severity of drug adulteration (Carpenter 2001, 269; High and Coppin 1988, 303-04).

The bill passed the House by a vote of 241 to 17, with 9 "present" votes, and 112 abstentions (High and Coppin 1988). Debate in the Senate was protracted due to fears that the Chemistry Bureau was given too much regulatory control. Therefore, substitute measures were introduced by Senator Hernando DeSoto Money (D-MS), limiting the power of the Bureau. But, in the end Money voted for the bill, and the Senate passed the McCumber measure by 63 to 4, with 22 senators abstaining.² Despite Congressional concern regarding the extension of federal police power into the states and resistance to intrusion by the federal government into private activities, the Wiley-Hepburn bill passed 241 to 17, and President Roosevelt signed the Pure Food and Drugs Act of 1906 and the 1906 Meat Inspection Act into law the same day (Carpenter 2001, 269-270). The 1906 Pure Food and Drugs Act set forth requirements for food and drugs sold in interstate commerce—it prohibited the interstate transport of unlawful food and drugs under penalty of seizure of the products and/or prosecution of the responsible parties. Therefore,

¹ Publication of Sinclair's *The Jungle*, also influenced the passage of the Meat Inspection Act, signed into law the same day as the Pure Food and Drugs Act (High and Coppin 1988, 304).

² According to High and Coppin, the large number of abstentions may have been a protest to the public pressure Wiley's publicity campaign aroused (1988, 304).

the act prohibited the shipment or delivery of adulterated or misbranded goods, but did not directly regulate the adulteration or misbranding of food and drugs—it was *product labeling* that was regulated (Ahmad 2007, 26).

Debate exists as to whether the passage of the 1906 Act was due to special interests (Kolko 1967) or as an attempt to expand bureaucratic power (Coppin and High 1999; Carpenter 2001), and yet others suggest the law was enacted due to a “mixture of bureaucratic, producer and consumer interests,” including consumer interests brought about by muckraking journalism (Law 2004, 5). What is apparent is that the Progressive Era was influenced by the political maneuvering of Harvey Wiley, industrialization, the rise in laissez-faire capitalism, and the growth in collective action organizations (Wood 1986, 67).

Business advocates of the Pure Food and Drugs Act were interested in reducing competition for their businesses, consumer advocates desired the public be safeguarded from “unscrupulous business principles,” and Congress was viewed by many interest groups as a tool for their self-interest (Wood, 1986, 68). The entrepreneurial activity of Harvey Wiley coalesced the interest of many business and public interest groups in an effort to overcome the equilibrium that had resulted in a protracted legislative battle for pure food and drugs. In combination with a venue change from the Agriculture Committee to the Senate Committee on Manufacturers and the House Interstate and Foreign Commerce Committee, these interests proceeded to influence congressional members by framing adulteration as an issue of public safety and truth-in-advertising—resulting in the passage of the Pure Food and Drugs Act.

Enforcement of the Pure Food and Drugs Act rested with the Bureau of Chemistry, which was renamed the Food, Drug, and Insecticide Administration in 1927. The name was shortened in 1931 to the Food and Drug Administration (FDA) and was transferred from the USDA to the

Federal Security Agency (later renamed the Department of Health and Human Services –DHHS) (Law 2004, 5). Following the 1906 Food and Drugs Act, from 1906 to 1929 drug legislation focused on prohibiting false labeling—congressional oversight committees became more aware of the profits garnered by the drug industry as drug sales rose.

Between 1906 and 1929 drug industry sales increased by a factor of six, with patent medicines, those that contained secret ingredients, accounting for half of all sales (Temin 1980, 38; Grabowski and Vernon 1983). Further, in 1911 the Supreme Court ruled the 1906 Food and Drugs Act prohibited false and misleading statements about the ingredients or identity of a drug, but not false therapeutic claims. In 1912, Congress enacted the Sherley Amendment to overcome the 1911 ruling, prohibiting labeling medicines with false therapeutic claims intended to defraud the purchaser (FDA 2006). A difficult standard to prove. This flaw would lead to further regulatory reform over the following decades.

The policy entrepreneurship of Harvey Wiley led to an alliance of multiple networks, which culminated in the passage of the Pure Food and Drugs Act. The research revolution, Wiley’s “Poison Squad,” and market competition drew attention and support for the first federal food and drug law. Business advocates—the nonadulterating producers, consumer advocates and Harvey Wiley were the winners in this protracted battle. On the other hand, despite their ardent opposition, the Proprietary Association lost their effort to have patent medicines excluded from the new law. The U.S. government did not have a direct interest in the success of the pharmaceutical industry. Thus, early drug safety laws indicate the pharmaceutical industry was not yet an influential actor in the policy domain (Ceccoli 2004). Further, the transfer of pure food and drug legislation from the Agricultural Committee to the Commerce Committees impacted the thrust of the bill. The Commerce Committees interpreted the regulatory issue at

hand to be one of mislabeling. Over the following decades, pharmaceutical regulation would further evolve in a centralized and regulatory fashion.

1938 – 1961: Market Mechanisms and Centralized Control

The second period of drug regulation from 1938 to 1961 was often a result of focusing events opening a policy window for legislative action and expanded bureaucratic authority. For example, the diethylene glycol (1937), sulfathiazole tablets (1941), and chloramphenicol (1952) incidents led to legislation requiring proof of safety *and* efficacy. The 1906 law had provided the Bureau of Chemistry with little enforcement power. Therefore, from 1930 through the 1950's, the focus was on extending control and regulation over prescription drug manufacturing vis-à-vis quality control measures enforced by the FDA. The reform legislation was written within the FDA; therefore, it is no surprise the law would end up strengthening the agency (Temin 1980).

Similar to the 1906 act, congressional debate was protracted. President Roosevelt was supportive, but did not work actively for its passage. Public support or opposition was scant and the proprietary drug industry did not openly oppose the bill for fear they would destroy public confidence in their products (Temin 1980). Yet, the patent medicine manufacturers worked behind the scenes to weaken the law. It was also during this time that the pharmaceutical industry evolved into an industry that “discovered, developed, and marketed drugs of real use in treating disease” (Hilts 2003, 95). The drug tragedies of this period, the political maneuvering of Rexford Tugwell, Assistant Secretary of Agriculture, Walter Campbell, the FDA bureau chief, and pressure from consumer advocates provided the attention necessary to end the five year legislative battle. The passage of the Federal Food, Drug, and Cosmetic Act of 1938 broadened

the definition of drugs, included medical devices, restricted the range of drugs that could be offered, and mandated what information should be supplied to the consumer.

The “Tugwell Bill,” as it was commonly known, was introduced in 1933 by Senator Royal S. Copeland (D-NY), member and later chairman, of the Commerce Committee (Cavers 1939). Tugwell, a Columbia University economist, had a preference of planned economies. He “was universally unpopular with those in the business community” (Ceccoli 2004, 69). The new bill would prohibit misstatements and advertising claims and all ingredients were required to be listed on the bottle. Tugwell’s intent was to improve self-medication by safeguarding the consumer. Despite his unpopularity with the business community, the entire food and drug industry were not unified against the bill. Only those who stood to lose the most profit were particularly vigilant in their attacks of the measure. The two trade groups most active in their attacks were the Proprietary Association and the Institute of Medicine Manufacturers (Hilts 2003). The major issues of concern to the opposition, particularly the Proprietary Association, were, (1.) the FDA’s power of multiple seizures, (2.) whether control of advertising of foods, drugs, and cosmetics should be under the jurisdiction of the FDA or the FTC, and (3.) the power of the Secretary of Agriculture to establish tolerances for poisons (Cavers 1939).

The American Medical Association, women’s clubs, scientists, state health officials, pharmacists, public health groups, and a few companies that sought a competitive advantage supported the bill in its original form. Some of these groups were interested in further consumer protection. Indeed, the AMA, the Consumers’ Research group, and the American Pharmaceutical Association did not support revised versions of the bill, because industry groups were allowed to remove the requirement that drugs should be proven safe before being marketed (Hilts 2003, 88). In an effort to imitate Harvey Wiley’s Poison Squad, the FDA assembled a

graphic display of the 1906 pharmaceutical and other regulation shortcomings referred to as the “Chamber of Horrors”³ (Hilts 2003; FDA 2006). By the time hearings were scheduled, trade organizations were well organized against the bill—with the drug industry charging the bill was an effort to prevent the American people from exercising their right to self-medication.

As a result of the hearings held before the Senate Committee on Commerce and the House Committee on Interstate and Foreign Commerce, it became obvious that concessions would be required in order to appease the opposition to the point where the measure could be passed. Senator Copeland agreed to numerous modifications along the way, but while one concession appeased one interest, yet another grew in opposition. The Federal Trade Commission (FTC) became a strong opponent, due to the jurisdictional turf battle between the FTC and the FDA over false advertising. The Tugwell bill ended in a legislative disaster; however, the glycol tragedy would serve as the basis for increased regulation (Ceccoli 2004).

In 1937 diethylene glycol killed 107 people, many women and children. The Massengill Company, a respected drug firm, sought to sell a liquid form of sulfanilamide by dissolving sulfanilamide in diethylene glycol, which was later found to be toxic (Cavers 1939; Temin 1980, 42; Hilts 2003). The FDA recovered almost the entire amount of product that had been distributed, but only because it had been falsely labeled an “elixir,” otherwise the FDA would have had no legal basis for the seizure. In addition, the label did not include the fatal ingredient—diethylene glycol. This focusing event placed greater relevance and importance on banning interstate commerce of harmful substances. After five years of legislative hearings, four major revisions, and the diethylene glycol incident, President Roosevelt signed the Federal Food, Drug, and Cosmetic Act (FDCA) into law on June 25, 1938.

³ The exhibit included pictures, labels, and adulterated or deceptive packaging that was beyond the enforcement of the FDA under the 1906 Act.

The Federal Food, Drug, and Cosmetic Act of 1938 overhauled the 1906 Food and Drug Act, requiring drugs to be marketed with adequate directions for safe use, extended FDA authority to include medical devices and cosmetics, eliminated the Sherley Amendment requirement to prove intent to defraud in drug misbranding cases, and introduced *mandatory pre-market approval for new drugs* (Law 2004, 6). Manufacturers would now have to demonstrate the safety of their products and obtain the approval from the FDA via a new drug application (NDA). Equally important, the 1938 regulation allowed the FDA to inspect production facilities to ensure accuracy and credibility of manufacturer-provided information. It also made it mandatory for consumers to visit licensed doctors in order to receive a prescription for certain classes of drugs thought to be unsafe, without direction by a physician (Temin 1980, 49-50; Wertheimer and Santella 2007, 305). While the 1906 Act had focused on the prevention of consumer fraud, the 1938 act outlawed unsafe products in the interest of protecting the consumer. It was apparent government regulation was moving in a direction to provide more protection to the consumer.

Despite the passage of the Act, the Winthrop Chemical Company of New York distributed sulfathiazole tablets tainted with phenobarbital, resulting in approximately 300 deaths and injuries in 1941 (Swann 1999; FDA 2006). This event opened a policy window for the FDA to revise manufacturing and quality controls, commonly known as good manufacturing practices (GMP). In 1948 the Supreme Court upheld the FDA interdiction in the sale of illegal drugs by pharmacies. The court ruling extended the jurisdiction of the FDA into retail distribution where the sale of illegal drugs, especially barbiturates and amphetamines was rampant (FDA 2006). Disagreement over whether to include amphetamines and barbiturates as prescription drugs led

to conflict between physicians, pharmacists, drug companies, and the FDA (Temin 1980; Law 2004, 7).

The policy response was the Humphrey-Durham Amendment in 1951, which defined prescription drugs as those unsafe for self-medication and which should therefore be used only under a doctor's supervision (FDA 2008). Shortly following the 1951 amendments, the FDA conducted a nationwide factory investigation which revealed that chloramphenicol, an antibiotic, was linked to 180 incidents of blood diseases. The American Society of Hospital Pharmacies, the American Association of Medical Record Librarians, and the American Medical Association were engaged by the FDA in a voluntary drug reaction reporting program (FDA 2006). The remainder of drug regulation in the 1950s focused on factory inspection and the intricacies between proof of safety and efficacy.

From the development of penicillin in 1941 to the late 1950s, major advances in pharmaceutical innovation occurred, including the introduction of antibiotics (e.g. penicillin, tetracyclines), tranquilizers, antihypertensives, diuretics, and antidiabetic agents (Temin 1980, 65; Grabowski and Vernon 1983, 2). Competition in the pharmaceutical market increased, with a focus on new chemical entities (NCE) at the rate of over fifty per year. Following World War II the drug industry transformed from one of small firms to one of large firms. Companies introduced products for which they held patents or patent rights—together with aggressive advertising—these new drugs resulted in “high profits, growing sales, and growing firms in the 1950s” (Temin 1980, 76). With increased competition and development of NCEs congressional oversight committees began to turn their attention to the high profits earned by a portion of the industry. In addition, patents and trademarks received increased congressional attention, as they were thought to be the source of above-average profits (Grabowski and Vernon 1983).

The drug tragedies of this era opened a window for policy change in combination with the political maneuvering of Assistant Secretary of Agriculture, Rexford Tugwell and bureau chief, Walter Campbell. The passage of the Federal Food, Drug, and Cosmetic Act of 1938 broadened the definition of drugs, to include medical devices and introduced *mandatory pre-market approval for new drugs* among other provisions. This premarket approval process is the basis for current drug regulation in the U.S. With the passage of the 1938 Act, consumers were ensured stronger safeguards, and the FDA expanded their enforcement authority. The drug industry on the other hand, came under intense scrutiny due to drug related deaths and their increased profit margins. Following the 1938 Act, pharmaceutical regulation would change little over the next three decades until the early 1960s.

1962 – 1991: Stringent Centralized Controls

The policy entrepreneurship of Senator Estes Kefauver (D-TN) and the thalidomide drug tragedy catalyzed the third period of drug regulation. Kefauver's 1962 amendments strengthened and centralized the drug review process while also expanding the regulatory jurisdiction of the FDA. Following passage of the 1962 amendments, pharmaceutical manufacturers were required to receive regulatory approval prior to clinical testing and marketing—standards that would impact the agency's performance over the next three decades.

The debate concerning pharmaceutical profits, markups, the availability of over the counter drugs, and drug efficacy continued to dominate the agenda in the late 1950s and early 1960s. In 1959 Senator Estes Kefauver (D-TN), Chairman, of the U.S. Senate Antitrust and Monopoly Subcommittee held a series of hearings in an effort to raise salience and gain expertise regarding pharmaceutical pricing and patenting (Temin 1980; Meier 1985, 83). Kefauver introduced an amendment to the Food, Drug, and Cosmetic Act in an effort to expand Judiciary

Committee turf. The amendment sought to foster competition among drug companies and increase FDA authority over drug manufacturing and introductions by requiring drug companies to license, produce, and sell their products at a maximum of 8 percent of sales (Temin 1980). The bill also focused on safety—requiring new drugs to be proven safe and efficacious before being marketed. Although several notable physicians supported the bill, the legislation was completely revised—the licensing provision was completely removed before being reported out of the Judiciary Committee. Shortly after, the thalidomide drug tragedy raised public awareness concerning drug dangers.

In 1960 a subsidiary of the Vick Chemical Company, Richardson-Merrell, Inc., applied for FDA approval of thalidomide, (a sedative, marketed as a remedy for the symptoms of morning sickness). An FDA examiner, Dr. Frances Kelsey, refused to let the application take effect on the grounds of insufficient information. In 1961 thalidomide was identified as the source of phocomelia—a condition where children are born without hands or feet—in thousands of babies in Europe (Temin 1980; Grabowski and Vernon 1983; Hilts 2003; Law 2004).

Evidence from Europe linking thalidomide with birth defects caused the Kefauver committee to refocus its attention on safety issues (Grabowski and Vernon 1983; Meier 1985, 83). The thalidomide incident was the impetus for the Kefauver-Harris bill. The revised bill required claims of effectiveness in new drug applications (NDA) to be supported by “substantial evidence,” but the provision to lower the price of brand name drugs was removed on the Kennedy administration’s orders (Temin 1980, 124). President Kennedy and Senator Kefauver differed on pharmaceutical pricing reform (Ceccoli 2004).

The 1962 Kefauver-Harris drug amendments required FDA approval before a drug could be marketed and gave the FDA jurisdiction over the testing of new drugs. Drug companies

would have to receive FDA approval of their procedure before beginning their investigational drug tests, now regulated by investigational new drug (IND) requirements (Temin 1980; Grabowski and Vernon 1983; Hilts 2003; FDA 2006). In addition, drug companies were required (1) to adhere to a set of good manufacturing practices, and (2) use generic names and brand names on labels and advertisements. The FDA was granted further administrative power to withdraw applications that had been approved prior to 1962 (Temin 1980, 125). These amendments were revolutionary—for the first time drug companies would be required to conduct scientific studies.

Drug company executives and their allies claimed the new regulations would result in the slashing of expansion plans and slow new drug development—resulting in higher costs for the consumer (Hilts 2003, 161). The Pharmaceutical Manufacturers Association representative, L.T. Coggeshall, claimed, “in the present climate of strict regulation, scientists would no longer want to go into drug company research” (Hilts 2003, 161). The AMA also fought the new law—as a threat to their authority to determine the effectiveness of drug treatment. Despite this opposition from the pharmaceuticals industry, the bill passed—further expanding the regulatory role for the FDA.

Since the passage of the 1962 Drug Amendments, federal drug regulations have evolved over several lines. In some cases, regulation strengthened the government’s authority over drug trade. For example, the agenda of the 1980s and 1990s focused on drug application review, concerns over a drug lag, availability of generic drugs, and reimportation restrictions due to safety concerns. In the 1980s more than one thousand AIDS activists staged a demonstration in front of the FDA’s headquarters in an effort to lobby for access to investigational drugs (Ahmad 2007). As a result of this interest group pressure, the 1983 Orphan Drug Act was passed, which

enabled the FDA to promote research and marketing of drugs needed to treat rare diseases that would normally be unprofitable or unpatentable (Villarreal 2001).

Disease-based interest groups continued pressuring the FDA and in 1987 drug regulations were revised to expand access to experimental drugs for patients with serious diseases with no alternative therapies. The FDA began to allow personal importation of drugs as a result of AIDS activist lobbying for access to medications not yet available in the United States (Wertheimer and Santella 2007, 306). Yet, in 1988 Congress found the resale of drugs outside commercial channels resulted in the distribution of mislabeled, adulterated, and counterfeit drugs to the public. Therefore, the Prescription Drug Marketing Act of 1988 was passed, which banned the diversion of prescription drugs from legitimate commercial channels, required drug wholesalers to be licensed by the states, and restricted reimportation from other countries (Greenberg 1988; FDA 2006). Manufacturers of drugs in other countries were thus required to meet FDA standards and allow FDA inspections. Despite these provisions, the importation of pharmaceuticals continued.

In other cases, regulations were enacted to encourage the pre-market approval process for new drugs. The pharmaceutical industry and medical community became concerned about the pace of FDA review for new drugs—defined as the rate at which new pharmaceuticals become available to consumers. William Wardell, a Board-certified Clinical Pharmacologist, identified what he termed a “drug lag”—showing that the United States fell behind other similarly advanced countries in the number of new drugs available (Wardell et al. 2007). In the 1990s, partially due to concern over a drug lag, there were many requests to overhaul the FDA drug regulations, especially from the Republican-controlled Congress, led principally by the House speaker, Newt Gingrich (Ahmad 2007, 28). The drug lag debate highlighted the substantial

differences in performance between the FDA and its international counterparts over the next decade.

Pharmaceutical regulation in the 1960s was ushered in by the political maneuvering of a skilled policy entrepreneur—Senator Estes Kefuaver (D-TN) and a high profile drug tragedy. The 1962 amendments further expanded the regulatory jurisdiction of the FDA, and strengthened consumer confidence in drug safety. For the first time drug companies would be required to conduct scientific studies and receive premarket approval. Following this landmark legislation, the FDA came under intense scrutiny regarding their drug review performance. The “drug lag” debate opened a window for the pharmaceutical industry, academic reformers, and disease-based interest groups to pressure the FDA into altering their processes. The next period of drug regulation reflects this change in policy actors—evidenced by the evolving relationship between the pharmaceutical industry and the FDA.

1992 – 2002: Accommodating Public Access

The fourth period of drug regulation sharply diverged from the post-1962 emphasis on safety and efficacy standards. By the late 1980s the pharmaceutical industry and an academically based regulatory reform movement started to compare FDA performance with their international counterparts. William Wardell published numerous articles documenting the existence of a drug lag in the United States. For example, he demonstrated that between 1962 and 1976 the U.S. had 3.5 times fewer drugs available compared to the United Kingdom (Ceccoli 2004). The existence of a drug lag was further documented from organizations and economic departments such as the American Enterprise Institute (AEI), the University of Chicago, and the Tufts University Center for the Study of Drug Development (CSDD). In 1980 a subsequent international drug lag comparison was conducted by the General Accounting Office of Congress

(GAO), they concluded the U.S. and Sweden had the longest average approval time (Ceccoli 2004; Hilts 2003, 277).

In 1980 Congress also began holding oversight hearings to investigate the slow approval process of the FDA. The Republican Party spearheaded the investigation, but was later joined by the pharmaceutical industry, academics, disease-based interest groups and Democratic and Republican members of Congress (Ceccoli 2004). The drug lag debate provided the window of opportunity for the pharmaceuticals industry, the academic reform movement, and disease-based interest groups to challenge the policy monopoly that supported a more risk-averse approach to drug regulation.

David Kessler, FDA Commissioner, was instrumental in aligning the interest of industry, Republicans, and a diverse group of patient activists. Kessler worked with the Pharmaceutical Manufacturers Association and PhRMA to draft a bill that would provide user fees to the FDA and extend the types of drugs that were eligible for expedited review (Ceccoli 2004). The legislation was co-authored in the House by Energy and Commerce Committee chairman Henry Waxman (D-CA). Edward Kennedy (D-MA) and Orin Hatch (R-UT), the chair and ranking Republican respectively, co-authored a similar bill in the Senate Labor and Human Resource Committee. In 1992 the Prescription Drug User Fee Act (PDUFA) was enacted and later renewed in 1997, 2002, and again in 2007. The FDA began to require drug and biologics manufacturers to pay fees for product applications, supplements, and other services, including hiring reviewers to assess applications (Law 2004, 8; FDA 2006). The passage of the PDUFA ushered in a transformation of the relationship between industry and the FDA.

Prior to 1992 the industry and the FDA had a contentious relationship, because the pharmaceuticals industry perceived the FDA as being too cautious. The FDA in turn questioned

the motives of the pharmaceuticals industry (Ceccoli 2004). With the passage of the PDUFA review times began to drop immediately, but concern rose that the FDA was at the mercy of the drug industry due to the substantial financial fees the agency received (Hilts 2003; Okie 2005). The dependency of the FDA on the pharmaceutical industry fees was further exacerbated by Congress' tendency to reduce overall federal funding to the FDA since the mid 1990s (Ceccoli 2004; Hilts 2003). This dependency is evidenced by the fact that user fees from pharmaceutical companies account for more than half the money dedicated to the review process (Hilts 2003, 280; Okie 2005, 1064; Ahmad 2007).

In 1997 the Food and Drug Administration Modernization Act (FDAMA) reauthorized the PDUFA of 1992 and mandated the most wide-ranging reforms since the Food Drug and Cosmetic Act of 1938 (FDA 2008). The FDAMA "liberalized the FDA's approval criteria, reduced the number of clinical trials required to demonstrate the effectiveness of a new drug, and accelerated the drug-approval process" (Ahmad 2007, 29). The 2002 renewal of the PDUFA was included in a bioterrorism bill which increased industry fees to the FDA—earmarked to speed drug approvals. Subsequent renewals have been viewed by some as "giant giveaways to the pharmaceutical industry," due to the Act's requirement that the FDA lower its standards for drug approvals (e.g., accepting one clinical trial) (Angell 2004, 204).

The passage of the 1992 Prescription Drug User Fee Act was catalyzed by a coalition that helped change the image of pharmaceutical regulation from one of safety and efficacy to that of consumer access. AIDS activist effectively pressured such change due to their expertise and their relentless activism. The PDUFA represented a major change in focus from protecting the public from adulterated, misbranded, and unsafe drugs to one of assuring access to new drugs more quickly. Some have argued that the PDUFA and the FDA's shrinking resources to monitor

post-marketing safety problems, suggest the industry receives greater attention than the public health mission (Isamail 2005).

With the passage of the PDUFA, user fees were levied on the pharmaceutical industry in order to sponsor new drug applications and annual regulatory guidelines were also mandated for the FDA. Such changes reflect a policy image that moved from safety and effectiveness to one of access. The pharmaceutical industry and disease-based interest groups benefited by changes in the new drug application process, but the FDA came under increasing scrutiny. Two landmark drug events in 2004 would raise consumer protection to the forefront of the agenda once more.

2003 – 2007: Expanded Entitlement & Renewed Safety Concerns

On December 8, 2003 President George W. Bush signed the Medicare Prescription Drug Improvement and Modernization Act (MMA) into law, which made the largest overhaul in the history of Medicare by authorizing Medicare coverage of outpatient prescription drugs, in addition to other changes (Oliver et al. 2004). Despite this historical event, public opinion on the final bill was negative. According to a poll that was taken during the week the bill was signed into law, 47 percent of senior citizens were in opposition to the changes (Oliver et al. 2004, 284). However, the bill passed partly due to presidential and congressional changes, which opened a window of opportunity for the MMA. It is important to note the pharmaceutical industry resisted a centrally administered federal program and in the end influenced the provisions of the enacted bill.

One of the most significant provisions of the bill maintained the current ban on reimporting prescription drugs from other countries, but authorized the FDA to study the potential impact of reimportation from Canada. Thus, one of the major beneficiaries of the new

plan was the pharmaceutical industry, which spent more than 108 million dollars on lobbying for the MMA (Lipowski and McKercher 2007, 341). The pharmaceutical industry could now expect higher demand, no direct administration of benefits by the government, no cost control measures, and drug reimportation remained illegal (Oliver et al. 2004, 318; Oliver et al. 2007). The AFL-CIO, Association of Federal, State, County and Municipal Employees did not support the bill due to the inadequacy of the drug benefit. Despite this opposition the bill passed.

In 2004, pharmaceutical safety emerged on the agenda once more. Two landmark events: (1) the determination that the use of selective serotonin reuptake inhibitors (SSRI) antidepressants in children were associated with suicidal behavior, and (2) the withdrawal of the cyclooxygenase (COX)-2 inhibitor drug rofecoxib from the market due to its association with cardiovascular events affected all stakeholders in the pharmaceutical policy domain. Once again drug safety rose to the top of the systemic agenda (Ahmad 2007, 30).

Over the past century drug tragedies and policy entrepreneurs have been the catalyst for major changes in drug regulation. The antidepressant and rofecoxib debacles may be an opportunity for yet a new period in U.S. drug policy. Recent debate has centered on the creation of a new center for post-marketing drug regulation, whether the FDA can meet its mission, and pharmaceutical industry post-market compliance. These events may be an indicator of a new period in U.S. drug regulation—a move to recentralize control with the FDA to ensure greater safety. Whether meaningful policy change will occur—only time will tell.

Conclusion

The story of the development and evolution of U.S. pharmaceutical regulation illustrates the dynamic of policy change, which is dependent on shifts in issue salience, as well as, the actions of actors and events inside and outside of government. The major component of post

New-Deal pharmaceutical policy has been a mix of safety and access policies. These policies began by increasing the control and authority of the FDA (and its predecessors in the USDA) and ended with a new relationship between Congress, the FDA, the pharmaceuticals industry, and disease-based interest groups.

The historical development of the Food and Drug Administration began with the passage of the 1906 Pure Food and Drugs Act. Responsibility for enforcement of the 1906 Act was later transferred to the FDA's predecessor, the Bureau of Chemistry. In July 1927, the Bureau of Chemistry's name was changed to the Food, Drug, and Insecticide Administration, which also led to the non-regulatory research function of the bureau being transferred to other divisions within the department (FDA, 2008). In July 1930 the name was further shortened to the present version. "FDA remained under the Department of Agriculture until June 1940, when the agency was moved to the new Federal Security Agency. In April 1953 the agency again was transferred, to the Department of Health, Education, and Welfare (HEW). Fifteen years later FDA became part of the Public Health Service within HEW, and in May 1980 the education function was removed from HEW to create the Department of Health and Human Services, FDA's current home" (FDA, 2008).

Although the relationship between the FDA and the pharmaceuticals industry was contentious for the better part of a century, the passage of the Prescription Drug User Fee Act resulted in a shift in the policy actors. The pharmaceuticals industry and disease-based interest groups effectively pressured the FDA to modify their regulatory processes. In the remaining chapters I am concerned with detailing how the pharmaceutical subsystem functions over a long period of time. Once it has been established that participation in the subsystem varies over time, the task becomes understanding how political variation impacts the policy process. In order to

do this, in Chapter 4, I map political change over a sixty-year time span by focusing on bill introductions and referrals.

Table 3.1 Distinctive Periods in the Regulation of New Medicines

	1906-1937	1938-1961	1962-1991	1992-2002	2003-2007
Fundamental Philosophy	Patent Medicine Correction	Centralized Control	Stringent centralized controls	Accommodating Public Access	Expanded entitlements & renewed safety concerns
Focusing Event	Unsanitary conditions; quacks	Elixir Sulfanilamide (diethylene glycol)	Thalidomide	AIDS-related deaths	Selective Serotonin Reuptake inhibitors; rofecoxib
Landmark Law	1906 Pure Food and Drugs Act	1938 Federal Food, Drug, and Cosmetic Act	1962 Kefauver Amendments	1992 Prescription Drug User Fee Act	Medicare Modernization Act
Benefactors	Harvey Wiley; Consumers; food commissioners; Women's Clubs; AMA	Scientists; Consumers; State Health Officials; Public Health Groups; a few Companies	Consumers; FDA	AIDS activist; Cancer activist; industry; FDA	Pharmaceutical Industry; Physicians; AARP
<i>Source: Ceccoli 2003 & Author</i>					

Table 3.1 Milestones of Drug Regulation in the United States-1848-2003

1848

Drug Importation Act passed by Congress requires U.S. Customs Service inspection to stop entry of adulterated drugs from overseas.

1906

The original Food and Drugs Act passed by Congress prohibits interstate commerce in misbranded and adulterated foods, drinks and drugs.

1911

U.S. vs. Johnson, the Supreme Court rules that 1906 Food and Drugs Act prohibits false and misleading statements about the ingredients or identity of a drug.

1912

Congress enacts the Sherley Amendment to overcome the ruling in U.S. vs. Johnson. Amendment prohibits labeling medicines with false therapeutic claims.

1933

FDA recommends a complete revision of the obsolete 1906 Food and Drugs Act. The first bill is introduced into the Senate, launching a five-year legislative battle.

1937

Elixir Sulfanilamide, containing the poisonous solvent diethylene glycol, kills 107 persons, dramatizing the need to establish drug safety before marketing and to enact stringent drug laws.

1938

The Federal Food, Drug, and Cosmetic (FDC) Act of 1938 is passed by Congress. In addition to other provisions, new drugs had to be shown safe before marketing, thus starting a new system of drug regulation.

1948

Supreme Court rules in U.S. v. Sullivan that FDA's jurisdiction extends to retail distribution, thereby permitting FDA to interdict in pharmacies illegal sales of drugs--the most problematical being barbituates and amphetamines.

1951

Durham-Humphrey Amendment defines the kinds of drugs that cannot be used safely without medical supervision and restricts their sale to prescription by a licensed practitioner.

1962

Kefauver-Harris Drug Amendments are passed to ensure drug efficacy and greater drug safety. For the first time, drug manufacturers are required to prove to the FDA the effectiveness of their products before marketing them.

1966

Fair Packaging and Labeling Act requires all consumer products in interstate commerce to be accurately labeled, with FDA enforcing provisions on drugs.

1984

Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) expedites the availability of less costly generic drugs by permitting the FDA to approve applications to market generic versions of brand-name drugs without repeating the research done to prove them safe and effective.

Milestones of Drug Regulation in the United States-continued

1988

Food and Drug Administration Act of 1988 officially establishes FDA as an agency of the Department of Health and Human Services with a Commissioner of Food and Drugs appointed by the President with the advice and consent of the Senate.

The Prescription Drug Marketing Act bans the diversion of prescription drugs from legitimate commercial channels. The new law requires drug wholesalers to be licensed by the states; restricts reimportation from other countries; and bans sale, trade or purchase of drug samples, and traffic or counterfeiting of redeemable drug coupons.

1992

Generic Drug Enforcement Act imposes debarment and other penalties for illegal acts involving abbreviated drug applications.

The U.S. FDA with Japan and Europe establish the International Conference on Harmonization (ICH). The ICH works to reduce the burden of regulation by harmonizing regulatory requirements in the three regions.

Prescription Drug User Fee Act (PDUFA) requires drug and biologics manufacturers to pay fees for product applications and supplements, and other services. The act also requires FDA to use these funds to hire more reviewers to assess applications.

1997

Food and Drug Administration Modernization Act (FDAMA) reauthorizes the Prescription Drug User Fee Act of 1992 and mandates the most wide-ranging reforms in agency practices since 1938.

2003

The Medicare Prescription Drug Improvement and Modernization Act requires, among other elements, that a study be made of how current and emerging technologies can be utilized to make essential information about prescription drugs available to the blind and visually impaired.

Source: FDA 2007

Agenda Status and Policy Subsystems

“The complete “dance of the legislature” encompasses several discrete events—bill introduction, the referral of legislation to committee, hearings, the reporting of legislation from committee, and floor activity. These various activities are both the heart and soul of the legislative process and key determinants of winners and losers in the policy game.” – Worsham 1997, 64

In the preceding chapters I discussed how any attempt to understand the course of public policy, must inevitably, consider why one set of issues is addressed through policy while an equally important set of alternative issues are not. Specifically, the historical account of pharmaceutical policy in the United States provided an excellent example of how the variation of policy participants combined with external events can and does impact policy outcomes. Once an issue has been defined, policy actors must be engaged in order for the issue to be placed on the decision making agenda (Eyestone 1978). In an effort to determine how Congress has governed the agenda of pharmaceutical policy, I examine bill introductions in the House and Senate from 1947-2007.

Bill introductions serve as an important indicator of congressional interest in a policy area. Although few bills actually become law, bills are an indicator of the goals members of Congress wish to accomplish (Schiller 1995). Legislators are constrained by political and institutional contexts; therefore, bill introductions provide insight into the issues that are given priority status. Further, bill referrals provide insight into committee jurisdiction and competition.

I have three objectives for this chapter. First, I present analysis concerning the rise and fall of pharmaceutical bill introductions in both chambers, where the overall level of pharmaceutical policy activity is ascertained. Second, I provide an examination of the issue composition of the introductions in an effort to identify the topics that receive the most attention. Third, I present information concerning the referral of bill introductions. The presence of bill

referrals illustrates committee competition and monopoly (Wilkerson, Feeley, Schiereck and Sue 1999; King 1997). In addition, bill referral and sponsorship help to indicate the success or failure of entrepreneurial activity.

Congressional Interest and Policy Jurisdiction

Like others who have made an effort to track agenda entrance with a focus on legislative activity (Worsham 1997; Wilkerson, et al 2002; Ringquist, Worsham and Eisner 2003; Worsham 2006), I focus on legislative introductions as a first step in tracking the level of congressional interest in the policy domain. Similarly, I use bill referrals as a means of getting a feel for the level of competition in the pharmaceutical policy domain (King 1994, 1997). The data on legislative introductions were gathered using *The Congressional Bills Project*, as well as the *THOMAS* search engine. I include simple, concurrent, joint resolutions, and public bills in the count. The congressional bills project data were gathered using the topic codes “Regulation of Drug Industry, Medical Devices and Clinical Labs” and “Prescription Drug Coverage and Costs.” The congressional bills project data yielded 1,063 bills, 956 in the House and 107 in the Senate for the years 1947 to 1998. A *THOMAS* subject search using the key term “prescription drugs” yielded 402 bills, 214 in the House and 188 in the Senate for the years 1999 to 2007. The *Congressional Bills Project* data were combined with the *THOMAS* search yielding a total of 1,465 bills—1,170 in the House and 295 in the Senate.⁴

Associated with the move from a system characterized by a policy monopoly to one in the throes of competition is a loosening of subsystem control over the dominant image underlying the policy equilibrium. Thus, like others who have tracked legislative activity, (Worsham 2006; Hardin 2002; Baumgartner and Jones 1993) the topic of bills were coded after

reading the title and summary of each introduction. As suggested by Babbie (1998, 314), I utilized the “mostly” rule of thumb—meaning what is the content of the material *mostly* about. The coding scheme is intended to highlight six dimensions of pharmaceutical policy, coding legislation based on bill titles and/or summary remarks found in the *Congressional Bills Project* and *THOMAS*. Bills coded *Safety* include legislation dealing with the general safety and or effectiveness of pharmaceutical products. An example is a bill to amend the Federal Food, Drug, and Cosmetic Act and related provisions of law to improve the protection of the public health and safety with respect to drugs. *Manufacturing and Distribution* includes legislation that discusses drug manufacturing and distribution. For example, legislation regulating the manufacture, compounding, processing, distribution, and possession of habit forming barbiturate and amphetamine drugs, or a bill to amend the Federal Food, Drug, and Cosmetic Act relating to the distribution chain of prescription drugs.

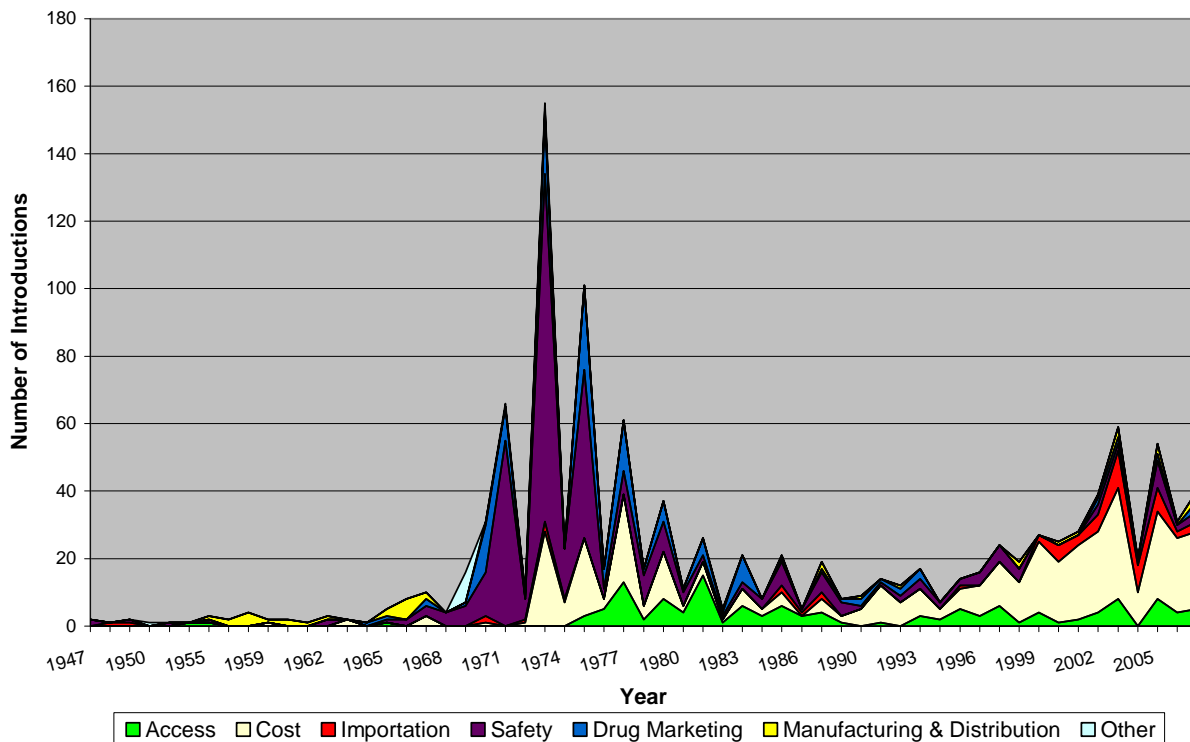
Drug Marketing includes legislation that discusses drug marketing, licensing, labeling, and advertising. *Access* includes legislation that focuses on increasing access to certain populations, such as veterans and Medicare or Medicaid recipients. *Cost* contains legislation that specifically seeks to address efforts to increase the affordability of prescription drugs. *Importation* includes legislation that discusses the intent to modify the law to allow importation from designated countries, restrict importations, discussions concerning the regulation of internet pharmacies, and exportation provisions. The final category, *Other*, is a catch-all for bills that do not fit the other six categories.

A review of figures 1 and 2 (House and Senate bill content, respectively) reveals the obvious, more legislation is introduced in the House than is the case in the Senate, and both

⁴The *THOMAS* search term “prescription drugs” was selected following verification of consistency between *The Congressional Bills Project* data and the *THOMAS* subject search. The data set was combined and completed by

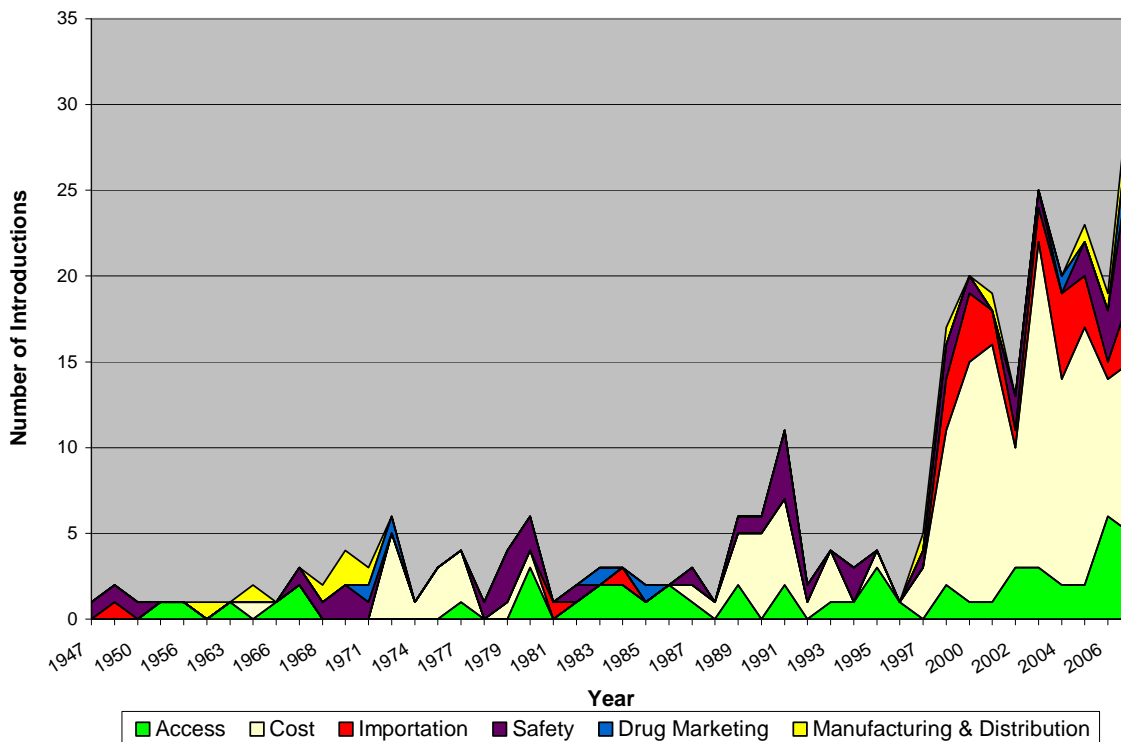
chambers explore multiple dimensions of pharmaceutical policy over the course of the study. Cost and safety receive the majority of attention in the House, compared to cost and importation in the Senate. The House initiated minor activity concerning pharmaceutical policy from 1947 to 1968, focusing mainly on manufacturing and distribution until 1968. Most surprising is the low level of activity around 1962, despite the focusing events associated with thalidomide and the passage of the Kefauver-Harris drug amendments that resulted. Then again, low issue salience is typical of a subsystem characterized by a dominant coalition, which the focus on manufacturing and distribution seem to suggest is the case in the House (an impression the referral data reinforce, as will become apparent in the following section).

Figure 1. Pharmaceutical Bill Content: House



searching and recoding the data based on textual summaries as suggested by Baumgartner and Jones (2002, 38).

Figure 2. Pharmaceutical Bill Content: Senate



Between 1968 and 1975 cost and safety became the primary focus of legislative introductions in the House. The increased attention to cost, particularly in 1973, was in response to the rising cost of intravenous and intramuscular prescription drugs furnished to Medicare recipients in physicians' offices—the result of a provision allowed under Medicare part B of the Social Security Act, an amendment which went into effect in 1966 (Oliver et al. 2007, 12).⁵ Virtually all cost legislation introduced from 1971 until the early 1990s concerned amending prescription drug coverage of the Social Security Act. Safety introductions during this juncture focused on bills to amend the Federal Food, Drug, and Cosmetic Act (FD&C) due to rising suspicion concerning cosmetic ingredients. Notably, in the early 1970s books were published and newspapers ran cosmetic safety articles constantly on a variety of issues including “asbestos

in baby talc,” and “hydrocarbons in hair sprays” (McEwen et al. 2000, 189). The single piece of legislation to emerge in response to the safety bill introductions was Public Law 92-387, which passed in 1971, amending the FD&C Act by imposing more stringent requirements for cosmetic ingredient labeling, among other provisions.

The increased introductions regarding drug marketing from the early to mid-1970s are a product of the Kefauver-Harris drug amendments. The drug amendments required drug manufacturers to prove to the FDA the effectiveness of their products prior to marketing. The requirements of the 1962 amendments resulted in conflict between the FDA, which was under order from Congress to remove ineffective products, and the pharmaceutical industry which preferred the pre-existing status-quo, moving subsystem politics into a more competitive mode (Wardell et al. 2007, 193). Indeed, during this period Congress “conducted hearings that regularly sought to expose problems with drug safety and alleged misconduct by the pharmaceutical industry or the FDA (or often both)” (as reinforced in the following chapter) (Wardell et al. 2007, 195). House legislative introductions decline from their dramatic highs in the 1980s, when cost and safety receive the most attention. In 1990 cost and importation begin to dominate the agenda prior to the passage of the Medicare Modernization Act (MMA) of 2003 when prescription drug costs increased by double digits and bill introductions again increase in dramatic fashion.

Senate bill introductions follow a slightly different pattern than was the case in the House. As was the case in the House, there is very little activity in the earliest years of the study, indeed, little action occurs on the Senate legislative front through the 1990s. The focus between 1947 and 1970 is primarily on manufacturing and distribution and safety. Similar to activity in

⁵ The disabled and persons with end stage renal disease were added to the Medicare program in 1972, which resulted in a rapid increase in expenditures for prescription drugs furnished in physicians’ offices (Oliver et al. 2007, 12).

the House, from 1973 to 1977, cost legislation increases in response to Medicare part B of the Social Security Act. Although legislation related to prescription drug coverage in Medicare was introduced and continued in subsequent years, the provisions “remained matters of heated debate rather than legislation until 1988 when the Medicare Catastrophic Coverage Act was enacted,” and later repealed (Oliver et al. 2007, 13). Legislative introductions concerning the topic of cost increased once again in the late 1980’s along with a focus on drug application review, the availability of generic drugs, and re-importation restrictions.

As was the case in the House, introductions accelerate dramatically in the late 1990s, with cost the dominant topic prior to the MMA of 2003. As noted in the historical analysis, introductions concerning safety of pharmaceuticals increase in 2005 following the association of selective serotonin reuptake inhibitors (SSRI) antidepressants in children with suicidal behavior and withdrawal of COX-2 inhibitor drug rofecoxib from the market.

The increased legislative activity in both chambers appears to be both a product of change in regulatory policy, and has in turn provoked more efforts to alter the regulatory landscape. Thus, the initial surge in introductions is no doubt a product of the Medicare part B program of the Social Security Act. The act was an effort to provide financial protection for the elderly against the high cost of inpatient hospital care after retirement. Subsequent inclusion of individuals under the age of 65 who were Social Security Disability Insurance beneficiaries and individuals with end stage renal disease, to the Medicare program resulted in a dramatic increase in expenditures for prescription drugs administered in the doctor’s office (Oliver et al. 2007, 13). For example, from 1993 to 2001, these expenditures increased from 2.9 percent to 10 percent of physician and clinical services expenditures (Oliver et al. 2007). As a result of the dramatic price increases, reimportation of drugs from other countries entered as an option to get around

the rising costs of prescription drugs (FDA 2006). If the 1965 act sparked increased introductions, and an increasing focus on cost, one result was the passage of the Medicare Prescription Drug Improvement and Modernization Act in 2003.

Clearly in both chambers legislative introductions cycle through a variety of concerns associated with the drug industry. Two observations stand out. First, the focus over time is one in which cost dominates the discussion. And second, increased bill introduction activity does not always create a more varied discussion (as Baumgartner and Jones have found in the case of hearings). For example, increased bill introductions in the House in the 1970s deal with essentially two topics—safety and cost. On the other hand, the increase in introductions in the 1990s is associated with a wider variety of concerns on the agenda in both chambers.

Turf Control

Having mapped the prescription drug agenda, I now turn to the issue of jurisdictional control. While a variety of studies have used hearing data to get a feel for congressional turf, I track bill referrals as a first step towards tracking the institutional boundaries of the prescription drug subsystem. As King (1997) has documented, controlling referrals is essential to a committee intent on preserving turf. Thus, I am interested in determining whether there is a change in legislative subject matter documented in the previous section and the identity of committees to which legislation is referred. The preceding gives rise to the following hypothesis:

Hypothesis 4.1: As bill referrals escape the policy domain, the image of pharmaceutical policy changes—resulting in a competitive subsystem.

Figures 3 and 4 map the referral of legislation in the House and Senate, respectively. A quick review of the figures reveals that the prescription drug policy domain in both chambers varies between the dominant and competitive coalition scenarios. In the House the Commerce

Committee enjoys virtually unchallenged status as the destination of legislation. The dominance of Commerce gives way to two periods of competitive politics in the 1970s and the 1990s, in which Ways and Means acts as a rival venue. Similarly, the committee on Health, Education, Labor, and Pensions (and its various predecessors) dominates bill referrals in the Senate for most of the time series. The exception is the period characterized by competition that begins in 1997 and continues to the present day, when the Finance committee actually serves as the dominant destination for legislation. An explanation for this switch is the changing subject matter of Senate legislation (figure 2), which is dominated by bills focused on prescription drug costs (supporting hypothesis 4.1).

Still, I am left to wonder about the lack of such sustained competition in the House, despite a similar shift in focus to costs. It appears that King’s (1997) observations regarding Commerce, and its ability to hold onto and expand its turf, is borne out by the data.

Figure 3. House Bill Referrals

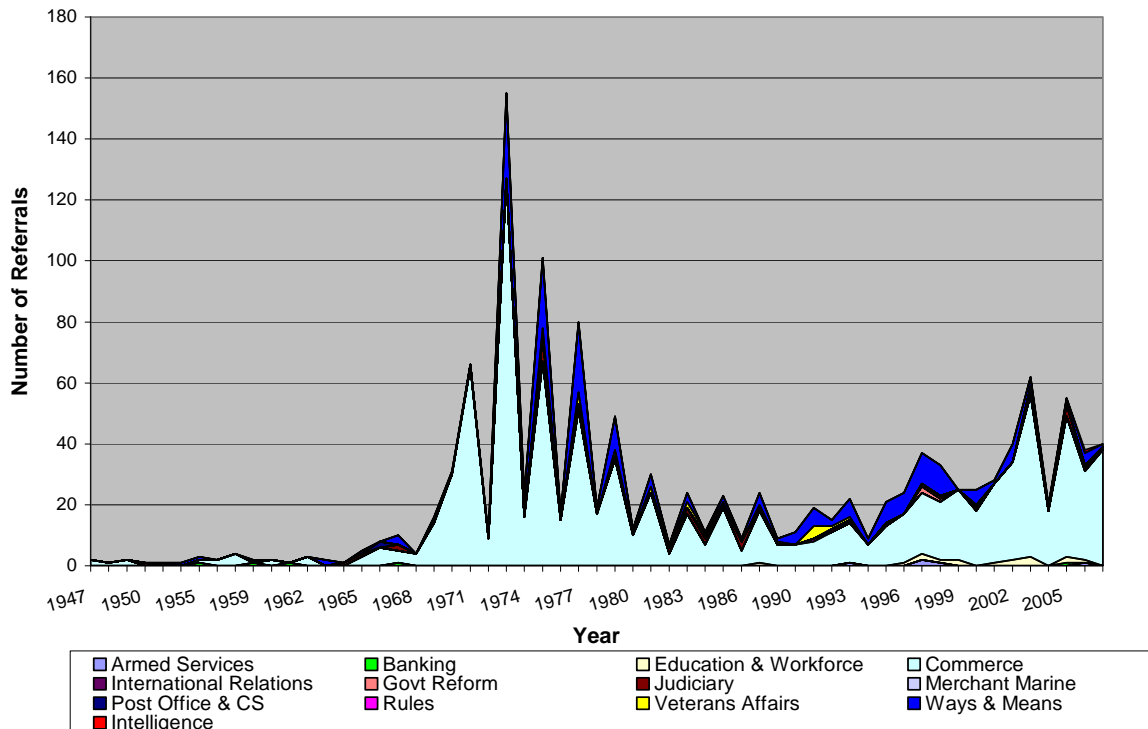
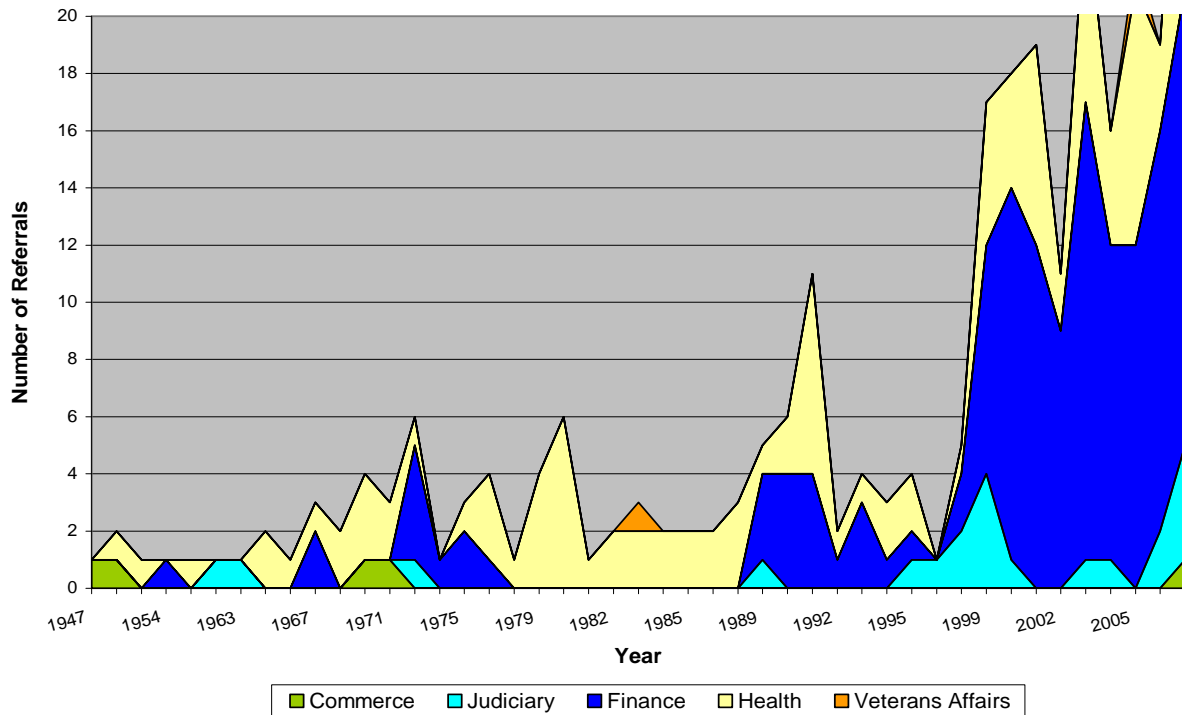


Figure 4. Senate Bill Referrals



Another means for getting a feel for jurisdictional control is through the construction of a Herfindahl index.⁶ A Herfindahl index score is calculated by squaring the proportion of committees receiving referrals and then summing the squares of those proportions. The result is an index score that ranges from zero to one, where a score close to zero indicates referrals are spread out among a large number of committees, and a score of one indicates a single committee receives all the referrals (Worsham, 2004). Indices were constructed for each year so as to offer a longitudinal measure of referral competition in both chambers. As figures 5 and 6 reveal, both chambers exhibit periods of perfect monopoly, which one would expect in a policy domain characterized by dominant coalition politics. That said, the Senate has clearly become more

⁶ In keeping with others (Worsham, 2004) who have utilized the Herfindahl index to get at jurisdictional control, a one is inserted for the years where no bill introductions or referrals were presented in order to reflect the lack of competition on the agenda.

competitive by the mid-1990s, whether the basis of comparison is referral activity in the House or referrals in earlier Senate sessions.

Figure 5. Herfindahl Index: House Bill Referrals

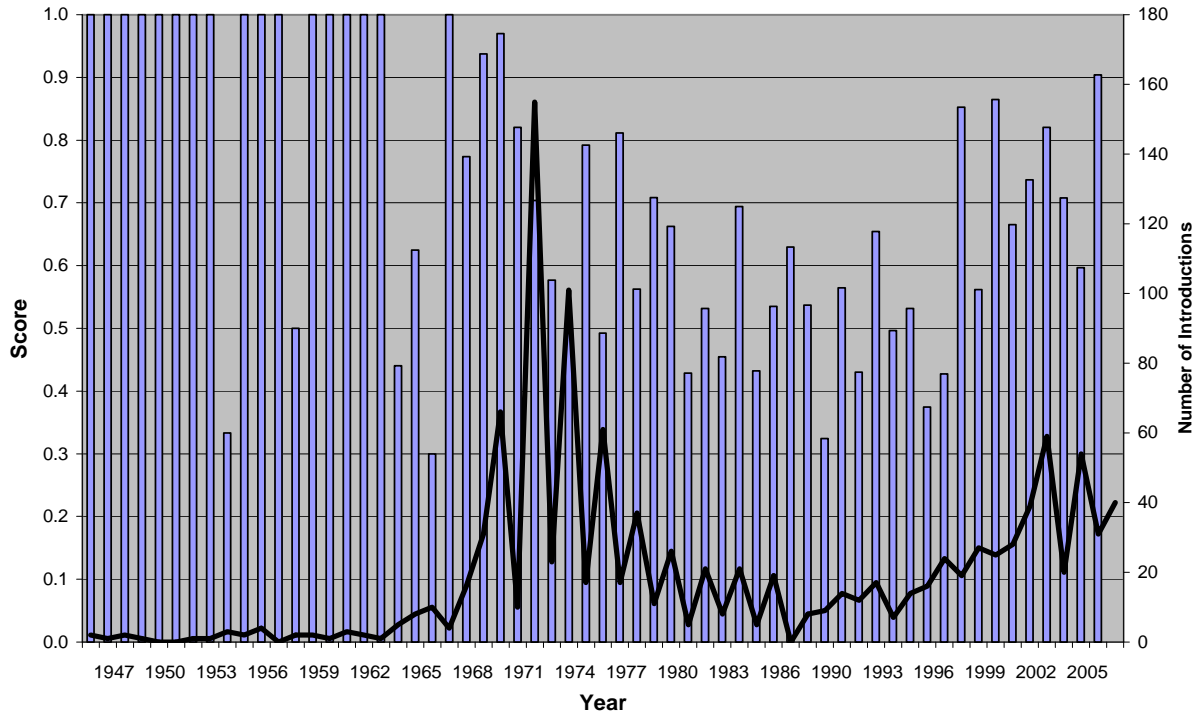
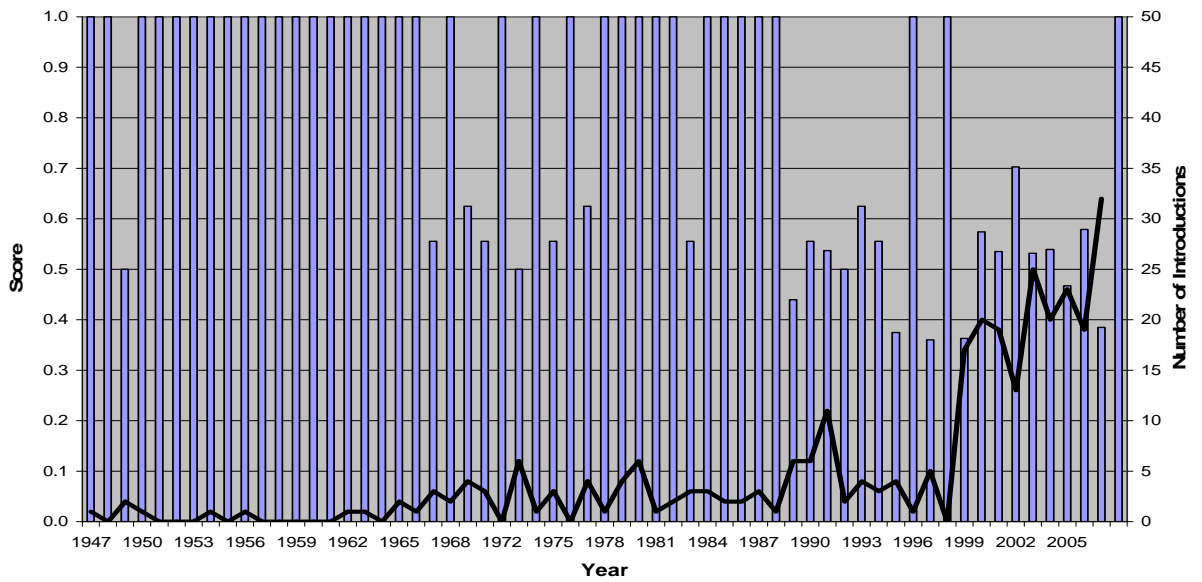


Figure 6. Herfindahl Index: Senate Bill Referrals



Battles for jurisdictional control are influenced by the receipt of bill referrals (King 1997; Talbert, et al. 1995). Further, claims of specialized knowledge and expertise influence the fate of bill referrals. A review of figures 5 and 6 reveal as introductions increase competition increases. Indicating outside committees are “gauging the position of other committees” (Talbert et al. 1995). I have established that the House Commerce and Senate Health committees have maintained a policy monopoly over the referral of bills throughout most of the analysis period. I have also discovered that mild competition and increased issue salience concerning pharmaceutical cost occur from the mid-1990s to 2007—more so in the Senate than the House. After running a correlation, as the number of introductions increase in the House, the level of competition slightly decreases (.27).⁷ Thus, the Commerce committee maintains its traditional dominance, which is reflected in the House bill referrals (figure 3) and the corresponding Herfindahl index (figure 5).

However, in the Senate, the Health committee is unable to maintain the same level of control secured by the Commerce committee. As expected, as the number of introductions increase the level of competition also increases. This moderate correlation (-0.33) is indicative of the competition by the Finance committee. Therefore, the primary concern of the following section is to identify if outsiders attempt to alter the venue in which pharmaceutical regulation is considered.

Sponsorship and Committee Competition

I examine bill sponsorship in both chambers during the time period characteristic of mild referral competition (1990-2007) in an effort to gauge whether representatives are introducing bills to stake a claim to issues in the chamber (Wawro 2000). Using the Congressional Directory,

⁷ The direction of a correlation is reversed when using the herfindahl index. Thus, a negative correlation is indicative of increased competition. Also, a correlation coefficient from 0 and 0.3 indicate a weak correlation, while

the Congressional Bills Project, and the MIT Congressional Committee dataset⁸, I was able to determine the percentage of bills sponsored by outsiders. Representatives not assigned to the House Commerce or Senate Health committees are regarded as outsiders. The notion holds that members of the House Commerce and Senate Health Committees are less likely to sponsor legislation, which may alter the status quo. As such, I argue that attempts to alter the venue or committee jurisdiction in which pharmaceutical regulation is considered should increase as one moves from a dominant committee scenario to a more competitive environment. The preceding gives rise to the following hypotheses:

Hypothesis 4.2: Outsiders, acting as entrepreneurs, will sponsor bills that escape referral to the dominant committees.

Hypothesis 4.3: Insiders, controlling the agenda, will sponsor bills that are referred to the dominant committees.

To begin, Table 4.1 contain the percentage of bills referred outside the Commerce Committee. As indicated, there were 455 introductions in the House. Of the 455 introductions, 13% escaped referral to the Commerce Committee. Further, 50% of the introductions that escape the Commerce Committee are sponsored by outsiders (offering support for hypothesis 4.2). Offering further evidence that representatives sponsor bills in an effort to stake a claim to a policy issue, 78% of the bills sponsored by outsiders dealt with cost. The findings in Table 4.1 indicate that Commerce Committee members' control over bill introductions slips under competitive coalitions (offering support for hypothesis 4.1). Combine this with the effects of salience, and it appears that as cost becomes the subject of increased attention, more and more outsiders become involved in attempts to set the pharmaceutical agenda in Congress. Outsiders are therefore attempting to alter the venue of the conflict under periods of competition.

0.3 and 0.7 indicate a moderate correlation (Ratner 2003).

⁸ Charles Stewart III and Jonathan Woon. Congressional Committee Assignments

Table 4.1 House Bills Referred to Rival Committees from 1990-2007

Year	Total Bills	% Referred to Rival Committees	% Sponsored by Outsiders
1990	9	22	100
1991	14	43	100
1992	12	8	100
1993	17	24	100
1994	7	0	0
1995	14	7	100
1996	16	0	0
1997	24	17	100
1998	19	0	0
1999	27	15	50
2000	25	28	86
2001	28	7	50
2002	39	18	86
2003	59	10	83
2004	20	10	50
2005	54	15	88
2006	31	6	100
2007	40	5	50
Total	455	58	49
Percentage		13%	84%

Table 4.2 Senate Bills Referred to Rival Committees from 1990-2007

Year	Total Bills	% Referred to Rival Committees	% Referred to Finance Committee	% Sponsored by Outsiders
1990	6	67	67	67
1991	11	36	36	36
1992	2	50	50	50
1993	4	75	75	75
1994	3	33	33	33
1995	4	50	25	50
1996	1	100	0	100
1997	5	80	40	80
1998	0	0		0
1999	17	71	47	29
2000	20	80	65	70
2001	19	63	63	53
2002	13	85	69	62
2003	25	72	64	56
2004	20	80	55	70
2005	23	61	52	52
2006	19	84	74	68
2007	32	66	50	56
Total Number	224	156	127	128
Percentage		70%	81%	82%

Table 4.2 contains the percentage of bills referred outside the Health Committee. As indicated, there were 224 introductions in the Senate. Of the 224 introductions, 70% escaped referral to the Health Committee. Further, 82% of the introductions that escape the Health Committee are sponsored by outsiders (offering support for hypothesis 4.2). Offering further evidence that representatives sponsor bills in an effort to stake a claim to a policy issue, 73% of the bills sponsored by outsiders dealt with cost. The findings in Table 4.2 indicate the Health Committee members' control over bill introductions slips under competitive coalitions (offering support for hypothesis 4.1). Similar to activity in the House (Table 4.1), it appears that as cost becomes the subject of increased attention, more and more outsiders become involved in attempts to set the pharmaceutical agenda in Congress. Based on the above data, outsiders in the Senate are even more aggressive in attempting to alter the venue under periods of competition.

Next, Table 4.3 (House) and 4.4 (Senate) document the sponsorship of introductions assigned to the House Commerce and Senate Health Committees from 1990-2007. As illustrated, members within the Commerce and Health domain sponsor the bulk of bills assigned to the committee compared to sponsors outside the domain (supporting hypothesis 4.3). For example, 97% in the House, and 44% of Senate introductions referred to the committee are sponsored by committee members. Only one importation proposal was introduced in the House and four in the Senate during this period of competition. Based on the topic of the importation proposals, they were introduced by both parties as a way to get around the high cost of prescription drugs in the United States.

Table 4.3 House Introductions assigned to the House Commerce Committee from 1990-2007

Year	Total Bills	% Referred to Commerce	% Sponsored by Outsiders
1990	9	78	0
1991	14	57	0
1992	12	92	0
1993	17	76	0
1994	7	100	0
1995	14	93	0
1996	16	100	6
1997	24	83	0
1998	19	100	5
1999	27	85	0
2000	25	72	0
2001	28	93	8
2002	39	82	3
2003	59	90	6
2004	20	90	0
2005	54	85	0
2006	31	94	3
2007	40	95	0
Total	455	397	9
Percentage		87%	2%

Table 4.4 Senate Introductions assigned to the Senate Health Committee from 1990-2007

Year	Total Bills	% Referred to Health	% Referred to Finance	% Sponsored by Outsiders (Assigned to Health)	% Sponsored by Outsiders (Assigned to Finance)
1990	6	33	67	0	67
1991	11	64	36	43	36
1992	2	50	50	0	50
1993	4	25	75	100	75
1994	3	67	33	0	33
1995	4	50	25	100	25
1996	1	0	0	0	0
1997	5	20	40	100	40
1998	0	0		0	0
1999	17	29	47	40	18
2000	20	20	65	50	55
2001	19	37	63	86	53
2002	13	15	69	50	54
2003	25	28	64	71	48
2004	20	20	55	25	50
2005	23	39	52	89	43
2006	19	16	74	67	63
2007	32	34	50	27	41
Total	224	68	128	37	104
Percentage		30%	57%	54%	81%

Conclusion

This chapter illustrated which issues on the pharmaceutical agenda receive attention, and where jurisdictional control and committee competition reside. The preceding analysis has provided a first look at the congressional landscape in the realm of pharmaceutical regulation, suggesting the domain is one in which negative feedback characterizes the policy process. Both chambers have periods of subsystem politics typical of a dominant coalition, as well as sessions characterized by competitive politics. In addition, by examining the sponsorship of policy proposals, I find that policy entrepreneurs are attempting to alter the policy venue under periods of competition.

In the early years, manufacturing and distribution was the main issue on the House agenda, but cost and safety quickly become the primary focus of legislative introductions. In the Senate, little activity occurs until cost legislation begins to dominate the agenda in the late 1990s. The rise in attention on prescription drug costs was a result of double digit price increases. While the majority of bill introductions that escape referral to the Commerce and Health Committees were sponsored by members outside the policy domain, representatives of the dominant committees sponsored the majority of proposals assigned to the committee. This analysis suggests the period of mild referral competition is in part due to the issue framing of policy entrepreneurs outside of the policy domain. The next chapter will further explore the agenda setting participants by examining congressional hearings and the witnesses that show up to the debate.

Subsystem Political Variation & Congressional Hearings: Who Shows Up to the Debate?

“Hearings present multiple opportunities for strategic behavior by both committee members and those testifying.” – Diermeier and Feddersen, 2000, 52

The previous chapter examined the rise and fall of pharmaceutical bill introductions in both chambers, including an examination of the topics that received the most attention. My analysis suggests the period of mild referral competition identified by examining bill introductions is partly due to the issue framing of policy entrepreneurs outside of the policy domain. This chapter broadens the investigation to include an examination of hearing activity, the composition of committees holding hearings, and tracks who shows up at hearings. This approach allows me to say something more definitive about the policy subsystem, as well as offer a more nuanced measure of subsystem political variation.

Many bills are introduced for symbolic purposes—as a way for members to gain constituency support (Wilkerson, Feeley, Schiereck, and Sue 2002, 255). A hearing on the other hand is less common, as the congressional agenda is necessarily limited (Talber and Potoski, 2002, 189). Congressional committees can acquire information in several ways, but hearings serve as fact-finding exercises—a way to publicize an issue, assess the level of support or opposition to a bill, or investigate new problems or issues (Oleszek 1996, 109-12; Hardin 2002, 98).

First, I assess the overall level of hearing activity in both chambers. The overall level of activity will provide a general understanding of the attention Congress gives to pharmaceutical regulation. Hearings, as compared to bill introductions, indicate a higher level of agenda status (Kingdon 1984, 186; Worsham 1997). Similar to the analysis of bill introductions, a longitudinal approach highlights whether a change in activity corresponds to a punctuating event. Second, I

examine policy jurisdiction and policy monopoly to further track the institutional boundaries of the prescription drug subsystem. I provide data regarding the committee or committees holding hearings and whether activity changes due to external events. Third, the topic of the hearings and the witnesses testifying have shown to influence the nature and extent of information acquired (Hardin 2002). Tracking the type of witnesses participating in the hearings allows me to determine who tends to dominate the discussion. These two dimensions of hearings information are examined in order to assess how pharmaceutical regulation and congressional activity have evolved.

An Assessment of Hearing Activity

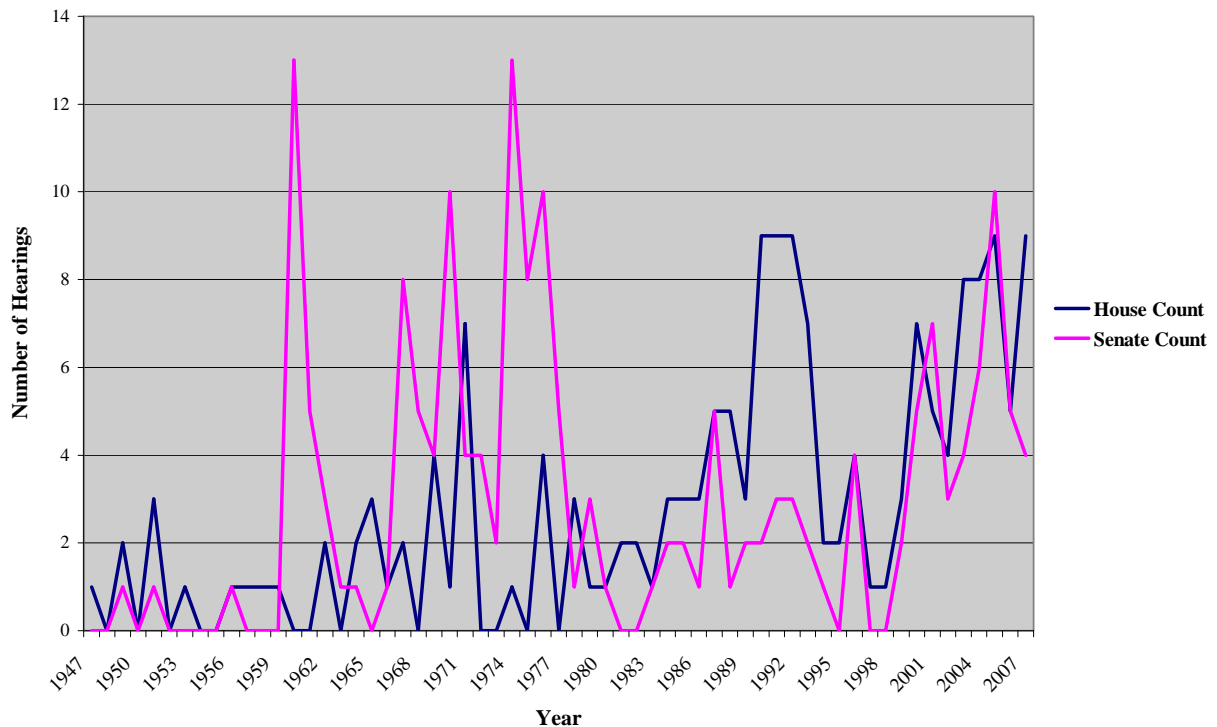
Like others who have tracked agenda control with a focus on hearing activity (Baumgartner and Jones 1993; Worsham 1997; Hardin, 2002; Hunt 2002; Wilkerson et al., 2002), I focus my analysis on congressional hearings addressing pharmaceutical regulation in order to identify the set of interests active in the pharmaceutical policy domain. The data on congressional hearings were gathered utilizing the Congressional Information Service (CIS) *Index to Committee Hearings* (available online through Lexis-Nexis Congressional). Following a review of the *Index to Committee Hearings*, the congressional hearings data were gathered using the search terms “Pharmacists and Pharmacy,” or “Pharmaceutical Industry.” The Lexis-Nexis Congressional data yielded 352 hearings, 172 in the House and 180 in the Senate for the years 1947 to 2007.

I begin with an exercise that maps hearing activity in each legislative chamber over the course of the study, providing a feel for variation in policy salience over time in each chamber. I then move to identify the committees holding hearings in an effort to get a feel for turf control in each chamber. The third part of the paper tracks the changing focus of pharmaceutical regulation

over time allowing me to say something about how a change in venue alters the focus of discussion. Finally, I end with an examination of who shows up at hearings, which allows me to say something about which venues favor particular interests, shedding further light on how interests and venues alter policy focus.

Figure 1 tracks hearing activity in both the House and the Senate between 1947 and 2007. The level of activity is similar in both chambers until 1960, when Senate hearings increase dramatically prior to the passage of the 1962 Kefauver Amendments to the Pure Food and Drug Act. It appears that Senator Kefauver's (D-TN) initial role as an entrepreneur set the Senate up as the venue to consider pharmaceutical policy, even after his death in 1963. As the figure indicates, there is more sustained hearing activity in the Senate than in the House through the 1970s. Hearing activity increases in both chambers beginning in the mid-1960s, falling off a bit in the 1980s, and picking up again in the 1990s, when the House becomes the more active chamber. This increased level of activity in the House corresponds with the emergence of concern over the availability of generic drugs and re-importation restrictions. Activity in both chambers increases as a response to President Clinton's proposed plan for a voluntary outpatient prescription drug benefit in 1999 and continues with the enactment of President Bush's 2003 Medicare Prescription Drug Improvement and Modernization Act.

Figure 1. Pharmaceutical Policy Hearings, 1947-2007



Policy Jurisdiction and Committee Competition

Figures 2 and 3 identify the committees that held hearings in the House and Senate, respectively. As the institutional anchor of subsystem arrangements, committees utilize hearings to protect or extend their policy turf (Baumgartner and Jones 1993; Hardin 2002; Worsham 2006). A review of figure 2 reveals that the Government Reform and Commerce committees serve as the dominant venues in the House. Competition from other venues increases beginning in 1981, although there are still periods (e.g., 1996-2000, 2003-2007) in which Commerce and Government Reform manage to sustain an oligopoly of sorts. The more competitive periods, it appears, are associated with attempts to stake a claim to access and cost issues influencing small businesses as well as issues related to access and the aged (see below).

Figure 2: House Hearings: Committee Competition

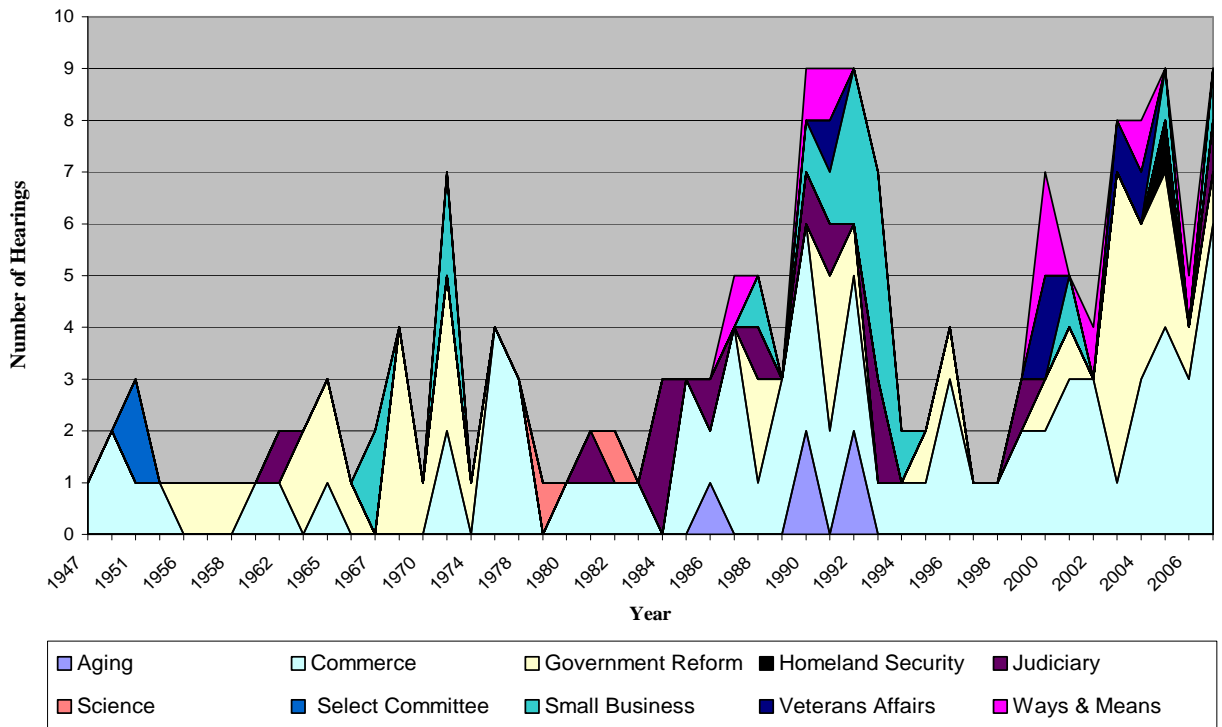
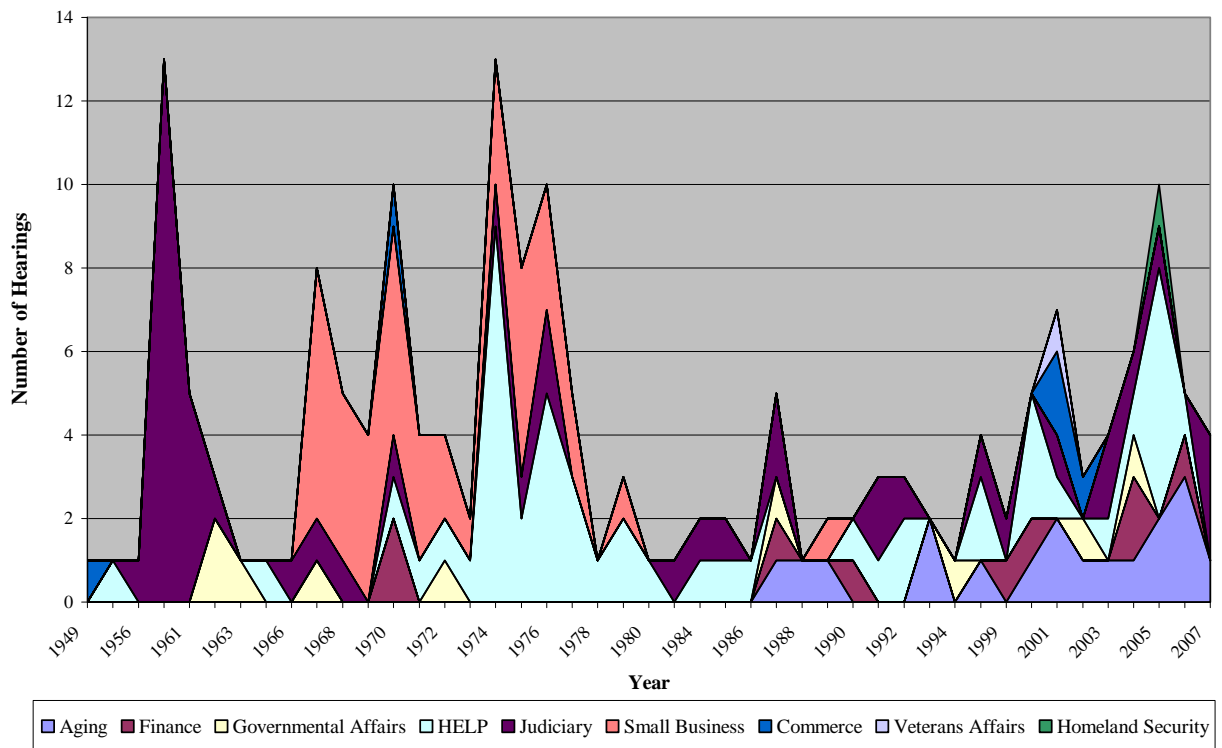


Figure 3: Senate Hearings: Committee Competition



A review of figure 3 suggests there is more competition, or at least venue shifting, in the Senate than was the case in the House. While Health, Education and Labor (and its various predecessors) is a nearly ubiquitous presence from 1974 onward, no single committee or pair of committees dominates the discussion like Commerce and Government Reform do in the House. Instead, pharmacy policy in the Senate starts out with the Judiciary Committee in charge, moves to a brief period in which Governmental Affairs monopolizes the discussion (1962-1965), followed by an interval in which Small Business dominates (1968-1974), followed by a turf sharing arrangement involving Small Business and Health, Education, and Labor which lasts through 1980, after which the system seems to settle into a period of prolonged competition.

Associated with the move from a system characterized by a policy monopoly to one characterized by competition is a loosening of subsystem control over the predominant image underlying the policy equilibrium (Worsham 2006, 442). To get at this phenomenon, the topic of hearings were coded and placed into one of six categories. When a hearing entails more than one topic, the predominant or most occurring topic is coded based on a reading of the textual summary and title. Hearings coded *Safety* include those dealing with the general safety and or effectiveness of pharmaceutical products. An example is a hearing to authorize the Federal Security Agency to issue subpoenas in food and drug product safety investigations. *Manufacturing and Distribution* include hearings to amend the Federal Food, Drug, and Cosmetic Act relating to the distribution chain of prescription drugs.

Drug Marketing includes hearings that discuss drug marketing, licensing, labeling, and advertising. *Access* includes hearings that focus on increasing access to certain populations, such as veterans and Medicare or Medicaid recipients or hearings that focus on competition limiting access to drugs. *Cost* contains hearings that specifically seek to address efforts to increase the

affordability of prescription drugs. *Importation* includes hearings that discuss the intent to modify the law to allow importation from designated countries, restrict importations, discussions concerning the regulation of internet pharmacies, and exportation provisions. The final category, *Other*, is a catch-all for hearings that do not fit the other six categories.

Figure 4: Pharmaceutical Hearing Content: House

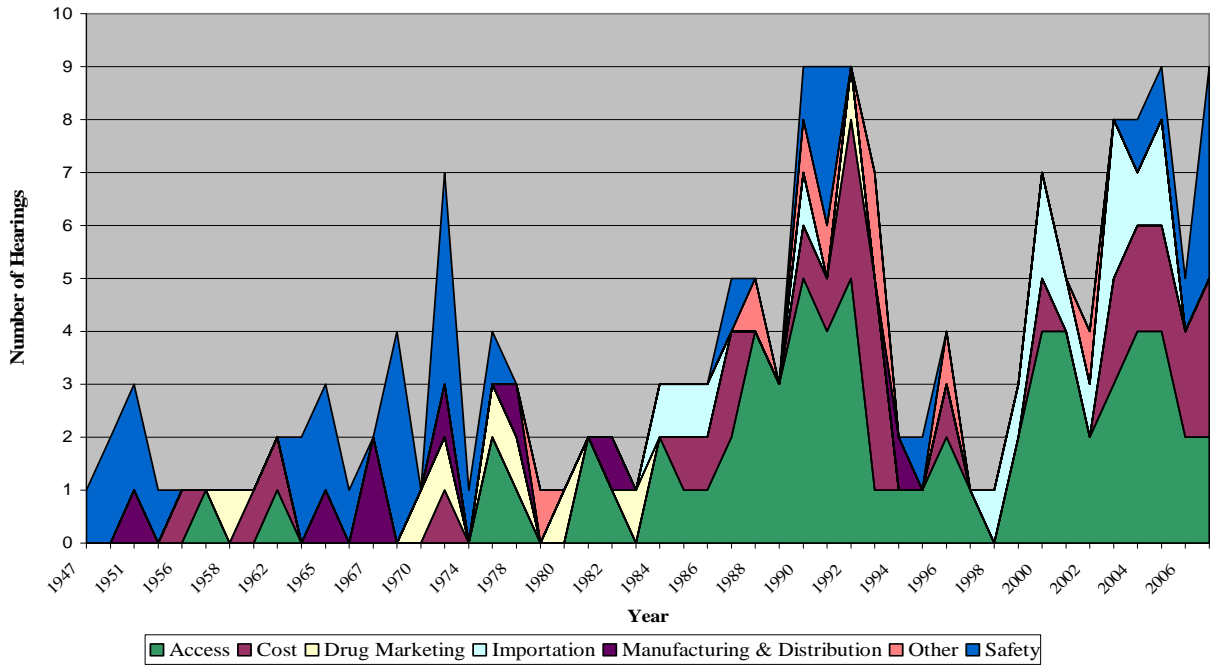
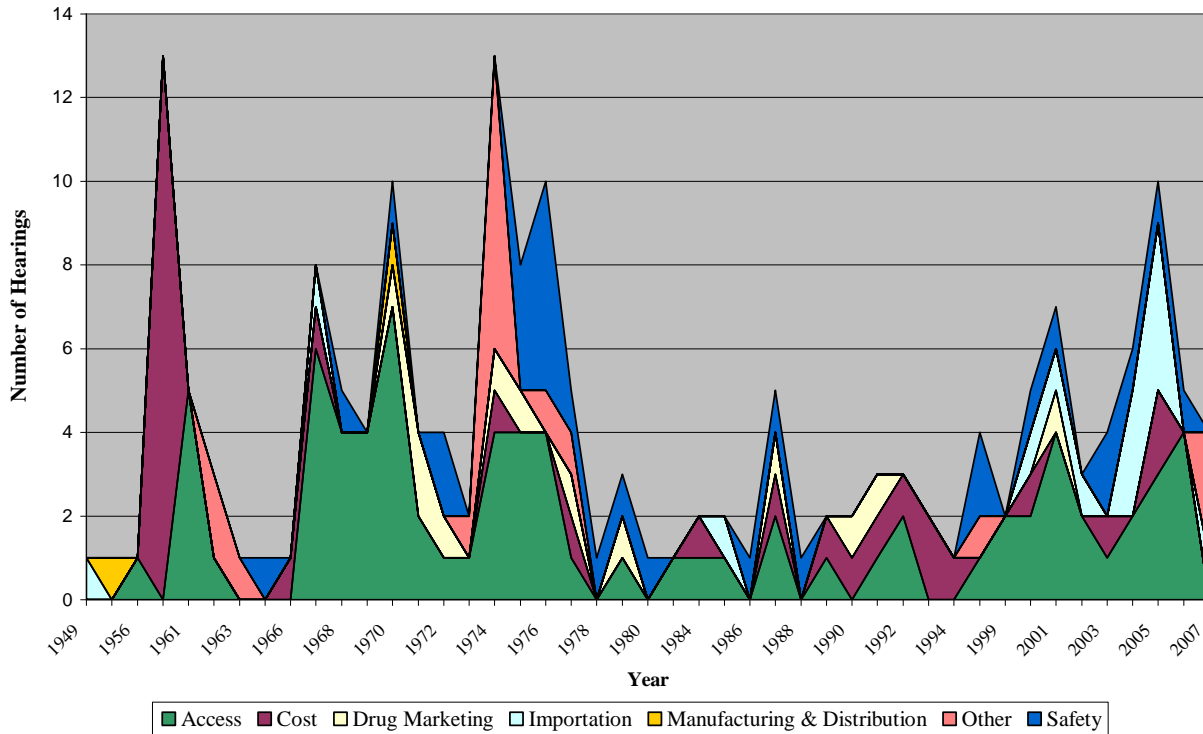


Figure 5: Pharmaceutical Hearing Content: Senate



A review of figure 4 reveals that while House pharmaceutical hearings are often focused on safety between 1947 and 1980, there are periods in which cost, access, and manufacturing and distribution dominate the discussion. Access becomes a regular topic of discussion in the late 1970s and is firmly enmeshed by the mid-80s in response to demonstrations from patient populations requesting access to investigational drugs. Although the discussion of access remains salient through 2007, competition for agenda space characterizes the period from 1990 onward. In the Senate (figure 5) access is a topic of discussion throughout the time series, at times dominating the discussion (between 1968 and 1972), at other times in competition with other issues.

The focus of pharmaceutical hearing content differs from that of pharmaceutical bill content for the same period in the same chamber. Bill content in the House from 1947 to 1968

focused on manufacturing and distribution followed by a period until 1975 where cost and safety become the primary focus of legislative introductions in the House. Followed by increased attention to cost and importation beginning in 1990. The Senate bill introductions vary slightly with little action occurring in the Senate through the 1990s. Between 1947 and 1970 manufacturing and distribution and safety receive the majority of attention. Following this period cost legislation increases in response to Medicare part B of the Social Security Act.

What causes the shift in focus in the pharmaceutical policy domain? Baumgartner, Jones and MacLeod (2000) suggest committee competition can induce a shift in the dominant image associated with a policy domain. In a first effort at getting how competition effects the topic of hearings I constructed Herfindahl indices for the House and Senate (figures 6 and 7).⁹ A review of figures 6 and 7 reveals that both chambers exhibit periods of near perfect monopoly through the 1960s, with the House period lasting well into the 1980s. Competition becomes a regular feature of the Senate policy domain in the late 1960s, while the House holds out until the early 1980s. Comparing committee competition with the content of hearings suggests some evidence to support the proposition that as more committees become involved in the discussion, more topics come to occupy agenda space.

⁹ A Herfindahl index score is calculated by squaring the proportion of committees holding hearings and then summing the squares of those proportions. The result is an index score that ranges from zero to one, where a score close to zero indicates hearings are spread out among a large number of committees, and a score of one indicates a single committee holds the majority of hearings (Baumgartner, Jones and MacLeod 2000; Worsham, 2006). Indices were constructed for each year so as to offer a longitudinal measure of committee competition in both chambers.

Figure 6: Herfindahl Index: House Hearings

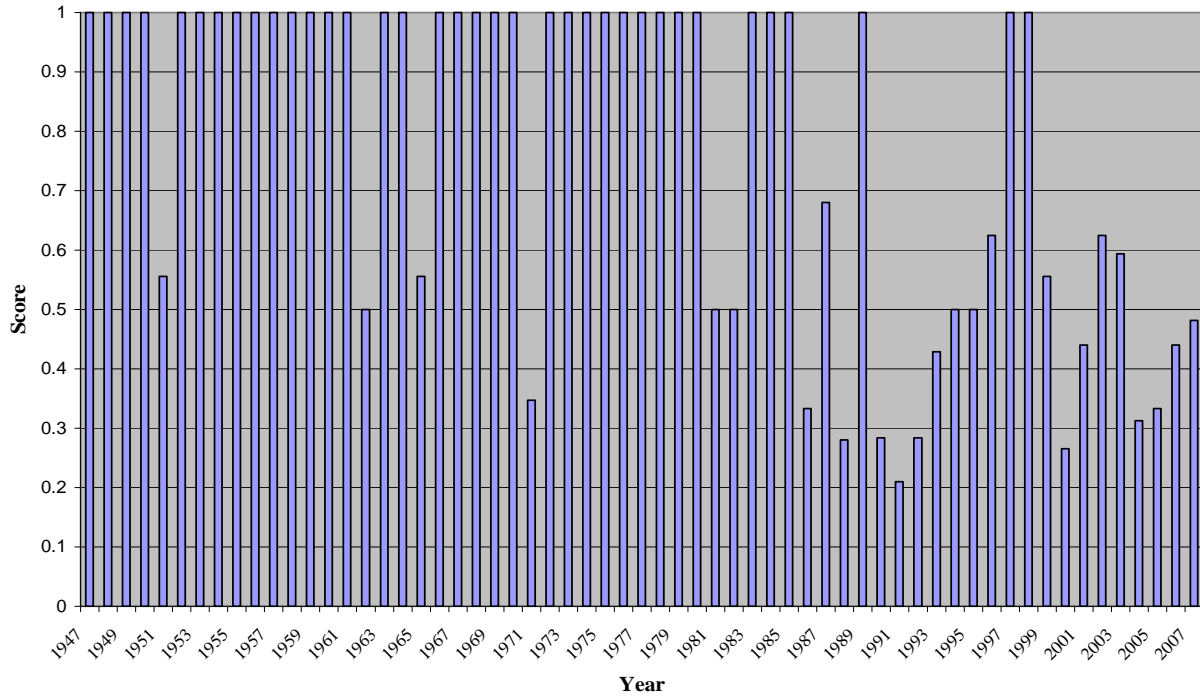
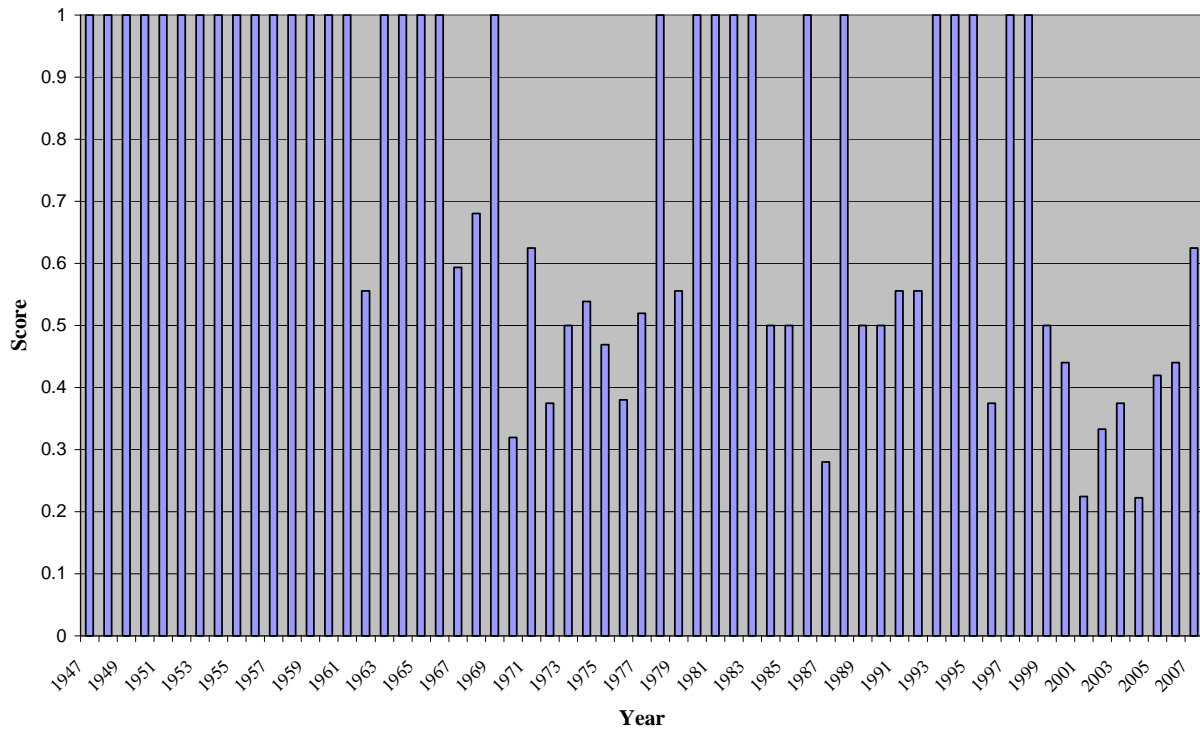


Figure 7: Herfindahl Index: Senate Hearings



Witness Participation: Who Shows Up to the Debate?

Another explanation for change in policy focus has to do with the identity of interests at the policy “table.” If congressional committees serve as the legislative anchor for subsystems and hearings allow the actors within the subsystem to negotiate over the distribution of resources, then who shows up at hearings has something to do with who gets policy benefits when it comes time to implement policy. An examination of witness participation provides an opportunity to pinpoint the key players involved in problem recognition and agenda setting. The witnesses that appear are thus an indicator of the interests that are viewed as legitimate to key players on the committee (Baumgartner and Jones 1993; Worsham 2006).

The identity of witnesses was determined by using the Congressional Information Service (CIS) *Abstracts to Committee Hearings* (available online through Lexis-Nexis Congressional). The *Abstracts* identify the group and membership association of most witnesses. In the event a witness appeared from the general population without an institutional affiliation the witness was coded as a *Consumer*. All witnesses were placed into one of five categories. The *Drug Industry* category includes anyone with a connection to the pharmaceutical manufacturing and distribution industry. Witnesses in this category include Pfizer, Wyeth, other large industry firms, the Pharmaceutical Research and Manufacturers Association, chemist, druggist, and pharmacist, as well as retail pharmacies. The second category, *Medical Industry*, includes any witness associated with a hospital or hospital association, the American Medical Association, physicians and similar. The *Government* category includes state or federal level officials, elected and non-elected, as well as government agencies such as the Food and Drug Administration. The fourth category, *Academics*, includes witnesses associated with academic institutions and the

final category, *Consumer*, represents witnesses from consumer groups, such as AARP, and those without an institutional affiliation.

Figure 8: House Pharmaceutical Witnesses, 1947-2007

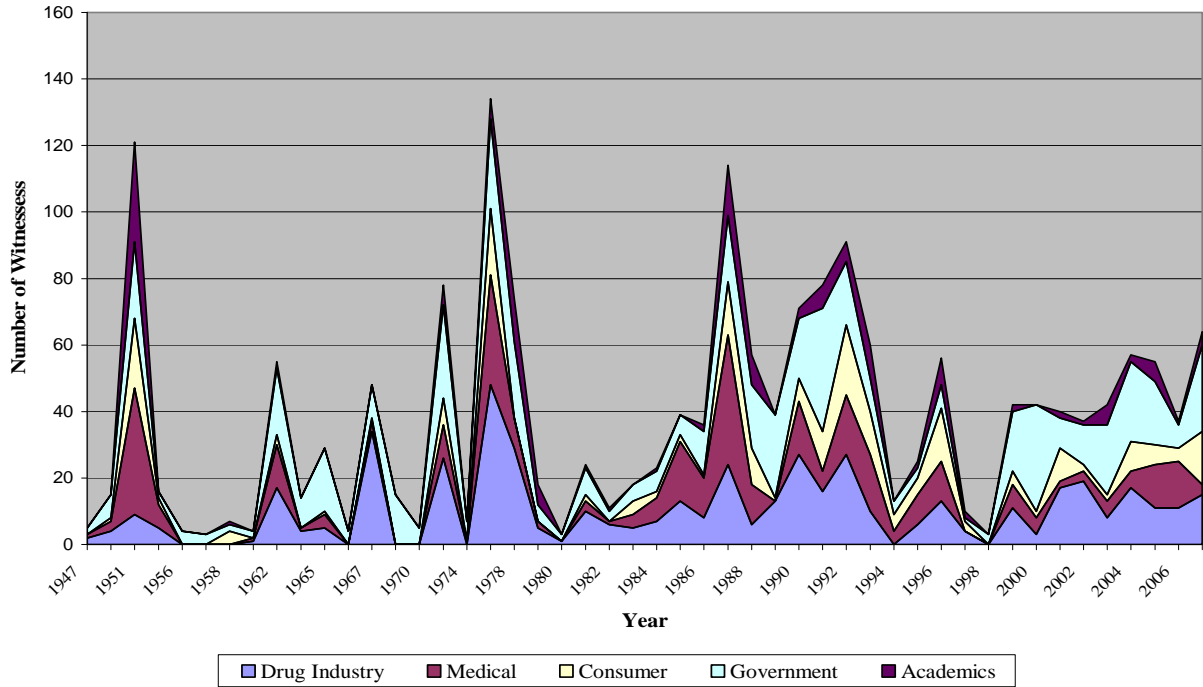
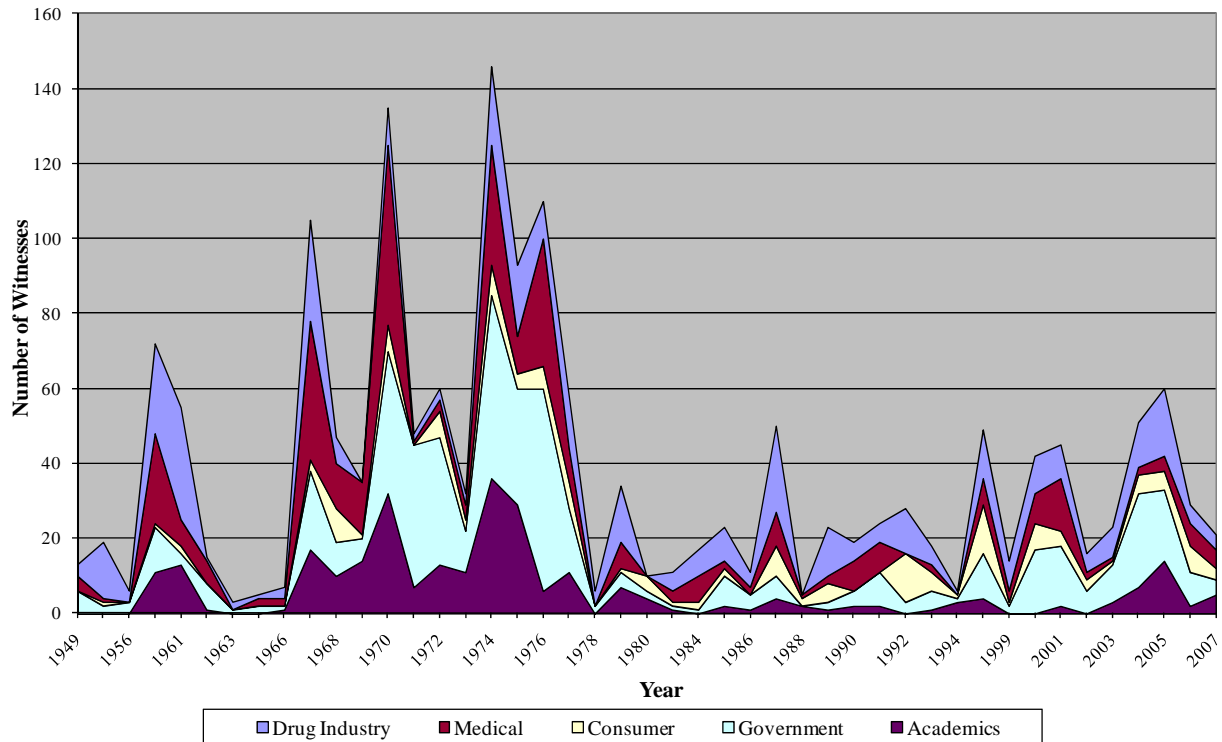


Figure 9: Senate Pharmaceutical Witnesses, 1947-2007



Overall, I coded a total of 3,542 witnesses, 1,843 in the House and 1,699 in the Senate. Review of figures 8 and 9 suggest the pharmaceutical industry and medical communities are a consistent presence at hearings. In the House (figure 8), government officials are a regular player in the 1960s, 1990s, and after 2000. Compare this to the Senate (figure 9), where they become entrenched in the 1970s, and then seem to drop off the map until after 2000. Consumers are conspicuous by their absence (although one might argue that at least some government officials are acting as representatives of the public interest). Indeed, consumers do not enjoy a sustained presence until the 1990s, when they become regular players in both chambers. The role of academics seems to mirror that of consumers. What is apparent from both figures is the increased proportion of non-pharmaceutical, non-medical interests at hearings beginning in the 1990s.

In order to get a feel for how a change in venue effects witnesses, Table 1 compares the mix of witnesses appearing at select venues in the House and Senate. Recall from the previous discussion that Commerce and Government Reform were the major players in the House, while the Health and Judiciary committees were among the regular venues in the Senate. I am interested in seeing if a change in venue results in a change in the composition of witnesses, and by inference, a change in policy focus and outcomes.

As table 1 indicates, a move from Commerce to Government Reform in the House involves a significant alteration in the role of representatives from both the drug industry and medical community at hearings. Staying with the House, it also appears that the Government Reform Committee prefers to hear from public sector actors when considering pharmaceutical policy. While a change in venue does not have as dramatic an effect in the Senate, the drug industry does do better at Judiciary and Health hearings, than it does when another committee claims a piece of the policy turf. It also appears that Judiciary is not as keen on hearing from public sector actors in the Senate than are other committees.

Table 5.1 The Correspondence between Committee Venue and Witnesses Appearing at Hearings in Pharmaceutical Policy, 1947 – 2007

House Committees	Type of Witnesses					
	Drug Industry	Government	Medical Industry	Consumer	Academics	Total (N)
Commerce	32	31	20	12	6	100 (980)
Government Reform	12	51	12	16	9	100 (249)
Other	26	27	22	13	12	100 (614)
Total	27	32	20	13	8	100 (1843)
Senate Committees						
Health	27	33	18	12	11	100 (505)
Judiciary	34	20	23	10	12	100 (335)
Other	17	33	22	7	21	100 (859)
Total	23	30	21	9	16	100 (1699)

Note: Figures are the percentage of witnesses.

Conclusion

My review of the pharmaceutical policy agenda, which includes an examination of hearing activity, the identity of committees holding hearings, and the identity of witnesses, reveals that the 1990s appear to have ushered in a period of competitive coalitions in pharmaceutical policy, in that the policy domain is characterized by multiple committees holding hearings. Further, as the system moves from one characterized by a policy monopoly or oligopoly, to one characterized by competition, the focus of hearings shifts to previously neglected policy dimensions.

Finally, while the drug and medical industries represent the bulk of participants throughout the time frame under consideration, government players emerge as important actors in both the 1970s and after 1990, when they are joined by consumer interests. What this suggests is the changing identity of institutional players is associated with variation in the identity of interests and an increase in the variety of issues considered in the pharmaceutical policy domain. Whether the end result is meaningful policy change, only time will tell. The next chapter provides a summary of my findings, the research contribution, and ideas for further analysis.

Conclusion

“If institutions are often created and reorganized during periods of heightened attention to a given problem, they do not disappear when public concern dies away; rather, they may be the most important legacies of agenda access” - Frank Baumgartner and Bryan Jones (2002, 24)

I began this study with three objectives. First, was to understand how Congress governed the pharmaceutical policy agenda over the post-war period. Second, was to determine if periods of agenda access led to venue changes in pharmaceutical regulation, and third, to gain insight as to whether the image of pharmaceutical policies led to positive or negative feedback, and if so, what factors precipitated such change. In seeking to accomplish these objectives, I have utilized three qualifiers: (1) congressional committees as the venue of focus, (2) bill introductions and (3) hearings as the measures of agenda status and governmental attention. Congressional committees were selected because they are the legislative anchor for subsystem arrangements (Worsham 2004; Baumgartner and Jones 1993).

So what does my research illustrate regarding agenda setting and pharmaceutical policy? First, political entrepreneurs must be engaged to stoke the political fires (Eyestone 1978, 2). Players of the agenda setting process on the inside and outside of government were instrumental in framing how pharmaceuticals have been defined over the past century. The agenda setting process is dynamic and inherently political. The pharmaceutical subsystem is one that fluctuated between dominant and competitive scenarios partly due to external events that challenged the subsystem power brokers. As the subsystem cycles over time, interest group participation, agenda control, and public policy are impacted (Worsham 1998). What I have found is that the multidimensional nature of U.S. pharmaceutical policy created opportunities for competing policy venues to challenge the dominant subsystem. For example, in the House the Commerce Committee enjoyed virtually unchallenged status as the destination of legislation. The dominance

of Commerce gives way to two periods of competitive politics in the 1970s and the 1990s, in which Ways and Means acts as a rival venue. Similarly, the committee on Health, Education, Labor, and Pensions (and its various predecessors) dominated bill referrals in the Senate for most of the time series. The exception is the period characterized by competition that begins in 1997 and continues to the present day, when the Finance committee actually serves as the dominant destination for legislation. As bills escaped the policy domain the image of pharmaceutical policy changed—leading to a more competitive system.

When the policy equilibria maintained by the dominant coalition is disrupted by focusing events, the emergence of previously excluded interests enter the debate. Thus, there is more competition, or at least venue shifting, in the Senate than was the case in the House. Pharmacy policy in the Senate starts out with the Judiciary Committee in charge, moves to a brief period in which Governmental Affairs monopolizes the discussion (1962-1965), followed by an interval in which Small Business dominates (1968-1974), followed by a turf sharing arrangement involving Small Business and Health, Education, and Labor which lasts through 1980, after which the system seems to settle into a period of prolonged competition. Associated with the move from a system characterized by a policy monopoly to one characterized by competition is a loosening of subsystem control over the predominant image underlying the policy equilibrium (Worsham 2006, 442).

As illustrated in the historical description, as competition increased the image of pharmaceutical policy changed from one of safety to that of safety and efficacy, and finally to one of access and accommodation. This change occurred due to the skillful political maneuvering of several key policy entrepreneurs and the intense pressure of outside actors. According to Baumgartner and Jones, a subsystem-induced equilibrium is subject to radical

change during certain periods of time in response to an increased interest in the policy area. The pharmaceutical policy story supports the notion of a punctuated equilibrium model. Periods of heightened salience are accompanied by an increase in the variety of interest groups and institutional players involved in pharmaceutical policy. Yet, the subsystem arrangement is not radically changed. As suggested by Worsham (1997), the subsystem wavers, allowing outsiders to participate without a dramatic restructuring. This study demonstrates that outsiders can make a difference in policy outcomes and provides indicators for when change is likely to occur. Further, the development of the pharmaceutical industry seems to be a prerequisite to regulation and subsystem formation, not unlike that which occurs in agriculture (see Carpenter, 2001). Mastering technological change is a key component of the subsystem, and may possibly be a prerequisite to its formation--further explaining change in policy dynamics.

Aside from the approach I have taken in this study, there are additional venues and perspectives worth exploring for future research. At the micro-level, focusing on whether the civil service within the FDA is responsive would provide insight concerning their degree of argumentation (Golden 2000, 168). Does the civil service of the FDA challenge policy directives or enter the fray of the policy debate? If not, does it matter? Such an analysis would provide further information regarding the role we want civil servants to play in the political system. Another direction for exploration could originate at the state and local level. An evaluation of how pharmaceutical policies diffuse across states and influence federal dialogues is an interesting area for further exploration (Manna 2006). Finally, examining the impact of globalization on pharmaceutical policy outcomes would provide insight concerning how the reduction of trade barriers may impact pharmaceutical policy in industrialized countries

(Daemmrigh 2004). In short, the congressional approach utilized for this research is only one strategy for exploring the dynamic evolution of pharmaceutical policy.

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