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Factors Influencing State Prescription Drug Policy

Rochelle Rene' Henderson
University of Missouri-St. Louis, rrhende@rocketmail.com

FACTORS INFLUENCING STATE PRESCRIPTION DRUG POLICY

by

ROCHELLE RENE' HENDERSON, M.P.A.

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Dissertation Committee
Brady Baybeck, Ph.D. (Chairperson)
David Kimball, Ph.D.
William R. Lowry, Ph.D.
David B. Robertson, Ph.D.

University of Missouri St. Louis

ABSTRACT

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Within the realm of health care, prescription drugs have been of particular concern for state legislators in terms of cost, safety, and distribution. Whether prompted by financial, social, or political pressure, states have tried to address issues associated with prescription medications by adopting or attempting to adopt a variety of prescription drug policies. My dissertation expands beyond the analysis of a singular prescription drug policy and examines the factors affecting prescription drug policies aimed at acquisition, safety and distribution. A negative binomial regression model is employed for each of the prescription drug policy areas to ascertain the influence of internal, external and political factors. The results suggest that factors influencing state prescription drug policy differ for each of the policy subareas. In particular, proportion of the population with a bachelor's degree, neighboring states with a policy, and liberal ideology had an effect on the number of prescription drug policies aimed at acquisition. However, the slack financial resources, neighboring states with a policy and issue saliency had an effect on the number of prescription drug policies aimed at safety. Additionally, the proportion of the population with a bachelor's degree, neighboring states with a policy, and interest group financial contributions to legislators had an effect on the number of prescription drug policies aimed at distribution. This dissertation expands on our understanding of the factors influencing prescription drug policy. The results indicate that factors influencing one particular policy arena may vary when analyzing a subset of policies within a particular policy. Specifically, the results suggest that factors influencing the adoption of prescription drug policy vary across the three types of prescription drug policies of acquisition, safety and distribution.

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LIST OF TABLES

CHAPTER 1: INTRODUCTION

> *"a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."* –
> *Supreme Court Justice Louis Brandeis*

In his 1932 New State Ice Co. v. Liebman dissent, Justice Louis Brandeis is often credited with coining the term "laboratories of democracy." He indicates that although a weighty responsibility, states have the authority and obligation to experiment, lest the nation as a whole suffer. In their role as laboratories, state governments have attempted to address public concerns on issues ranging from agriculture to transportation. State influence and impact on citizens is paramount and strongly interlocked into the social and economic structure of the United States. Furthermore, state policies affect almost every facet of American life including marriage, employment, education, and health. Given the current political and economic climate, state experimentation on the issue of health care is of particular interest to political science scholars, the health care industry, patients and professional groups.

Although health care is only one of the many issues on the public agenda, state and local governments have been actively involved in supporting citizens' quest for good health. With the establishment of state health boards in the 1870s, states to a certain degree assumed responsibility for the public's health through the regulation of medicine and the promotion of sanitary and hygienic activities to control and prevent disease. While initially focused on public health issues (e.g., water pollution, hygiene education, infectious diseases), states later addressed concerns of professionalism by regulating physicians, hospitals, and nursing

homes. Additionally, states' role and responsibilities in health policy continued to expand with the passage of Medicaid in 1965. Through the administration and financial support required by Medicaid, states have become an integral part in the health care of the poor and aged. In addition to the expanded reliance on states, medical and technological advancements are also culprits in increased cost of health care (Garrison, Jr. and Wilensky 46-58;Poisal et al. w242-w253). The rising costs of health care, growing number of uninsured, and lack of a federal plan have prompted states to address issues associated with the health of their citizens.

Within the realm of health care, prescription drugs have been of particular concern for state legislators both in terms of cost and utilization. In the more than 70 years since Franklin D. Roosevelt signed the 1938 Food, Drug and Cosmetic Act, the number of prescription drugs that have been given FDA approval has reached more than 3,000 (Preskorn 41-50). Although prescription drug costs account for only 10% of the total health care costs, the rate of cost increase has been larger than for other health care services. While other health care services have experienced year over year increases in the single digits, prescription medications have had double digit increases from one year to the next year (Centers for Medicare & Medicaid Services). In addition to an increase in the type of medications available, the quantity of prescriptions sold in retail pharmacies has increased significantly; reaching 3.4 billion sold in 2006 (National Association of Chain Drug Stores Foundation). Prescription medications today are being used to treat a variety of ailments ranging from hypertension to erectile dysfunction and are being used to complement and, on occasion, replace physician office visits,

hospitalizations, and other medical procedures (Lichtenberg 485-490Benefits and costs of newer drugs: an update). However, the effect that prescription medications have had on improved health outcomes has not come without a corollary in terms of cost, utilization, and safety.

Whether prompted by financial, social, or political pressure, states have tried to address issues associated with prescription medications by adopting or attempting to adopt more than 3,000 policies aimed at addressing acquisition, safety, and distribution of prescription medications (National Conference of State Legislatures). Policy scholars have not ignored this phenomenon. For example, Gray, Lowery, and Godwin (2007) analyzed factors affecting prescription drug policy, focusing on a singular prescription policy aimed at access (i.e., Prescription Assistance Programs). My dissertation expands beyond the analysis of a singular policy and examines the factors affecting prescription drug policies aimed at acquisition, safety, and distribution. In essence, my dissertation explores the principal question "Why do some states tackle the issues of prescription drug acquisition, safety, and distribution, while others do not?" In doing so, my dissertation is operationalized into four questions. First, what are acquisition, safety, and distribution state prescription drug policies? Second, in which states have prescription drug policies been adopted? Third, what factors explain prescription drug policy adoption? Are the explanatory factors consistent across the three types of prescription drug policies (i.e., acquisition, safety, and distribution)? In other words, are the factors that explain prescription drug policy aimed at acquisition the same as the explanatory factors aimed at safety and

distribution? Fourth, are the factors present in prescription drug policy consistent with the factors found in other health policy analyses?

In essence, the purpose of this dissertation is to examine the demographic, political and institutional factors that influence whether a state chose to adopt prescription drug policies. By analyzing the factors influencing the categories of prescription drug policies as opposed to a singular prescription drug policy, the dissertation explores the further application of innovation theory to the broader issue of prescription drug policy.

Exploring the theoretical framework

With the passage of the U.S. Constitution and specifically the Tenth Amendment, states have self-governing legal authority to create legislation. Examining the factors related to legislation created by each state's legislative system as it relates to prescription medications is conceivably one of the most interesting investigations of health policy in recent history. Prior to model estimation, it is necessary to examine the theoretical framework that would assist in explaining the phenomenon that is state prescription drug policy which includes policy typology theory and innovation theory.

Typology theory

Although the overall objective of state prescription drug policies is to provide citizens with access to much needed medications while protecting their well being, there are variations in the types of approaches employed by states to achieve this goal. The assortment of policy objectives, forms, and stakeholders involved in these policies suggest a difference in factors affecting state prescription drug

policy. The application of policy typology theory assists in the systematic evaluation of the more than 3,000 prescription drug policies. It is through the development of typologies that scholars have attempted to simplify the examination of the complex system that is public policy (Lowi 677-715;Lowi 298-310;Wilson;Longest).

Undoubtedly, Theodore Lowi is considered one of the most influential scholars in the area of policy typology. Lowi's theoretical development of policy classification allowed for the examination of policies in terms of their impact on society and arena of power by examining whether actors have similar interests, competing interests, and ideological foundation. Simply stated, policy typology literature suggests that policies differ in their influence on political actors, their relationships and the power structure and corresponding stability. His initial analysis indicated that the three unique policy types existed (i.e., distributive, redistributive, and regulatory) and had differing effects on politics and stakeholders. Lowi defined distributive policies as those policies that benefit a few and most often associated with policies that bring benefits back to the Congressional district. Redistributive policies benefit those of a particular class -; most often through the process of reallocating wealth. According to Lowi's typology, redistributive policy has clear winners and losers with the winners tending to be of lower social class. Regulatory policies are those policies that limit or enable the actions of one group or another. Regulatory policy "involves a direct choice as to who will be indulged and who deprived" (Lowi, 1964, 690).

Beyond simple categorization of policy, typology literature suggests that the stakeholders involved, policy objectives, and ideological foundation vary by policy category. Lowi (1964) provides theoretical foundation suggesting that not all policies are created equal in terms of their effect. While acquisition, safety and distribution policies may be categorized as regulatory policy, under Lowi's typology, safety and distribution policies differ in their effect on policy objectives, stakeholders, and forms; thus, each is discussed separately in this analysis. In the case of prescription drug policies, acquisition policies are those that enable or limit one group over another.

Hence, for both theoretical and practical purposes, this dissertation employed a "big three" approach in policy presentation that is similar to John Kingdon's (2003) discussion of the "big three" health policy issues (i.e., cost, access, and quality). Using Lowi and Longest as a guide, the prescription drug policies are categorized into acquisition, safety, and distribution. From a practical perspective, the categorization of prescription drug legislation into three general categories (1) acquisition, (2) safety, and (3) distribution allows for analysis of the more than 3,000 different prescription drug policies into three succinct constructs.

At a high level, all prescription drug policies might be considered access because each piece of legislation is designed to either limit the means of acquiring medications (e.g. those considered potentially harmful) or provide the means to needed medications (e.g. state funding). Although the underlying assertion of prescription drug policy may impact access to medications, the specific prescription drug policies adopted over the past ten years have coalesced around

three primary objectives. The first include policies that are designed to assist individuals with the means to acquire prescription medications. These policies include financial, informational, or institutional strategies to facilitate the acquisition of prescription medications. Acquisition policies include those policies that are intended to increase access to needed prescription medications through employment of market approaches; those policies that use state dollars to assist the elderly or poor with access to prescription medications; policies that utilize institutions to maximize access. The second set of policies includes those designed to address the safety issues related to prescription medications. Safety policies are regulatory policies that are intended to mitigate the possibility of misuse, abuse, adverse drug events or medication errors. Lastly, the policies designed to regulate the pharmaceutical distribution within the state borders. Distribution policies are regulatory policies intended prohibit or restrict the marketing and advertising of prescription medications or in some other way regulate the prescription drug distribution entities.

Theoretically speaking, while policy specifics vary within each particular category (i.e., acquisition, safety, or distribution) the policy participants and objectives are cohesive and can thus be examined in terms of the factors affecting prescription drug policy. For example, although safety and distribution would be categorized as regulatory, the actors, interests, and objectives are dissimilar and thus suggest differing factor influences. Thus these policies were examined separately.

Innovation and diffusion theory

In addition to typology theory, innovation and diffusion theories provide a framework for evaluation of the numerous state prescription drug policies. Over the past 40 years, political science scholars have spent a great deal of time and energy investigating why state governments do something new rather than continuing with the status quo. Political scientists have conducted a number of state policy analyses exploring the factors influencing policy adoption and diffusion (Walker 880-99;Mohr 111-26;Gray 1174-85;Berry and Berry 395-415;Case, Hines, and Rosen 285-307;Mintrom 41-59;Berry and Baybeck 505-19). Much of their focus has been directed in studying the degree to which external and internal factors influence state policy adoption. Previous researchers have evaluated policy adoption in terms of policy stages (Dye 1984) and resources (Bingham 1976; Downs and Mohr 1974; Downs 1976; Walker 1969) and at least three researchers have considered the effects of internal or external determinants on state health policy (Gray et al., 2007b; Pracht and Moore 2003; Miller, 2005). Much like an Agatha Christie mystery novel, there are many suspects in the adoption of prescription drug policy, some of which include internal factors (e.g., state budget, elderly, poverty) and external factors (e.g., other state activities, political party control).[1] While Gray, Lowery, and Godwin (2007) have used innovation theory to examine a single access prescription drug policy (i.e., State Pharmacy Assistance Programs), no known research has been conducted analyzing the factors affecting safety or distribution prescription drug policies. This

[1] In his article, Tuning in, Tuning Out: The Strange Disappearance of Social Capital in America, Robert Putnam uses the Agatha Christie analogy to examine why citizen engagement has declined over time. (Putnam 664-83;Putnam)

dissertation relies on innovation theory as the theoretical foundation for examination of the factors of prescription drug policy adoption.

Study Specifics

Four approaches were used to address the key questions of interest. First, a literature review on policy typology and policy innovation was conducted. The theoretical framework provides the foundation for examining which factors influence adoption of the three types of prescription drug policy.

Second, state prescription drug policies were examined and categorized according to the policy typology previously described. The unit of analysis was one observation for each state each year. The study comprised a pooled cross-sectional time series using data from 1999 through 2008 where each case represented a state-year. Both practical and theoretical reasons guided the selection of this time period. From a theoretical standpoint the last ten years have been the most active in terms of prescription drug policy. The increased use, changes in approval process, and rising drug costs have put prescription medications on the public agenda. From a practical standpoint, the National Conference of State Legislatures (NCSL) compiled data on prescription drug policy for the last ten years.

The methodology for the classification of state prescription drug policies as acquisition, safety, or distribution is discussed in Chapter 6. Given the breadth and depth of prescription medication use, it is conceivable that states adopt policies with either multiple or ambiguous objectives and are not easily categorized. These prescription drug policies are isolated for additional exploration.

Third, a series of maps are presented to depict the number of prescription drug policies by each state. The maps illustrate the density and dispersion of prescription drug policies across the U.S. over the last decade.

Fourth, a statistical model was employed to analyze the factors influencing prescription policy. For the three types of prescription drug policy, a model to identify the key factors that contribute to the state policy adoption was created and tested. Based on the work of previous innovation and diffusion scholars as a framework, the explanatory variables for model consideration included state demographic characteristics, state wealth, interest group activity, legislative professionalism, issue saliency, and political factors (i.e., state ideology, legislative party) (Walker 880-99;Mohr 111-26;Gray 1174-85;Berry and Berry 395-415;Berry and Baybeck 505-19;Case, Hines, and Rosen 285-307;Mintrom 41-59;Gray, Lowery, and Godwin 89-129;Miller Edward Alan 2639-57).

Dissertation Plan

Over the course of eight chapters, this dissertation examines the state characteristics present in prescription drug policy expanding on the existing knowledge base related to policy innovation and diffusion. In the first chapter, I introduce the reader to the topic of this dissertation and why it is important. In the second chapter, I discuss the previous empirical evidence related to policy innovation and describe the theoretical constructs with which to examine state prescription drug policy. This chapter discusses innovation and interest group literature which are critical to the examination of prescription drug policy adoption. In particular, I will make a case for the inclusion and/or exclusion of factors

attributed to influencing state policy adoption. The third, fourth, and fifth chapters contain a description and discussion of the specific state prescription drug policies within the constructs of acquisition, safety, and distribution. I propose that the factors influencing each policy category (i.e., acquisition, safety, and distribution) are theoretically different and thus should each be discussed in a separate chapter. The sixth chapter contains my methodological approach and research design, while the seventh chapter presents the analytical results. In the final chapter, I draw conclusions on the factors influencing state prescription drug policy. In essence, I will explore how my analysis complements, contradicts, and contributes to the existing understanding of state prescription drug policy. State lawmakers, political scientists and others may be interested to find the variation in factor effect across prescription drug policies.

CHAPTER 2: *CAUSAL MECHANISMS OF STATE PRESCRIPTION DRUG POLICY*

> *"He who loves practice without theory is like the sailor who boards ship without a rudder and compass and never knows where he may cast" –*
>
> *Leonardo da Vinci*

Since the time of Woodrow Wilson and the Progressive Movement, political scientists have developed theories intended to improve the effectiveness and efficiency of government. From the time when Harold Lasswell first introduced the concept "policy science" in 1951 the concept has become a "growth industry" for political scientists (Lasswell 85-104;Doron 303-09). The proliferation of government programs in the 1960s and 1970s to address complex public problems (i.e., poverty, equality, etc) created a need for more rigorous policy analysis (McCool). While advances in technology made analysis of larger datasets easier, the complexities of the new policy process continued to challenge analysis (McCool). Analysis of the unlimited number of actors, variables, and relationships involved in public policy proves a daunting task without an analytical roadmap. It is the use of theoretical frameworks that assist in our quest to understand the political phenomenon.

While many theoretical frameworks have materialized since Lasswell (1951), innovation and diffusion policy theories have become dominant in exploring the factors influencing state policy adoption. In this chapter, I will discuss the theoretical framework of state policy innovation and diffusion, argue the theoretical application to prescription drug policy, and identify the relevant factors for considering the legislatures' adoptions of state prescription drug policy.

Theoretical Framework

While the social scientist Everett Rogers ([1962], 2003) is most often associated with the diffusion of innovation theory, it was the early work of Walker (1969) that brought innovation theory to political science. In his seminal work, *The Diffusion of Innovations Among States*, Walker (1969, 881) defined innovation as "a program or policy which is new to the states adopting it, no matter how old the program may be or how many other states may have adopted it." In his analysis of 88 various policies, Walker established that some states were more expedient than other states in their policy adoption. Succeeding Walker (1969), Gray (1973) concluded that while some states are faster to act than other states, the diffusion pattern does vary by policy topic. Specifically, Gray found that states quick to adopt education laws were not necessarily that quick to adopt welfare or civil rights laws (1973, 1184).

Since the initial work of Walker (1969) and Gray (1973), innovation theory in political science has developed into two divergent methods of explanation. The first approach focuses on the internal determinants (e.g., political composition of legislation, unemployment rates, and public opinion) that affect state policy innovation. Under the internal determinants model, a state's internal socioeconomic and political factors are examined to ascertain their influence on state policy innovation (Sabatier). The supposition that states' internal characteristics are influential is founded on previous findings suggesting a relationship between state policy innovation and state population, urbanization, wealth, and industrialization (Walker, 1969, 851-861).

At the heart of the second approach is the examination of external factors (e.g., professional networks, influence of neighboring states, influence of federal government) (Berry and Berry, 1990). Unlike the internal determinants model which focuses on the economic, demographic, and political characteristics within the state, the external determinants model explores the influence of political, professional and financial dealings outside the state.

While the work of Walker (1969) and Gray (1973) focused on either the internal or external factors effecting state policy, Berry and Berry's (1990) analysis of state lottery policy adoption incorporated both the internal and external determinants in a combined theory. Berry and Berry (1990) created a more inclusive analytical framework by employing Mohr's theory (1969, 111). Mohr indicated that public policy was a function of the "interaction among the motivation to innovate, the strength of obstacles against innovation, and the availability of resources for overcoming such obstacles". In essence, Berry and Berry (1990, 400) argue that the information gathered from neighboring states assist in overcoming the obstacles or uncertainty associated with innovation. Whether it is for reasons of competition or constraints, there is sufficient evidence to suggest that states' public policies are influenced by external forces.

Linking to Prescription Drug Policy

Prescription drug policy can be quite complex, both substantively and in the policy making process. Although there are competing values, competing issues, and competing solutions, a significant number of states have adopted, or have attempted to adopt, prescription drug policies over the past decade

(National Conference of State Legislatures 2009). This begs the question of what factors influence state adoption of prescription drug policy. The detailed discussion on varying factors affecting separate prescription drug policy construct is an important contribution to the innovation and diffusion literature.

As previously mentioned, state prescription drug policy is best suited for analysis using the policy innovation framework. Prior theory suggests multiple structural factors (i.e., citizen need, capacity of the state to meet that need, and the structure of the policy subsystem) influence state policy adoption (Walker 1969; Gray 1973). While scholars have built upon the seminal work of Walker (1969) and Gray (1973) in continued examination of factors contributing to the adoption or attempted adoption of state policy, Gray, Lowery, and Godwin (2007) and Kingdon (2003, 92) provide an organizational method for discussing the factors influencing prescription drug policy. While Gray, Lowery and Godwin (2007) suggest four possible constructs (structural conditions of the state, interest group influence, public preferences on an innovation and political party influence), Kingdon's theory suggests examination of factors associated with the *policy streams* of problems, policies, and politics. While this dissertation does not apply Kingdon's theory in the purest form, the use of Kingdon's theory in conjunction with Gray, Lowery, and Godwin (2007) provides a sound structure for examining the factors influencing state prescription drug policy.

For the purpose of this analysis, structural conditions refer to the internal factors indicating to state legislators that a problem exists; therefore, the first set of factors discussed are those that indicate need for government intervention. So,

how do state legislators become aware of citizen need and what means are available to deal with it? As suggested by Kingdon's assertion that indicators assist in bringing attention to an issue, states with a disproportionate share of subpopulations (i.e., elderly, poor, rural, and sick) associated with greater use of pharmaceuticals may serve to demonstrate the necessity for government intervention.

Second, state legislators must consider the states' means to deal with the issue. Kingdon suggests that the window of opportunity for policy adoption increases when problems and politics are coupled with viable policy options. Kingdon argues that the policy community in essence creates a short list of viable policies that largely address the problem within the political confines (2003, 139). Undoubtedly, the identification of viable policy options includes those that are financially feasible. The popular catch phrase "Show me the money" from the motion picture *Jerry Maguire*, seems befitting the situation. Similarly, state legislators undoubtedly ask themselves "How are we going to pay for this?" Thus, policies that address the funding questions undoubtedly influence the policy options considered and those ultimately adopted.

Lastly, beyond demographic indicators, policy makers are also influenced by what Kingdon construes as political factors (i.e., national mood, election results, administrative and ideological changes, and interest groups). Kingdon (2003, 163) denotes that these factors serve as indicators of pressure to either promote or deter public policy. It is the effect of these political factors coupled with problem

identification and viable policy options that must converge to create windows of opportunity for policy adoption.

The remainder of this chapter will discuss the factors thought to influence state prescription drug policy adoption. The factors are presented in accordance with the supposition identified in Kingdon and Gray, Lowery and Godwin. In essence, the order in which I will discuss the factors include structural conditions, state intrinsic characteristics, and external factors.

Demographic Conditions

States are comprised of a multitude of individuals with varying needs and wants from their state legislator. State legislators must somehow ascertain the needs of the citizens by whom they were elected. One such way is to examine the structural conditions of the state. In other words, what is the situation of being within the state? It seems plausible to expect state legislators to consider policies that impact a significant portion of their population. It is my hypothesis that in the case of prescription drug policy, the states' population aspects of age, poverty, education, urbanization, and health status serve as indicators to state legislators of the need for government action.

State population over the age of 65: Research suggests that the age distribution of citizens within a state may influence state policy adoption for two reasons. First, researchers have substantiated the positive relationship between age and utilization of health care services (e.g., prescription medications) with older patients using more health services (Poisal et al. 2007; Roe and McNamara 2002). Thus states with a disproportionate share of citizens over the age of 65

may have a greater need for pharmaceuticals. Not only are states with an older population more likely to adopt prescription drug policies aimed at access but states with a larger percentage of elderly are likely to be early adopters of health care reform policy (Carter and LaPlant 1997, 23).

Second, research suggests a relationship between age and public policy. Specifically, evidence suggests that those over the age of 65 are more supportive of health policies that increase the government's financial contribution to health care costs (Weaver 610-19). Additionally, research indicates that the subpopulation that would benefit from the legislation is more politically active (Campbell 565-74). States with a larger proportion of the politically active elderly have a greater likelihood to adopt generous prescription assistance programs (Gray, Lowery, and Godwin, 2007, 97). State legislators may fear negative reaction at the next election from what is commonly perceived to be the largest voting community. Founded on the evidence that older patients have greater utilization of prescription drugs and are more likely to be politically active, one could easily suppose that the greater the states proportion of elderly the more likely legislators to endorse prescription drug policies (Kaiser Family Foundation 2007).

Poverty: In addition to addressing the needs of the elderly subpopulation, state legislators have adopted policies to address the health needs of the poor. For example, in 2006 Massachusetts adopted legislation designed to provide access to health insurance for all state residents (Blendon et al. 2008; Kaiser Family Foundation 2009). Beyond health insurance, research indicates that

states' unemployment and poverty levels have been positively linked to Medicaid enrollment and spending levels (Albin and Stein 1977; Carter and LaPlant 1997). Additionally, literature suggests that public policy for a particular group is influenced by the extent to which the citizen group needing assistance is considered worthy (Grogan 1994). However, the fact that a significant number of Americans across a wide variety of socioeconomic conditions have difficulties paying for prescription drugs may mitigate the resistance to assist the "unworthy" amidst the breadth of citizens needing assistance. Conventional wisdom suggests that citizen income would likely influence the individual's ability to purchase prescription medications. I hypothesize that states with a disproportionate population in poverty may have a greater likelihood to adopt prescription drug policy aimed at acquisition and safety. On the contrary, I hypothesize that adoption of distribution policies which target the pharmaceutical distribution entities are unlikely to be influenced by the proportion of state citizenry in poverty.

Education: A disproportionate population of less educated citizens may have an effect on prescription drug policy for reasons similar to those of the elderly and poverty subpopulations. Education may serve as an indicator of need. Evidence suggests that education is positively associated with better health outcomes. As anyone who has tried to navigate the U.S. health care system quickly finds, health care is a complex issue. Research indicates that individuals enrolled in educational programs have better health outcomes (Bunting and Cranor 2006; Cranor, Bunting, and Christensen 2003). Specifically, education is a predictor of good health (Pincus et al. 1998, Daniels 2001). Even when controlling

for age, ethnicity, and gender, individuals who fail to complete high school are more likely to develop chronic diseases (e.g., diabetes, cardiovascular) (Pincus et al. 1998). While little evidence links education level to utilization of prescription medications, one could suppose that the education of an individual would be correlated to his or her knowledge and understanding of the disease. Scholars argue that states with a greater proportion of high school graduates were more concerned with health risks (Shipman and Volden 840-57). Thus states with a less educated population may have a greater need for government intervention.

Urbanization: The evidence suggests that states with unbalanced rural and urban populations vary in their needs. Specifically related to health care services, scholars argue that urban and regional differences exist in the need, utilization, access, and legislator sophistication (Holahan, Berenson, and Kacavos 1990; Casey 2001). At an early age, we discover cultural differences between rural and urban areas by reading Aesop's Fable, Country Mouse City Mouse. Beyond fictional depictions of cultural differences, scholars have found the rural and urban variation in utilization of services (e.g., child care and municipal services) and public policy (Walker 1969, McMillan and Amoako-Tuffour 1991).

According to the 2000 U.S. Census Bureau, over 50 million Americans live in nonmetropolitan areas. Individuals living in rural areas are associated with a greater need for services as they are older, sicker, and poorer (Ormond, Zuckerman, and Lhila 2000). In addition to need, access to care varies regionally. The National Rural Health Association states that in spite of 20% of Americans living in rural areas only 10% of physicians practice in rural areas. In terms of

prescription drug policy, access to physicians has a direct link to access to prescription drugs in that patients are unable to secure prescription medications without approval of a physician. Those in urban areas have greater access to health care providers and pharmacies, thus influencing their ability to get prescription medications.

Beyond the influence of needs and access, research suggests that regional differences are associated with legislator sophistication, indicating a positive relationship between state urbanization and policy adoption (Walker 1969). Based on the supposition that legislators from urban areas are more sophisticated and thus more likely to be policy innovators, scholars suggest that urbanization influences policy adoption. In the case of prescription drug policy, I concur that urbanization will influence state prescription policy, however, contrary to Walker, I posit the influence is based on citizen representation of need rather than the legislator sophistication. It is important to note that for the purpose of my dissertation urbanization refers to the metropolitan (e.g., cities and surrounding suburbs). Thus, I suggest that the greater the proportion of the population living in rural areas, the greater the influence on state prescription drug policy adoption.

Health status: Similar to the aforementioned factors, health status may serve as an indicator of need. Although one might intuitively expect patients in poorer health to use more medication, scholars have empirically substantiated the finding that those in poor health status will consume more, regardless of insurance type (Poisal and Murray 2001). The research suggests that patients in poor health have less price sensitivity to needed medications than those with better health

status (Remler and Atherly 2003). In essence, patients with poor health have greater need and are less sensitive to changes in prescriptions drug costs. However, as prescription drug costs continue to rise, the acquisition of prescription medications becomes more challenging. Undoubtedly, state legislatures have an interest in assisting residents with access to prescription medications. While, I hypothesize that the health status of a states' citizenry may influence the adoption of access and safety prescription drug policies, I can find no evidence to suggest that the health status would affect the adoption of distribution policies. As previously mentioned, distribution policies attempt to regulate the entities involved in distribution not address the needs of one segment of the population.

Institutional Characteristics

State Financial Capacity: Unlike the factors mentioned up to this point which serve as indicators of need, this factor provides an indicator of the states' financial capability. The early work of Walker (1969) and Gray (1973) found that wealthy states had more resources with which to explore policy options and therefore, were more innovative than poor states. Additionally, scholars have found that resources affect policy adoption changes (Bingham 1976; Downs 1976; Downs and Mohr 1980; Mohr 1969; Walker 1969). In his analysis of policies mandating Medicaid recipients to enroll in managed care plans, Satterwaite (2002) found consistent results that poor states were less likely to adopt such policies. Berry and Berry (1990, 411) found states with "poor fiscal health" were more likely to adopt lottery policy. Unlike the lottery policy, which would bring revenue into the state and thus would more likely be adopted by states facing financial difficulty,

prescription drug policy aimed at providing prescription drugs to citizens would incorporate financial outlays and thus would more likely be adopted by wealthier states. With regard to state pharmacy assistance programs, Gray, Lowery, and Godwin (2007, 115) found wealth of a state to be positively associated with adopting prescription drug assistance programs.

Many states provide access to prescription medications either through the Medicaid program or with separate state-funding programs. Providing such assistance to citizens can be quite expensive. In 2006, states funded 7% of prescription medications via public assistance programs (i.e., Medicaid, SCHIP, and General Assistance), worker's compensation, and temporary disability (National Health Expenditure). Undoubtedly, state budgets affect the ability to pay for such things as prescription drugs. In general, states have the option to either reduce spending or increase taxes to pay for such policies. State legislators are keenly aware of the political implications of tax increases. Therefore, I posit that the wealthier a state, the greater the likelihood of adopting prescription drug access policies.

Legislative Professionalism. Similar to state wealth, the degree of professional resources (e.g., skill, knowledge, and staff) serve as an indicator of a states capacity to address the complex issue of prescription drug policy. The 1960s reform movement to increase legislative professionalism resulted in a significant increase in staff, higher legislative salaries, and longer session length by the 1980s (King 2000; Rosenthal 1996; Advisory Commission on Intergovernmental Relations 1985, 364). Scholars have found that increased

professionalism has had a positive impact on winning elections, citizen contact, and initiatives among legislators (Rosenthal 1996, Berry, Berkman, and Schneiderman 2000; Grossback and Peterson, 2004). The extent to which longer sessions and increased staff have permitted legislators to gain a significant understanding of the policy issue may have the potential to influence other legislators. In essence, legislative experts provide information and influence other legislators with internal knowledge and are regarded as "trusted sources" by colleagues (Dahl 2005 [1950]). As previously stated, prescription drug policy is a complex system involving economic, scientific, and financial constructs benefiting from the additional staff and session length to navigate and develop an understanding of the policy issue. To the extent that staffing and length of session have a positive effect on understanding a complex policy, one would reason that having session time and personnel available would also positively affect state prescription drug policy adoption.

Neighboring States. Conventional wisdom suggests that we are influenced by the things around us. Scholars suggest this may also apply to state influences on other states (Walker 1969). The argument rests on the idea that external factors on state policy adoption are a consequence of constraints and competition. One of the most difficult challenges for any legislator is to figure out the best solution to an issue based on limited and often imperfect information. While rational choice theory suggests that decisions are based on complete knowledge surrounding the problem and potential solutions, as human beings, state legislators have significant limitations on what they can grasp, process, and

base a decision on (Lindblom 79-88;Lindblom 79-88;Kingdon vii-253;Lindblom 79-88;Sabatier). Legislators, like many Americans, operate in an environment where our actions are a consequence of time, physical, mental, and political constraints. In part because of the limited time and resources to consider all possible options, state legislators may borrow from an already successful policy (Walker, 1969). A policy that has been "tried and true" in another state may appear to have reduced risk and thus be more appealing to state legislators. State legislators may address the internal political and social constraints by looking to states with similar social and political characteristics (Boehmke and Witmer 39-51).

In today's environment of technological and communication advancements, state legislators have access to an abundance of policy information related to the policy actions of other states. For example, media markets often service more than one state. As a result, states may receive information on public policy initiatives being conducted by their neighboring state. In addition, state legislators may rely on personal and professional contacts for guidance on state policy. Scholars argue that the presence of media and professional networks allow for opportunity for policy leaders to gain knowledge about policies and their likelihood of success (Carter and LaPlant 17-26). Furthermore, scholars argue that emulation of successful policies may occur outside of neighboring states (Karch 2007). Specifically, legislators may also become aware of successful policy options through membership in professional organizations and attendance at professional conferences. In addition to

knowledge of successful policies, research has indicated participation in professional organizations positively influences policy adoption. In his 2001 analysis of Health Maintenance Organizations, Balla (2001) found that states whose insurance commissioner was involved in the National Association of Insurance Commissioners were more likely to adopt the Health Maintenance Organization (HMO) Model Act.

In addition to the physical, mental, and political constraints, "competitive federalism" may influence state policy adoption (Tiebout 1956). States sometimes compete with one another for an advantage on economic development and to avoid being at a disadvantage on items such as welfare benefits (Grogan 1994, 593, Karch 2007, 62). The similarities across states with regard to law, politics, language, and culture make movement between states easier for business. Couple the ease of relocation with the financial benefits business provides to states, one can easily see why states engage in bidding wars to persuade business to locate in their state (Grady 1987). States also incentivize business and labor through lower tax rates as evidenced by research reporting a positive correlation between relocation rates of citizen and business and the tax to service ratio of states (Tiebout 1956).

In addition to competing for business and labor, states also face competition with regard to lost revenue. In their seminal work, Berry and Berry (1990) posit that out of fear of losing revenue, states considering lotteries were influenced by whether or not neighboring states had lotteries. Scholars have also found similar results that economic competition positively influences Indian

gaming policy adoption (Boehmke and Witmer 2004). In both cases, the evidence suggests that state lawmakers may experience pressure to emulate public policy or face negative consequences (e.g., loss of jobs and revenue). States may also compete in policy adoption to avoid being attractive to unwanted entities (e.g., welfare recipients) (Peterson, and Rom 1990)[2]. While the evidence suggests a seemingly consistent finding that competitive federalism influences state policy adoption, Berry and Baybeck (2005) indicate that states may compete on issues such as state lottery but not on the issue of welfare benefits, thus suggesting that the influence of competition varies by policy issue. Additionally, on the issue of pharmacy assistance programs, Grogan (1994) presents evidence suggesting the neighboring effect to be nil on actual policy adoption yet have a negative effect on program generosity and a positive effect on program expansion.

The research literature has suggested that the policy adoption of other states may influence state policy adoption. In the case of prescription drug policy, I speculate this to be the case, particularly on the issue of acquisition and distribution. While state legislators may be more influenced by competitive federalism on the issue of distribution, on the issue of prescription drug policies aimed at acquisition, state legislators may look to other states for both reasons of emulation and competition.

Interest Group Influence

[2] Scholars have challenged this supposition on the basis of methodological design flaws including failure to adjust for inflation (Volden, 2002, 353).

According to E.E. Schattschneider (1986, 247), “The diet on which the American leviathan feeds is something more than a jungle of disparate special needs.” While most individuals, not just the political scientists, are aware of the escalating number of interest groups since the 1960s and 1970s, it is political scientists who have explored the influence of interest groups (Walker, 1983; Berry, 1987, Baumgartner and Leech, 2001, Yackee and Yackee, 2006). In general, the research indicates that business interest groups are prolific in politics and that they are influential in policymaking (Baumgartner and Leech 2001; Yackee and Yackee 2006). In 2002, of the 17,880 registered lobbyists in Washington DC, 40% indicate advocating for a health care issue. In other words, there were 13 health care lobbyists for every member in the U.S. Congress. (Glabman 2002). Prescription drug policy is no different than other health policy issues in regard to the breadth and depth of interest groups. To illustrate Schattschneider’s point of diverse interests, one need only look at the issue of prescription drug policy at the federal level where the involvement of Pharmaceutical Research and Manufacturers of America (PhRMA), AARP, American Hospital Association (AHA) American Association of Health Plans (AAHP), American Medical Association (AMA), U.S. Chamber of Commerce was present (Oliver, Lee, and Lipton, 2004; Weissert and Weissert 2006). It has been suggested that the more than 400 pages of MMA legislation was significantly influenced by lobbyists (Hall and Van Houweling 2006).

While legislators face considerable political pressure from a myriad of health care interests, according to some scholars, interest groups provide an

indispensable service through their willingness to provide information and campaign support (Dahl 1961; Kingdon 2003; Lindblom 1959; Weissert and Weissert 2006). Policy innovation commands labor resources necessary to research policy options and correlated costs (Mohr 1969). Lobbyists can employ techniques of testifying at legislative hearings, meeting personally, and doing favors to affect what the government does (Nownes 2006, 17). Additionally, the willingness to write letters, make calls, etc. can potentially get the attention of government officials (Heaney 2006, 891). Scholars argue that the interest group engagement in the political process can have an effect on the government's agenda (Kingdon 2003). While the evidence suggests that interest groups are influential in public policy, scholars have argued that interest groups tend to favor business (Schattschneider 1986). However, Grogan (1994) suggests that influence of business and provider may be greater when the public interest is low.

The interest groups most commonly associated with prescription drug policy are those representing drug manufacturers. Groups representing health service providers (e.g., Illinois Pharmacist Association) and groups representing patients (e.g., National AIDS Foundation) are also active prescription drug policy. For example, the National AIDS Foundation website indicates advocating expansion of access to Narcan a useful to reverse the onset of overdose (Aids Foundation of Chicago). Whereas, the Illinois Pharmacist Association website indicates their mission is "dedicated to enhancing the professional competency of pharmacists, advancing the standards of pharmacy practice, improving

pharmacists' effectiveness in assuring rational drug use in society, and leading in the resolution of public policy issues affecting pharmacists" (Illinois Pharmacists Association)

At the state level, research indicates that advocacy organizations can have a strong positive effect on health policy (Miller 2007; Pracht and Moore 2003). Grogan (1994) found that the pressure exerted by interest groups affected state Medicaid policy decisions. While Gray, Lowery, and Godwin (2007) argue that the effect may be greater on the policy revisions as opposed to policy adoption, interest groups such as the Pharmaceutical Research and Manufacturers of America (PhRMA) have been successful in stopping or at least delaying policy adoption. In the case of preferred drug lists and Medicaid discounts, PhRMA filed lawsuits in Michigan, Florida, and Maine to challenge state legislation. This same group was also successful in restricting the importation of prescription medications from Canada (Silow-Carroll and Alteras 2004). The impact of interest groups state policy adoption may be reflective of the sheer magnitude of contacts at a state level compared to that at a national level.

Consistent with research literature, I hypothesize adoption of state prescription drug policy will be influenced by the involvement of interest groups. In particular, state regulatory policies aimed at distribution of prescription drugs will be of particular interest to those representing the distributive entities. Similarly, state legislation related to acquisition and safety of prescription

medications is of particular interest to the entities representing the patients and providers.

Public Preference

Issue Salience: Scholars have long since recognized that issues matter. The seminal work on Congress found that legislator actions are different for issues that get local or national attention compared to issues that are not (Mayhew 1974; Fenno 1978). Additionally, research indicates that issues of broad public concern affect public policy in terms of attention, timing, and type (Dahl 1969; Key 1961).

Americans face many challenges in their day to day lives; however, it is the movement from a personal challenge to a public distress that increases the salience of an issue (Baumgartner and Jones 1993, 27; Northington, Gamble and Stone 2006). Kingdon suggests that problems that violate our societal values are likely to be construed as a problem needing attention (2003, 198). The strongest of those values include equity, individual responsibility, and faith in market solutions. As demonstrated in the latest public discourse over health care reform, perception of inequitable distribution of health care resources has moved the issue from an individual problem to a government problem.

Momentous issues that resonate with the public will undoubtedly gain greater legislative attention than issues with minimal interest which will quickly dissipate from the public agenda (Weissert and Weissert 2006, 333). At the national level, the Medicare Modernization Act of 2003 illustrated how the salience

of an issue can factor into policy adoption. The rising costs of prescription medications, a critical issue for seniors (a major voting bloc), became an important matter for legislators. Additionally, it has been suggested that the saliency of issues may be stronger if they can be associated to a "villain" (Downs 1972). In the case of prescription drug policy, the issue of rising drug costs is often associated with the "villainous" entities that are pharmaceutical manufacturers and insurance companies.

Additionally, issues that are perceived as critical will impact the timing and type of public policy. For salient issues that are perceived as critical, citizens expect immediate attention and appear comfortable in leaving the specific policy details to the experts. At the national level, prescription drug policy has a long standing practice of materializing subsequent to triggering events (Grabowski and Vernon 1983). For example, each of the three defining periods of the Food and Drug Administration regulatory policies resulted from a triggering event. The first period is demarcated by the actions of muckrakers like Samuel Hopkins Adams and Upton Sinclair. Subsequent to their expose', industry, legislators, and the general public got behind food and drug regulation, eventually passing the 1906 Pure Food and Drug Act (Hilts 2003, 51). The article written by Samuel Hopkins Adams in *Collier's* revealed the levels of acetanilide in Cuforhedake Brane-Fude was responsible for at least twenty-two deaths; these revelations subsequently mobilized public concern.[3] While this remedy was, as the name implies, aimed at reducing headaches, it was comprised of alcohol, caffeine, and acetanilide[4].

[3] Most of the historical accounts of FDA are from Hilts 2003.
[4] Acetanilide was commonly used as a pain reliever but was later found to be related to blood disorders.

Although the previous triggering events resulted in legislation, journalists, consumer protection groups and even the FDA itself indicated a need for additional legislation to address gaps in the 1906 law. However, it was not until a cataclysmic event involving the death of more than 100 individuals took place that public policy was adopted. The details surrounding the event included the Massengill Company of Tennessee, which developed and sold a product for children that contained a chemical similar to antifreeze. One of the gaps of the 1906 Act was that food and drugs did not have to be tested for safety (U.S. Food and Drug Administration). The tragedies of the 1930s rallied support for a change to food and drug law. Shortly after the catastrophic event, Roosevelt signed the Food, Drug and Cosmetic Act (FDCA) into law.

As clearly demonstrated by events surrounding FDA policies and health care reform, cost, safety, and distribution of prescription medications are concerns that resonate with citizens. In essence, the "government does what the people want in those instances where the public cares enough about an issue to make its wishes known" (Wright, Erickson, McIver 1987, 981). Therefore, I hypothesize that issue saliency positively affects the adoption of prescription drug policy.

Political Influence

Ideology: To the extent that the goal of elected officials is to gain as much public support as possible in hopes of getting reelected, policies that are consistent with prevailing beliefs or values of the citizens are more likely to be adopted than when those beliefs are threatened (Zaltman, Duncan, and Holbek 1973). Generally speaking, citizen beliefs and values are manifested through association

as either conservative or liberal. Mohr (1969) identifies ideology as a motivating factor in the construction of public policy. Scholars suggest that within a state it is the public identification as liberal or conservative that impacts policymaking; superseding the effect of the demographic factors (i.e., age, poverty, education, urbanization, and wealth) (Wright, Erikson, and McIver, 1987). For example, those states supporting civil rights and health policy are most commonly associated with liberal ideology. The innovation of public policy is believed to occur more frequently in states with liberal ideology because of their willingness to bring more issues to the table and their openness to experimentation (Nice, 1984). On the issue of health care policy, several scholars deem ideology to be a significant influence (Starr 1982; Marmor 2000; Miller 2005).

Based on the literature research, I argue that states with a disproportionate liberal citizenry will be more likely to adopt acquisition, distributive and safety policies than those with a conservative ideology. As indicated earlier, assisting with access to prescription medications is a redistributive policy in that it requires taxpayers to subsidize the medical care of those in need. Additionally, the regulatory nature of acquisition, safety, and distribution policies challenges our societal belief of reliance on the market solutions and laissez-faire approach. Thus, I hypothesize that those states with a more liberal ideology will be more likely to adopt

Political Party Control: Both in terms of public policy and government elections, political parties have undoubtedly played a fundamental role in the United States. From America's infancy, the utility of political parties was quite apparent

particularly to people such as Thomas Jefferson, who revealed in a letter to Henry Lee (1824) that “they (*political parties)* are censors of the conduct of each other and useful watchmen for the public." In addition to serving as a watchful eye, political parties simplify the political choice in terms of candidates and policies (Nivola and Rosenbloom 1986). Through the political primary process, political parties abridge the list of potential candidates. Beyond safeguarding against abuses by the other party and condensing the pool of political candidate, political party ideology, issue selection, and committee staffing have been linked to policy adoption.

According to Erikson (1971), political party made a difference in adoption of progressive civil rights legislation; states with Republican or divided control were less likely than nonsouthern states with Democratic control of both the legislature and the governorship to adopt progressive civil rights legislation. At a national level, one of the most significant prescription drug policies (i.e., MMA 2003) was passed under a Republican Congress and Republican President; however state level analysis suggests that Democratic states are more likely to support distributive policies than those aimed at regulating business. To the extent that the state prescription drug policies are redistributive or regulatory, I posit the less likely to be supported by states with Republican controlled legislatures.

Chapter Summary

It is no surprise that cost and access are challenges to the U.S. health system. Equally well known is the fact that policymakers have spent the better part of 80 years attempting reform to address the various challenges to our health care system. At the state level, lawmakers have adopted or attempted to adopt policies to address the cost and access of prescription drug policies. However, variation in policy adoption of prescription drugs is as varied as the states themselves. By utilizing innovation and diffusion theory, one can gain a better understanding of the factors affecting prescription drug policy.

As presented in this chapter, the literature research suggests that state policy adoption of state prescription drugs is influenced by the population composition, financial capability, legislative professionalism, neighboring states, interest groups, issue saliency, ideology, political party, and political control. Table 1 identifies the influential factors and their hypothesized influence which will be further discussed in Chapter 6. Through the use of innovation and diffusion theory one can explore the phenomenon of state prescription drug policy. More specifically, one can identify and examine the factors that influence acquisition, safety and distribution policies.

Factor	Acquisition	Safety	Distribution
Age	+	+	0
Poverty	+	+	0
Education	+	+	+
Urbanization	+	+	0
Health Status	+	+	0
State Wealth	+	+	0
Legislative Professionalism	+	+	+
Neighboring State Policy Adoption	+	+	+
Interest Group Influence	+	0	+
Issue Salience	+	+	+
Political Ideology	+	+	+
Political Control	+	0	+

Table 1: Factors Influencing State Prescription Drug Policies
This table highlights the hypothesized effect of each factor on the prescription drug policy classification. A plus sign indicates a positive effect on state prescription drug policy. A zero indicates no effect on state prescription drug policy adoptions. A negative sign indicates a negative effect on state prescription drug policy.

CHAPTER 3: *STATE PRESCRIPTION DRUG POLICY: ACQUISITION*

What can be added to the happiness of man who is in health, out of debt, and has a clear conscience?- Adam Smith

For some individuals, the growing expense of prescription medications has made it difficult to attain the happiness described by Adam Smith. In fact, patients have been forced to modify their utilization of prescription medications, perhaps sacrificing health to avoid debt (Cunningham, Miller, and Cassil 2008). Beyond the individual, states are reeling from the economic pinch as well. State and local government prescription drug costs exceeded $200 billion in 2005 compared to only $3.7 million in 1960, prior to the adoption of Medicare and Medicaid (Center for Medicaid and Medicare Services 2008).[5] Price inflation, therapeutic drug mix, newer more costly medications, and increased utilization all contribute to the increased cost of prescription medications (Express Scripts Drug Trend Report 2007). Out of necessity, states have had to be innovative in terms of how to pay for prescription medications. The legislative approaches to prescription drug policy are as different as the states themselves. Thus, in order to determine the factors influencing prescription drug policy, one must closely examine the policies.

As mentioned above, the past ten years have produced a multitude of state prescription drug policies, coalescing around the three general constructs of acquisition, safety, and distribution. For the purpose of this analysis, acquisition policies are defined as those that rely on financial mechanisms, use state dollars to assist citizens with access to prescription medication, or policies that utilize institutions to maximize access. In particular, acquisition policies include

[5] Not adjusted for inflation.

legislation related to Medicaid and Medicare. While current provisions within Medicare and Medicaid provide some resources to assist the poor and elderly with the acquisition of prescription medications, state legislators have adopted policies to maximize the utility of these programs. For example, states have adopted legislation to take advantage of federally negotiated pricing for prescription medications.

Additionally, acquisition policies included legislation that employ economic principles of supply and demand. The United States has a long standing tradition of reliance on market solutions to address public problems, and state prescription drug policy is no exception. While policy specifics vary, state policies intended to expand access to prescription medications have generally been based on the economic theory of supply and demand. In general, state legislators employ two policy approaches: one aimed at the price of prescriptions and the other aimed at the quantity demanded. Policies intended to affect the price utilize a myriad of strategies including maximization of purchasing power, price controls, and other financial incentives. On the demand side, states' have utilized incentives to encourage patients to demand the equally efficacious affordable options. In essence, state legislators hope to increase access to needed prescription medications by reducing the financial barriers patients confront.

Table **2** is a list of the eight policies selected from the National Council of State Legislatures and included in the acquisition classification. Only legislation designed to increase access through a policy associated with Medicare or Medicaid, those policies attempting to intercede on the price or quantity of

prescription medications, or utilized institutions to maximize access were included in the acquisition classification. It is my supposition that the summative categorization of acquisition policies allows for a more parsimonious analysis of the factors influencing prescription drug policies. Chapter six describes the methodological approach to categorization. During my analytical time period, executive orders related to prescription drug policy did occur; however, state legislative actions are the focus of this analysis. Although each state may not be specifically mentioned, each of the various access policies adopted by states over the past decade will be discussed in this chapter. While this chapter independently presents the policies used by states to increase access to prescription medications, many of these approaches are used in conjunction with one another. It is this combination of approaches within one policy that further supports my analytical approach to examine factors that affect access prescription drug policies. For example, many of the states will have both a brand and generic component within the same policy.

Name of Acquisition Prescription Drug Policies
Expand use of 340B drug discount price program
Bulk Purchasing
Rx discount programs
Medicare Prescription Drug Act(MMA)
State Rx subsidy program
Importation
Tax deductions
Preferred Drug List
Generic drug use
Access to brand name pharmaceutical products

Table 2: Types of Prescription Drug Acquisition Policies
This table presents the prescription drug policies identified as Acquisition.

Price-Side Approaches

Expanded use of 340b drug discount price program

One of the prominent mediums by which states provide access to prescriptions is through the federal entitlement program, Medicaid. Established in the 1960s as a way to assist the poor in accessing health care, Medicaid is a program that grants states liberty in design and administration within the broad general guidelines of the federal government. States have authority in setting eligibility criteria and benefits. In 2007, the total Medicaid outlay was $333.2 billion with the federal government paying about 57% to finance health care for approximately 49.1 million people (Centers for Medicaid and Medicare Services, 2008; Kaiser Family Foundation 2009). Medicaid provides a safety net by funding health care for one in five Americans. During economic downturns, when states face additional demand for assistance and a decrease in revenue stream, providing assistance becomes particularly problematic.

In reaction to financial pressure, states have explored many viable options to reduce prescription drug costs. One possible solution has come at the hands of the federal government. Under the expansion of the 340b Drug Pricing Program, states are able to secure reduced pricing for prescription medications (Mertz 2007). According to the Medicaid Drug Rebate Program under the Omnibus Budget and Reconciliation Act of 1990 (OBRA 1990), manufacturers are required to afford drug rebates to State Medicaid agencies. Subsequent to OBRA 1990, the Veterans Health Care Act of 1992 established the 340b Drug Pricing Program of 1992, administered by the Department of Health and Human Services (DHHS), which required manufacturers to limit the cost of covered outpatient drugs for

federally qualified health centers. Specifically within the DHHS, the program is administered by the Pharmacy Affairs Branch (PAB) of the Bureau of Primary Health Care. So how does a country that reveres freedom of the market get an industry with one of the most influential interest groups to agree to limit its prices? While participation was voluntary, manufacturers who failed to participate would not receive the federal Medicaid matching funds as stipulated under the Medicaid Program (Health Resources and Services Administration 2009).

In an opportunity to reduce the costs of prescriptions paid by governmental entities, state agencies and counties were authorized, and encouraged, to search for opportunities to utilize the 340b pricing. Table 3 presents the type of entities that are considered appropriate federally-qualified health centers. Given that the 340b program was established in 1992, all states had adopted the initial program; however, economic pressure and increased demand for Medicaid assistance have forced states to expand their use of the 340b program. Undoubtedly, the push for greater participation in the 340b program resulted from financial pressure; the 1998 DHHS audit highlighted the underutilization of the program (Brown, 1998). According to the 1998 audit, two-thirds of eligible HRSA grantees did not participate, thus leaving money on the table.

Over the past decade a number of states have adopted legislation to expand the use of 340b within their states. In general, state expansion has entailed legislative action mandating state agencies participate or encourage education about the benefits of the 340b program. While states like Maine and New Hampshire have adopted legislation mandating state agencies explore the

increased use of 340b program for many diseases, other states like Utah have targeted specific diseases such as hemophilia. The results have been significant with states like Rhode Island (Heinz Foundation Report) reporting $2 million dollars in savings the first year and other states reporting between 20% to 50% off of Average Wholesale Price[6] (Scholz 2008).

[6] Average Wholesale Price is defined as the national price by Center for Medicaid and Medicare Services regulation (42 C.F.R §405.517).

Types of Entities Eligible
Disproportionate share hospitals
Family planning projects
Community health centers
Federally Qualified Health Center Look-Alikes (FQHCLA)
Migrant health centers
Section 340S school-based programs
Health centers for residents of public housing
Health centers for the homeless
Tribal contract clinics
State-operated AIDS drug assistance programs (ADAPs)
Black lung clinics
Comprehensive hemophilia diagnostic treatment centers
Native Hawaiian health centers
Urban Indian organizations
Entities receiving assistance under the Ryan White Care Act
Sexually transmitted disease (STD) clinics
Tuberculosis (TB) clinics

Table 3: Entities Eligible to Participate in the 340b Drug Price Program
This table presents the entities approved to apply for participation in the 340b Drug Price Program administered by DHHS. Source: PL 102-585 Section 602.

Bulk Purchasing

In addition to exploring prospects presented at the federal level, states have looked within and across borders for opportunities. The result is that states have entered into intragovernmental or intergovernmental state purchasing agreements. In essence, these purchasing pool arrangements allow states to combine their orders and buy in bulk, thereby obtaining a reduced purchase rate and increased rebates for prescription medications. While some states have entered into these arrangements to reduce the prescription medication costs related to Medicaid, other states have entered into these arrangements for all prescription medications purchased by the state regardless of group (e.g., state employees and SCHIP). Intragovernmental purchasing pools like the one in the state of Georgia created the Department of Community Health (DCH) to oversee the purchasing of prescription drugs for the entire state. The DCH negotiates on the behalf of state agencies to facilitate the best prescription drug purchase price (Krause 2004). On the other hand, states like Delaware, Missouri, New Mexico, and West Virginia have formed the intergovernmental purchasing group RXIS. Under RXIS, the states utilize the services of a Pharmacy Benefit Manager (PBM) to negotiate with pharmaceutical manufacturers for greater drug discounts. The multi-state pooled purchasing reported substantial savings from the better negotiated price (Krause 2004). While pooled purchasing arrangements offer significant benefits in terms of cost and pharmacy management, they also present states with significant managerial and political challenges (National Governors Association 2004). In order to optimize the savings and strengthen their bargaining power, states need to develop similar

lists of covered medication[7]. In doing so, the state is pushing market share to a particular product, therefore, maximizing the savings. Developing a multi-state coalition requires the political prowess necessary to navigate through the logistical challenges associated with such an endeavor.

Prescription Drug Discount Programs

The variety of prescription drug discount programs is almost as varied as the states themselves; however, the objective is consistent. State legislators are exploring opportunities to reduce the prescription drug costs facing their constituents of which drug discount programs have become one such method. While Medicaid provides a safety net for many, there are many Americans who exceed the financial qualifications for Medicaid but still have difficulty paying the high price of prescription medications. In an effort to assist these individuals, states like Maine, Illinois, Hawaii, and Iowa have negotiated with pharmaceutical manufacturers to create drug discount programs. Patients who are not eligible for Medicaid may enroll in these programs and receive discounts on their medications. According to the National Conference of State Legislatures (2009), half of all states offer some form of prescription drug discount programs. While multiple states have drug discount programs, the eligibility requirements and estimated discounts vary by state. For example, Maine residents who meet income requirements may enroll in the discount program, *Maine Rx*, to save 15% on branded medication and 60% on generic medications (State of Maine, 2009). On the other hand, Colorado's *Cares Rx* program negotiated with pharmacies to offer residents, who do not have health insurance but do meet the financial necessity criteria,

[7] Preferred Drug Lists are discussed later in this chapter.

prescription medications at a fixed price for individuals (State of Colorado, 2009). Similarly, Iowa's Drug Card program has negotiated with pharmacies to offer savings between 30 to 70%; however, the Iowa program has no income or insurance requirement (Iowa Drug Card Program, 2009).

While drug discount programs have significant benefits to citizens in terms of dollars, not everyone has been supportive of the programs. In the case of Maine, PhRMA challenged that the state was in violation of interstate commerce and harmful to Medicaid recipients (Pharmaceutical Research and Manufacturers of America v.Walsh, 2003). Upon reaching the Supreme Court, the court ruled in favor of Maine, stating that neither undue harm nor violation of interstate commerce had occurred (Reforming States Group, 2003).

Medicare Modernization Act

On December 8, 2003, President George W. Bush signed into law one of the largest Medicare changes. Simply stated, the Medicare and Modernization Act of 2003 (also referred to as MMA or Part D) was designed to provide prescription drug coverage for Medicare enrollees (CMS PL108-173 summary). With the passage of MMA, Medicare eligible citizens had access to prescription drugs. Prior to the passage of MMA, Medicare beneficiaries could purchase supplemental insurance coverage that covered prescription medications or, if eligible, enroll in Medicaid. However, the legislation resulted in more than 400 pages detailing a complex policy. While the legislation was signed in 2003, the program was phased in with the federal government offering a drug discount program beginning in 2005 and going into full effect in 2006. In 2005, Medicare enrollees could sign

up for a drug discount program similar to the states' plans previously discussed but at the federal level. In 2006, Medicare enrollees were able to enroll in Part D plans.

In response to MMA, states began crafting legislation to deal with issues brought about by MMA. In particular, the states developed policies to address the immediate needs of dual-eligibles.[8] According to NCSL, 37 states adopted policies to temporarily assist dual-eligibles in the acquisition of prescription medications (National Conference of State Legislatures, 2006 Prescription Drug State Legislation). While most of the state legislation occurred in the 2006, states have continued to produce legislation to address MMA dilemmas.

State Subsidy

While the passage of MMA resulted in access to prescription medications for seniors, it was not comprehensive. Members enrolled in Medicare Part D are still responsible for deductibles and copayments, thereby influencing their ability to purchase prescription medications. Often termed "wrap arounds," the subsidy programs pay the premiums, deductibles, and copayments associated with prescription medications for Medicare enrollees who meet financial eligibility requirements. Similar to the drug discount programs, the criteria and coverage vary by state. Most states' pharmacy assistance plans (SPAPs) pay for deductibles, copays, and pharmaceuticals of those residents who do not reach a percentage of federal poverty level. For example, the state of Hawaii program has

[8] According to the Center for Medicaid and Medicare Services website dual-eligible is defined as "individuals who are entitled to Medicare Part A and/or Part B and are eligible for some form of Medicaid benefit." Definition available at http://www.cms.hhs.gov/DualEligible/

limited benefits to individuals who have an income of up to 100% of the federal poverty level. A number of states, such as New York, Illinois, Hawaii, and Indiana, have adopted these Medicare wrap around policies. States like Delaware and Indiana have placed an annual subsidy limit per senior. According to Arizona's website, the copayment subsidy provided to seniors will be the latest casualty in the current economic crisis. As of February 2009, Arizona dual-eligible citizens will no longer be receiving financial assistance with prescription drug copayments.

Importation

In addition to domestic opportunities to save money, states have looked to international opportunities for discounted medications. While the reimportation of prescription medications is in violation of the United States Food, Drug and Cosmetic Act of 1938, in 2004, the state of Illinois developed a program whereby citizens could order a 90 day refill of their branded medications from Canada, United Kingdom, and Ireland. Under the I-Save Rx program, the state of Illinois contracted with CanaRx, a Canadian Pharmacy Benefit Manager, to allow residents the opportunity to purchase prescription medications at a lower cost. Use of the program is limited to patients who have already received their initial prescription medications in the U.S. and limited to certain brand medications. Generic medications, narcotics, and prescriptions requiring special handling such as refrigeration are not available through this program. According to a press release, the citizens of Illinois have saved 25% to 50% on 13,778 submitted prescription drug orders (State of Illinois, 2006). States like Kansas, Wisconsin, Missouri and Vermont have joined the I-Save Rx program. While the program

offers the potential for significant savings, citizen use has been lower than anticipated for a couple reasons (State of Illinois Office of the Auditor General, 2008). First, physicians argue safety concerns associated with reimportation of prescription medications and argue for greater use of domestic generic medications as opposed to reliance on foreign suppliers (Kesselhelm and Choudhry, 2008). While the I-Save Rx program relied on pharmacies approved by Illinois Health inspectors , the Canadian pharmacies began looking to other countries such as Fiji to supplement their supply when pharmaceutical manufacturers reduced the Canadian supply (Kaiser Daily Health Policy Report, 11/04/2005). Undoubtedly, the issue of Canada serving as a pass through country for prescription medications significantly raised the safety concerns. Second, the FDA flexed its administrative muscle by seizing prescription medications ordered from Canada, thus creating concern in citizens as to whether or not their prescription medication would actually arrive (Manning, 2004).

The reimportation of prescription medications was particularly pertinent prior to the passage of Medicare and Modernization Act of 2003 (MMA). As previously mentioned, the elderly are the largest consumers of prescription medications. Prior to MMA, news reports of seniors being bused to Canada were commonplace. Policy makers were undoubtedly motivated to take legislative action that would benefit a large voting bloc. As such, states adopted these drug reimporation programs. However, after the passage of MMA, which provides prescription drug coverage to seniors, the need to seek lower cost drugs from Canada has somewhat subsided.

Taxing Policies

Taxation dates back to Ancient Egypt when the pharaoh would assess the people and collect revenue in the form of grain, cattle, and labor. Although now paid monetarily, taxation remains an important government utility; that theoretically supplies the necessary revenue for services, such as financial assistance for prescription drugs. However, one should note that the U.S. has a long standing history with taxpayer revolt spanning more than 200 years beginning with events surrounding the American Revolution through the 1970s tax revolt to current Tax Day Protests (Kingdon 2003, 213; Reynolds 2009). Given that politicians are undoubtedly cognizant of political fallout associated with taxation, it would seem fitting that states sparingly approve prescription drug policies incorporating taxing mechanisms (e.g., levying, deductions, or exemptions). While only two states have adopted a prescription drug taxing policy, Louisiana has adopted two such policies. One policy applies a sales tax on prescription drugs paid by health insurance issuers, members, or insureds, while the other policy exempts prescription drugs purchased through Medicare Part D from local sales and use tax (Chapter 582; Act 608). In addition, Washington provided tax deductions to physicians and clinics for cost of drugs that are not typically self-administered (Washington State Department of Revenue 2007).

Preferred Drug Lists

Similar to pooled purchasing or drug discount programs, Preferred Drug Lists (PDLs) are another mechanism used to combat the rising costs of prescription medications. States negotiate with pharmaceutical manufacturers to obtain manufacturer rebates in exchange for a product being placed on the preferred drug lists. By and large, PDLs operate as a type of drug formulary identifying the drugs that will be reimbursed by the payer (e.g., employer, government, or health insurance company). In essence, patients face a lower copayment or discount by limiting their medications to those on the preferred drug lists. Patients who require medications not on the list may face higher copayment or be required to demonstrate clinical necessity in the form of a prior authorization.[9] Research suggests that PDLs are consistent across states with at least nine states having the same list (Ketchum and Ngai, 2008). The lists are not strictly created based on financial considerations but must also meet clinical requirements and be approved by drug utilization review boards. However, health service providers have expressed concern related to the negative impact on health status and health outcomes. In particular, physicians have raised concern about the delay or discontinuation of drug therapy that may result from patients being required to get prior authorization from drugs not on the PDL (Elam et al, 2005). Additionally, research suggests that while states may be saving money by limiting drugs to those with a lower cost, they may be spending more in terms of increased hospitalizations and office visits (Murawski, 2005).

[9] Prior authorization is an administrative tool requiring that a physician obtain approval from a payer prior to prescribing the medication (MacKinnon and Kumar, 2001). Medications typically listed on PDLs do not require prior authorization.

Quantity-Side Approaches

Generic Drug Use

The availability of generics is nothing new. Generic products are available in everything from peas to pencils and are most often priced at a considerable discount compared to their branded counterparts. In that way, generic products offer consumers an opportunity to save money. Generic medications provide a way to reduce the costs of prescription drugs by providing a safe and lower cost alternative to branded products. As the dollars spent on pharmaceuticals continue to rise, payers (e.g., patients, employers, and insurance companies) look for ways to reduce the costs. One such way is through the use of generic medications. According to the Food and Drug Administration (FDA) a generic medication is "identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance, characteristics, and intended use." (US Food and Drug Administration, 2007). According to the Kaiser Family Foundation (2007), generic medications cost $32 per prescription compared to $111 for brand medication. The difference in cost indicates that generic medication cost a third less than brand medication. The potential savings have prompted states to capitalize on the savings through legislative means. In general, states have adopted two policy approaches to encourage the use of generic medications, one targeting the patient and the other targeting the physician.

Patient related policies have focused on allowing automatic switching from brand to generic products. Starting in 1989, states began to pass legislation

allowing pharmacists to automatically dispense generic medications in place of branded medications. Prior to 1989, most states legally prohibited a pharmacist from dispensing a drug other than the one expressly written by the physician. The increase in costs did not go unnoticed by the states. Subsequent to 1989, all states had a law in place allowing pharmacists to dispense the lower cost (i.e., generic) alternative medication. To date most states allow a pharmacist to automatically substitute a therapeutically equivalent drug for the one written on the prescription (Hellerstein 1998; Rubenstein 2007). In 2006, an unprecedented number of brand named drugs had alternative generics come to market. The brand medications that went generic in 2006 could have resulted in $24.7 billion in savings to the nation (Cox, Behm, and Mager 2007). Physician related policies have focused on the approach commonly referred to as counter or academic detailing. While pharmaceutical representatives visiting physician offices to educate and advocate for the use of a particular branded medication is a common phenomenon, what is less known is that states also send out pharmacists to advocate and educate on the benefits of generic medications. In 2008, Pennsylvania adopted a counter detailing program to educate physicians within the state on the advantages of generic medications (Guadagnino, 2005). Massachusetts, South Carolina, and Washington, D.C. have all followed suit in hiring academic detailers in an effort to counter the claims of pharmaceutical representatives and yield savings for taxpayers. As expected, the pharmaceutical industry rejects the claim that physicians are unable to discern for themselves the appropriate medication for their patient (Buntin, 2009).

In addition to encouraging physicians to prescribe generics, states have also adopted programs to encourage the patient to utilize generic medications. Vermont's 2007 drug legislation S.115 created a generic sample voucher program providing a financial incentive to encourage patients to obtain generic medication.

Although generics have the potential for significant savings, they are not always the lowest priced option, presenting a quandary for states that mandate the automatic switching from brand to generic medications. States who only reimburse for generic medications when a lower cost brand product was available would not realize the expected savings. Thus, some states have also adopted legislation to accommodate such situations where brand name drugs are cheaper than generic medications. In particular, Utah has adopted legislation allowing Medicaid to reimburse for the lower cost rather than the generic only.

Brand Drug Use

Brand medications contribute a significant amount to prescription drug costs. As mentioned earlier, brand medications can cost three times as much as generic medications. For all intent and purposes, the difference in price is attributed to the initial research and development of new drug entities which is often quoted as approximately $800 million per new drug innovation (DiMasi, Hansen, and Grabowski 2003; Congressional Budget Office 2006). While the actual R&D costs provide fodder for an interesting debate, states have focused on policies to address the cost issue of brand name prescription drugs.

Even though states have adopted programs to promote the use of generics, states have also adopted policies aimed at the other half of the equation (i.e.,

brand name medications). In general, state brand drug policies have coalesced with the state generic drug policies. For example, if states have adopted policies to encourage generics, they have also adopted policies to limit the use of brand name medications to those situations that are clinically and financially prudent. States such as Rhode Island have used financial incentives, higher copayments for brand products and lower copayments for generic medications, to encourage the use of generics while discouraging the use of brand products. Similarly, Tennessee, legislation Ch. 564 specifies that barring any physician comment of medical necessity, patients of a state sponsored plan may receive the branded medication if they are willing to pay the entire cost of the branded product, whereas the generic products are reimbursed by the state.

Not all state legislation surrounding branded products is designed to mitigate their use. In fact, some states have adopted policies aimed at providing access to branded products. States like Vermont, have adopted policies allowing for the off-label use of prescription drugs for cancer (Act. 139, 2006). While the FDA approves drugs based on evidence presented for specific clinical situations, medical experts may find products to be effective for other medical conditions. For example, the use of aspirin as a prophylaxis against cardiovascular disease is commonly accepted by physicians as appropriate for diabetes (Stafford, 2008). In an effort to control costs, certain prescription drug coverage plans do not reimburse for the off-label usage of medications. A familiar example of off-label use not reimbursed is that of Wellbutrin, a commonly prescribed antidepressant medication that is also an effective smoking cessation product. Without special

provisions, individuals not diagnosed with depression would be faced with paying more, if not all, of the cost of a Wellbutrin prescription. However, states like Vermont have acted on behalf of their residents to provide prescription drug coverage for those products where the empirical evidence is not as strong (Stafford, 2008).

Acquisition policies and influencing factors

In the face of economic downturn and rising drug costs, states continue to develop prescription drug policies to alleviate this pressure. As demonstrated in the preceding pages, states have a variety of tools at their disposal. However, it is apparent that not all states have reacted uniformly. Table 4 presents the acquisition policies that have been adopted over the analytical time period. A one indicates that the state has adopted at least one acquisition policy over the study period. The sum of acquisition policy types is presented in the last column. In essence the table indicates there has been a variety in the acquisition policies employed by states.

Figure 1**Error! Reference source not found.** illustrates prevalence of acquisition policies by state. The map presents the total number of acquisition policies adopted over the study period by state. Not surprisingly, Maine had the most policies as it was a forerunner in terms of attempting legislation to place price restrictions on pharmaceuticals sold to Maine. For example, combining the information from the map with the information from the table indicates that Maine has the most number of policies adopted but did not adopt the most types of acquisition policies.

The purpose of this dissertation is to examine which factors influence state prescription drug policy. Each of the aforementioned prescription drug policies were designed to assist citizens in acquiring prescription medications. The price-sided policies presented indicate that states heavily utilized the financial tools as a means to increasing access to prescription medications. It is my hypothesis that acquisition policies were significantly influenced by the demographic indicators described in Chapter 2. The state demographics serve to communicate a need to state policy makers. Thus, states with a greater need for access to prescription medications may be more likely to support the aforementioned acquisition policies. States facing greater economic challenges may be more likely to adopt the price-sided strategies described in this chapter.

Additionally, a certain degree of clinical and economic knowledge would be beneficial in the development of the access policies. In the case of PDL, Generic and brand policies, clinical and economic knowledge is required to compare the efficacy and cost-effectiveness of competing products. An understanding of public finance would undoubtedly be of benefit in the construction of the acquisition policies. My supposition is that states with greater legislative professional resources would be more likely to adopt these types of access policies. As mentioned in Chapter 2, the state legislatures may be influenced by what other states are doing, especially in situations where policies have been successful. In the case of access policies, states reported significant savings, thus potentially influencing other states to follow suit. States facing economic pressures may look to the successful policies of other states for solutions. In addition to the media

attention given to rising prescription drug costs, individuals reel from the effects of rising costs when they get a prescription filled. For a majority of Americans prescription drug costs is a salient issue. Drug costs are perceived to be out of hand. Under each of the acquisition policies, states are expanding the role of government. From the 340b to the PDL policies, state legislatures are expanding the amount of services provided, the amount of money provided, government relationships, or the amount of taxation. States with a conservative ideology are generally opposed to the expansion of government. Thus, I would expect that states with a liberal ideology to be more in favor of such policies. Similarly, states with Democratic Party control are more often than not in support of redistributive policies.

	340B	Bulk purchasing	Drug Discount	MMA	Subsidy	Importation	Tax	PDL	Generic	Brand	Total
AL			1	1	1			1			4
AK				1				1			2
AZ			1	1							2
AR				1	1						2
CA	1	1	1	1	1	1		1			7
CO		1	1	1				1	1	1	6
CT	1		1	1	1	1		1			6
DE		1	1	1	1	1					5
DC		1		1	1			1			4
FL				1	1			1		1	4
GA			1							1	2
HI			1	1	1			1	1	1	6
ID		1		1				1			3
IL				1			1			1	3
IN			1	1	1			1		1	5
IA		1	1	1	1			1			5
KS				1	1						2
KY				1	1						2
LA				1	1		1	1	1	1	6
ME	1	1	1	1	1						5
MD		1	1	1	1			1	1		6
MA	1	1	1	1	1	1		1	1	1	9
MI				1	1						2
MN				1	1		1	1		1	5
MS			1	1	1					1	4
MO		1		1		1		1	1	1	6
MT		1	1	1	1						4
NE				1	1						2
NV				1							1
NH		1		1				1			3
NJ	1			1	1			1	1	1	6
NM				1	1						2
NY	1		1	1	1						4
NC		1		1	1	1		1	1		6
ND	1			1	1			1			4
OH		1	1	1							3
OK			1	1						1	3
OR			1	1	1			1			4
PA				1	1						2
RI			1	1	1	1			1	1	6
SC		1	1	1	1						4
SD			1	1				1			3
TN	1			1	1			1	1	1	6
TX	1		1	1		1			1		5
UT	1	1	1	1				1	1	1	7
VT			1	1	1	1	1	1	1	1	8
VA	1	1		1	1	1		1	1	1	8
WA		1		1	1	1	1	1			6
WV		1	1	1	1			1			5
WI		1	1	1		1		1			5
WY				1	1			1			3
Total	11	20	27	50	36	12	5	30	14	18	223

Table 4: States with Prescription Drug Acquisition Policies
This table identifies which state has adopted at least one of the prescription drug policies between 1999-2008 classified as acquisition.

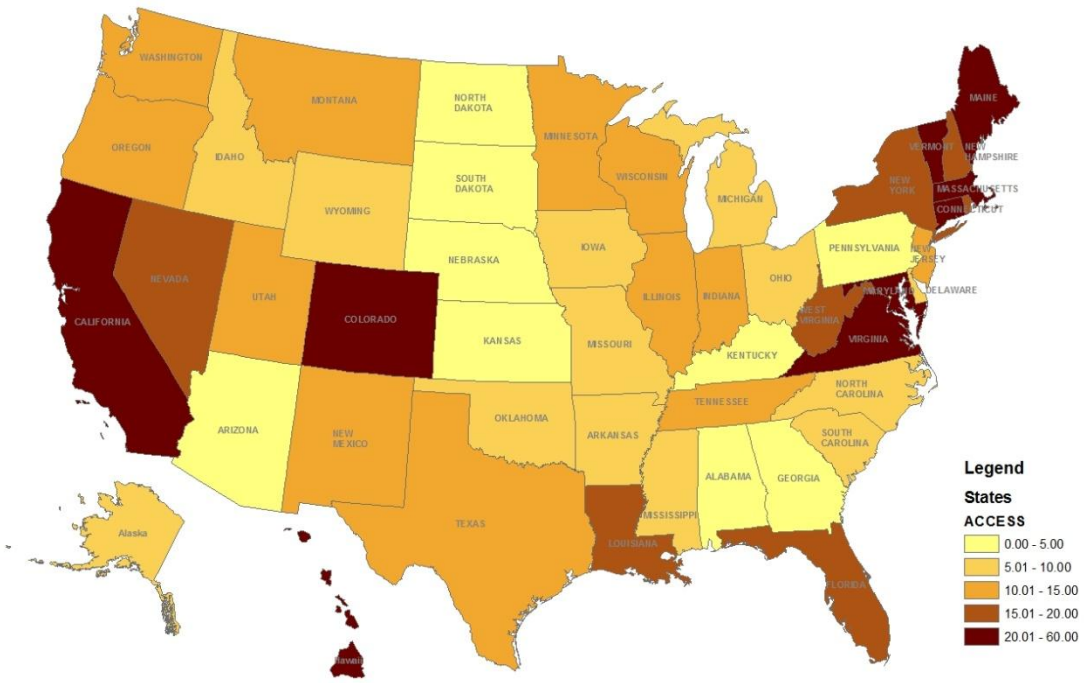

Figure 1: Geographic Variation of State Prescription Drug Acquisition Policies
This graph illustrates the variation in the number of acquisition policies adopted between 1999-2008.

CHAPTER 4: *STATE PRESCRIPTION DRUG POLICY: SAFETY*

The success or failure of any government in the final analysis must be measured by the well-being of its citizens. Nothing can be more important to a state than its public health; the state's paramount concern should be the health of its people.
~ Franklin Delano Roosevelt

Almost everyone in the U.S. has taken prescription medication at one time or another. On average patients fills 8.2 prescriptions per year in 1999 and 12.4 prescription per year in 2007, indicating an increase in the utilization (Express Scripts, 1999 & 2008). For the most part, the utilization of prescriptions is safe. In other words, patients obtain the correct medication without a negative effect on their health. In fact, medication is designed to improve or maintain health status. However, there are times when the medication proves harmful. The damage of prescription medication is often associated with *adverse drug events* (ADEs) or *medication errors* (MEs) (Bates et al. 1995). Adverse drug events are described as injuries resulting from the drug. ADEs are often a consequence of drug interactions or dosing issues. In addition, ADEs can be explained by serious side effects. For example, the heart attacks associated with Vioxx and rhabdomyolysis associated with Baycol were considered adverse drug events (Jameson, 2002; Kritz, 2008). The FDA eventually removed the drugs from the market. Medication errors, on the other hand, are mistakes that occur in the process of ordering or delivering prescription medication. MEs can occur during the ordering, dispensing, or administration. The 2006 Institute of Medicine report, contracted by Center for Medicaid and Medicare Services, cite several studies estimating the cost of ADEs and MEs range from $8,750 per hospital stay to annual cost of $887 million dollars.

States have developed policies to allay the safety concerns associated with medications since the 19th century when arsenic, cocaine, and opium were commonly used in medical care. Some of these early proposals, such as those suggesting manufacturers place drug ingredients on the label, were designed to increase patient safety (Hilts, 2003, 32). While manufacturers no longer use arsenic, cocaine, and opium in the medications, states have continued in their development of prescription drug safety policies.

While policy specifics fluctuate, prescription drug safety concerns in the 21st century have resulted in state policies targeting generics, labeling, reuse or recycling, regulation of clinical trials, and transmission of electronic prescriptions (National Conference of State Legislatures). For the purpose of this analysis, safety policies were defined as policies designed to mitigate ADEs or MEs and limited to those policies that were directed at the wellbeing of the individual.

Similar to the analysis of acquisition policies, I believe that the summative categorization of safety policies allows for a more parsimonious analysis of the factors influencing prescription drug policies rather than using the four separate safety policies. Table 5 depicts the legislation categorized as safety policies. This chapter will discuss the various state prescription drug policies designed to enhance prescription drug safety for residents.

Name of Safety Prescription Drug Policy
Generic Drugs
Electronic prescription orders
Reuse or recycling of pharmaceuticals
Disclose or regulate in-state Rx clinical trials

Table 5: Safety Prescription Drug Policies

This table presents that state prescription drug policies included in the Safety classification.

Policy Descriptions

Generic Drugs

Few argue that generic medications do not provide a cost effective alternative to the branded medications; however, criticism has mounted surrounding their safety, efficacy, and market advantage. Although the federal government has regulatory authority over food and drugs, state governments have adopted or attempted to adopt public policy designed to fill in gaps left by the FDA. In particular, opponents of the use of generic anti-epileptic medications indicate that these drugs are ineffective and have a lower likelihood of seizure control than their branded counterparts. In most states, pharmaceuticals may automatically be switched from a brand product to generic product as long as they are chemically equivalent as determined by the FDA (Rubenstein, 2007). In 2007, several states considered policy adoptions limiting the automatic switching from branded anti-epileptic medications to generic anti-epileptic medications.

On the issue of efficacy, some states have adopted policies to educate the public on the differences, advantages, and disadvantages of generic medications. In 2004, Vermont passed legislation to develop an evidence-based education program. With contributions from various health care professionals (i.e., physicians, pharmacists, private insurers, hospitals, pharmacy benefit managers, and the drug utilization review boards), the education program provides information and education on the therapeutic and cost-effective utilization of generic medications.

Electronic prescription orders

Undoubtedly the most prevalent method of obtaining a prescription involve first receiving a written order form from a physician. The patient then takes the prescription form to a pharmacy where the medications are then dispensed. Physicians are notorious for their illegible handwriting. As the name implies, electronic prescribing would replace the traditional pen and paper method with electronic transmissions of prescriptions. Electronic prescribing entails the use of technology (e.g., computer, personal digital assistant (PDA) by a physician to submit prescription orders directly to a pharmacy. Experts argue that the use of electronic prescribing would significantly reduce the number of medical errors associated with prescribing (E-health Initiative, 2004).

State policies were assisted at the federal level where policymakers set standards for the use of electronic prescribing (Leavitt, 2007). State legislative initiatives piggybacked on the federal legislation by further encouraging the use of electronic prescribing. In 2008, states like Minnesota required all providers, prescribers, and dispensers to "establish and maintain an electronic prescription drug program for transmitting prescriptions and prescription-related information using electronic media" (Chapter 358, 2008). While Minnesota required the development and maintenance, it did not require the use of the technology. Arguably the state, much like the character from the motion picture *Field of Dreams* supported the "Build it and they will come" approach. In essence, the state hope that once the technology was available that health service providers would begin using the system. California went even further to promote electronic

prescribing by providing hardware and software to prescribers (Chapter 698, 2006).[10] According to the National ePrescribing Patient Safety Initiative 2006 Legislation Fact Sheet, twenty-five states had adopted electronic prescribing legislation between 2003 and 2006.

Reuse or recycling of pharmaceuticals

As mentioned earlier, prescription medications can be quite expensive, particularly cancer medications. Initially prompted by the requests of cancer patient families, who saw expensive drugs being flushed down the toilet, states adopted policies allowing unused prescription medications to be recycled and reused. In general, these policies allow entities such as hospitals and nursing care facilities to donate approved medications to participating pharmacies. The recycled medications are then distributed to the indigent population. While the state policies appear consistent on only allowing unused, sealed, tamper-resistant medications to be donated, state policies vary on issues such as who can donate, what drugs can be donated, and who will accept the donations. By regulating which entities can donate and what can be donated, the policy attempts to address the safety concerns while providing access to much needed expensive medications. Prior to these state policies, donating entities were adhering to the federal rules specified in the Prescription Drug Marketing Act of 1997, whereby the FDA prohibited the reselling of pharmaceutical products. According to the American Medical Association, the FDA issued a "non-objection letter" on

[10] Although executive orders are outside the purview of this analysis, Illinois state governor Rod Blagojevich established the Division of Patient Safety to promote the use of electronic prescribing among all Illinois health care providers by 2011.

February 25, 2000 which stated that it would not object to the state recycling programs (Wang, 2000).

Since 1997, 37 states have adopted such recycling policies (National Conference of State Legislatures). Arkansas, Kentucky, California, Maine, Michigan, and Minnesota limit donations to health care organizations such as hospital or nursing care facilities (National Conference of State Legislatures, 2009). In Arizona, Colorado, Illinois, Massachusetts, and Missouri, individuals and families, in addition to health care organizations, are allowed to donate unused medications. Oklahoma Representative Darrell Gilbert argued that the reuse and recycle prescription drug policies also assist in tackling the environmental concerns of the discarded medications contaminating the water supply (Thompson, 2005). While Oklahoma and Iowa report policy success, physicians are cautionary about the effects on medication compliance (Wapner, 2009). Their concern rests on the fact that a voluntary donation program may result in medication being available for patients this month but not the next (Wapner, 2009). In an attempt to address the supply concern of physicians, proponents (e.g., pharmacists, health care providers, and volunteers) of the program have explored options including public education about what should be done with unused medications.

Disclose or regulate in-state Rx clinical trials

Prior to FDA approval of prescription medications, drug manufacturers provide empirical evidence of safety and efficacy. The evidence is gathered through an extensive clinical trial process. Figure 2 illustrates the four phases (i.e.,

pre-clinical, phase 1, phase 2, and phase 3), which correspond to the degree to which the drug is tested on humans. The drug is tested on animals in the pre-clinical phase and by phase 3 trials are tested on approximately 3,000 people (Food and Drug Administration, 2009). While the FDA goes through great pains to defend its reputation as safeguarding public health, incidents, such as the removal of Baycol and Vioxx, have called into question the approval process employed by the FDA (Carpenter et al. 2003; Carpenter 2004; Olson 2004). Therefore, states have proposed legislation requiring that clinical trial results be registered with health care providers. However, to date, no state has passed such legislation.

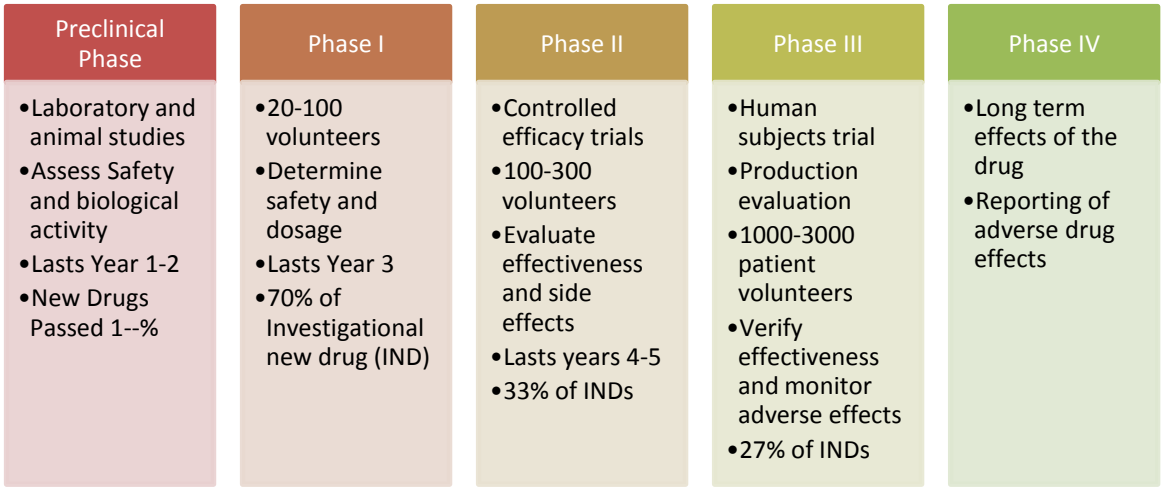

Figure 2: Food and Drug Approval Process*[11]
This graphic presents the activities involved at each phase in the FDA approval process.

[11] Modified from Lipsky and Sharp, 2001. From Idea to Market: The Drug Approval Process.

Chapter Conclusion

While physicians take the Hippocratic Oath, which espouses the medical duties to do no harm, others (e.g., pharmaceutical manufacturers and pharmacies) involved in prescription drug delivery make no such proclamation. To some extent, state legislators have taken on this responsibility to advocate for policies related to the safety of prescription medications; however, not each state has done so nor have states proceeded in a uniform approach. It is the purpose of this dissertation to examine which factors influence whether a state takes up this charge or not. This chapter has presented the various approaches employed by states.

For political, economic, and social reasons, state legislatures have a vested interest in the well-being of the citizens they represent. As discussed in Chapter 3, state legislatures have utilized a variety of financial techniques to promote the well-being of residents related to prescription drugs. Similarly, state legislatures have made use of various public policies to address prescription drug safety concerns (Table 6). Each of the aforementioned prescription drug policies were designed to tackle prescription safety problems such as those triggered by ADEs or MEs.

In each of the safety policies, states attempted to regulate entities involved in the delivery of prescription medication with the intent of safeguarding patients. As mentioned earlier, all state prescription drug policy may at the most basic level appears as though it is attempting to regulate access in one form or another. However, the prescription drug policies classified as safety are different from those listed in acquisition and distribution policy category based on the substantive

difference in the primary objective. The safety policies as they are defined here target the well-being of citizens.

Figure 3 illustrates the geographic distribution of prescription drug safety policies. Unlike acquisition policies, where every state had adopted at least one policy, not all states have adopted a safety policy. Similar to acquisition policies; however, Maine had the most policies adopted.

I hypothesize those demographic factors indicating prescription drug need influence the adoption of safety policies. Similar to the acquisition policies, state demographics serve to communicate a need to state policy makers. It is my supposition that safety policies were significantly influenced by the demographic indicators described in Chapter 2. In the same way that state demographics serve to communicate need to state policy makers, state demographics serve as indicators of potential safety risks associated with prescription medications. States with an older, poorer, less educated and more sickly population may be more likely to adopt the regulatory policies described in this chapter.

Throughout the history of prescription drug regulation in the United States, issue saliency has proved a major impetus for government intervention. In the case of reuse or recycling of prescription medications, the citizen demands to make sure the reuse of medication was implemented safety prompted response from legislators. Although the safety issues were different, public concern was the impetus for public action. Hence, issue salience may be a stronger predictor on safety policies than that of financial policies. According to one survey of

Americans, 51% indicated they “closely followed” news reports related to the Institute of Medicine report on the medical errors in hospitals.

In addition to demographics, the legislative professionalism within a state may influence adoption of prescription drug safety policies. In the case of generic drug policies, clinical and regulatory knowledge is required to assess the gaps in FDA regulation and the safety threats of prescription medications. An understanding of health information technology would undoubtedly be of benefit in the construction of the electronic prescription policies. My hypothesis is that states with greater legislative professional resources would be more likely to adopt these types of safety policies.

As mentioned in Chapter 2, the state legislatures may be influenced by what other states are doing especially in situations where policies have been successful. Unlike acquisition policies where the reported significant savings may influence other states to follow suit in adopting such policies, safety policies may be influenced by states that have successfully reduced the incidence of ADEs or MEs.

Under each of the safety policies, state governments are projecting themselves into the business that is prescription medications. From how prescriptions are written to the reuse of prescription medications, states’ legislatures are introducing policies to regulate the dispensing of prescription medications. States with a conservative ideology are generally opposed to the intrusion of government into the market. Thus, I would expect that states with a liberal ideology would be more in favor of such policies.

	Generic	Electronic Rx	Clinical Trials	Reuse	Total by State
AL					0
AK					0
AZ				1	1
AR		1		1	2
CA				1	1
CO	1	1		1	3
CT					0
DE					0
DC					0
FL		1		1	2
GA				1	1
HI	1			1	2
ID		1		1	2
IL		1			1
IN		1	1		2
IA				1	1
KS				1	1
KY		1		1	2
LA	1	1		1	3
ME		1			1
MD	1			1	2
MA	1		1	1	3
MI					0
MN		1		1	2
MS				1	1
MO	1	1			2
MT					0
NE					0
NV				1	1
NH				1	1
NJ	1				1
NM				1	1
NY					0
NC	1		1	1	3
ND					0
OH					0
OK				1	1
OR					0
PA				1	1
RI	1			1	2
SC		1			1
SD		1		1	2
TN	1	1		1	3
TX	1			1	2
UT	1				1
VT	1		1	1	3
VA	1	1			2
WA					0
WV				1	1
WI					0
WY				1	1
Total	14	15	4	29	62

Table 6: States with Safety Prescription Drug Policies
This table presents the state prescription drug policies adopted by each state between 1999-2008. One indicates the state adopted at least one prescription drug policy over the analytical period.

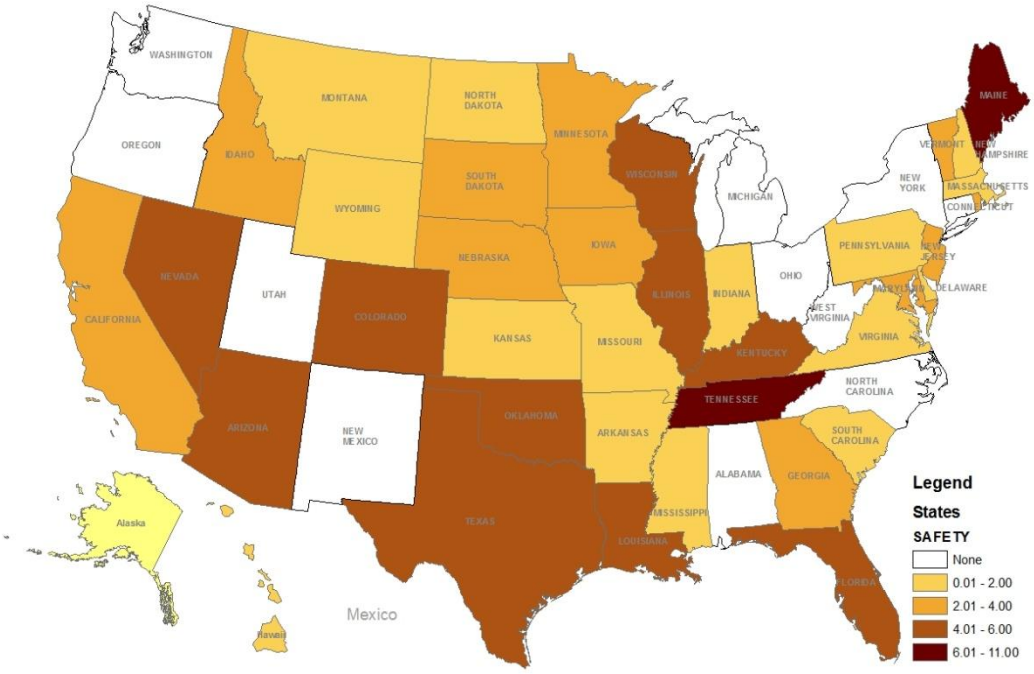

Figure 3: Geographic Variation of State Prescription Drug Safety Policies
This map illustrates the total number of prescription drug safety policies adopted between 1999-2008.

CHAPTER 5: *STATE PRESCRIPTION DRUG POLICY: DISTRIBUTION*

> "*Government is a trust, and the officers of the government are trustees, and both the trust and trustees are created for the benefit of the people*" – Henry Clay (1829)

While political science scholars explore the concept of public trust and its impact on society, legislators continue to act as trustees in policymaking for the interest of citizens (Damico, Conway, and Damico 2000). Public concern over *unfair* business practices have prompted states to develop policies related to the distribution of prescription medications. In particular, public trepidation regarding the effect of business practices on the use, access, and quality of prescription medications have prompted state action. It is the state prescription drug policies designed to regulate distribution organizations that is the focus of this chapter.

In 2005, 3.6 billion prescription medications were purchased in the United States (Kaiser Family Foundation, 2007). Patients were able to secure these medications through a myriad of sources including retail pharmacies, mail-order pharmacies, internet pharmacies, hospitals, and clinics. Figure 4 illustrates the various prescription drug distribution channels and the distribution hierarchy. State lawmakers have adopted a number of prescription drug policies to regulate retail pharmacies mail-order pharmacies, internet pharmacies, hospitals, and clinics (Table 7).

Although distribution policies are similar to safety policies in that they are both regulatory, it is my supposition that safety and distribution policies differ in their regulatory objectives, thus warranting separate chapters. Specifically, safety policies attempt to regulate with the objective of citizen wellbeing, whereas

distribution policies are designed to police those entities responsible for distribution of prescription medications with the objective of mitigating unfair business practices. The delineation between safety and distribution policies is based on the hypothesis that different factors will influence policy with patient safety objectives compared to those with more policing objectives.

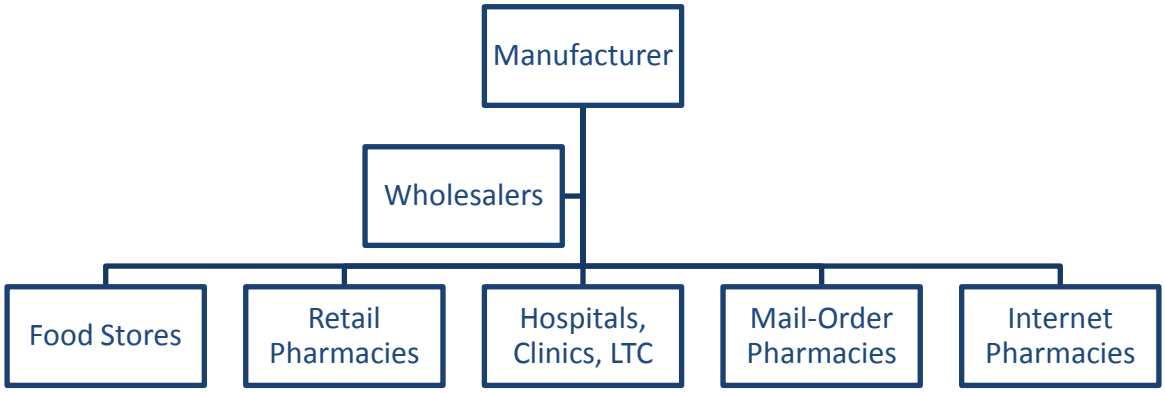

Figure 4: Prescription Drug Distribution Channel
This graphic presents the relationship between pharmaceutical manufacturer and pharmaceutical distributors.

Name of Distribution Prescription Drug Policies
Pharmaceutical marketing and advertising
Regulate retail pharmacies
Regulate mail-order pharmacies
Regulate internet pharmacies
Regulate wholesalers
Regulate of PBM

Table 7: State Prescription Drug Distribution Policies
This table lists the prescription drug policies classified as distribution.

Pharmaceutical marketing and advertising

There are two diametrically opposed positions when it comes to the marketing and advertising of pharmaceuticals. On one side is the position that marketing and advertising provide a public service by informing patients and physicians about disease and treatment options (Woloshin, et al, 2001). On the other side is the position that marketing and advertising undermine the patient and physician relationship, increase costs, and result in unnecessary demand for pharmaceuticals (Rosenthal et al. 2002; Rosenau, Lal, and Glasser, 2009). IMS, the leading expert on pharmaceutical related data, estimated that pharmaceutical manufacturers spent over $27 billion in 2004 on product marketing and advertising (IMS Health, 2005). While the marketing and advertising activities of prescription manufacturers may provide a public service, the fact remains that concern over the effect of the perceived unfair business practices have sparked state legislatures to address the issue. In particular, states have focused on the physician communications, leaving regulation of print and television media to the federal government[12].

Historically, pharmaceutical manufacturers would promote their products through physician detailing which refers to the use of pharmaceutical representatives to educate the physician on a given pharmaceutical product. Anyone visiting a doctor's office has undoubtedly seen the barrage of

[12] In 1997, the FDA released guidelines related to pharmaceutical advertising that increased the usage of direct-to-consumer (DTC) advertising. While, prior to 1997, manufacturers were allowed to engage in direct-to-consumer advertising, the requirement to disclose side-effects, effectiveness, and contraindications was somewhat ambiguous and difficult to interpret. The 1997 guidelines indicated that disclosure and adequate provision requirements could be met if the DTC mentioned that additional information could be obtained from their doctor, a telephone number or website.

pharmaceutical representatives entering the office with information (e.g., pamphlets or study results) and samples. Physicians indicate that they trust the information provided by pharmaceutical representatives and that the interactions with pharmaceutical representatives are beneficial to patient care (Fischer, et al., 2009). However, pharmaceutical representatives might bring gifts in addition to the educational information and samples. The gifts may range from low value items such as pens and memo pads to expensive gifts such as travel to conferences in exotic locations. It is the concern that gift giving will influence physician prescribing that has triggered public action. However, little evidence exists to substantiate the claim that gifts are harmful to patient care (Huddle, 2008).

One way states have attempted to address the problem is to reduce the financial incentives paid to service providers. For example, Arizona proposed legislation requiring manufacturers to fully disclose prescription marketing costs and prohibiting gifts of more than $50 made to physicians (Arizona HB2562, 2008). New York legislators have taken it one step further and attempted to require pharmaceutical drug manufacturers and wholesalers to report annually and publicly disclose contributions made to health care prescribing practitioners when they exceed a specific value (New York S2971, A 7468a, 2008).

In addition to financial gifts, pharmaceutical manufacturers also provide drug related information to those who prescribe prescription medications. States have attempted to tackle the issue of misleading information. Washington, D.C. passed the SafeRx Amendment Act in 2008 regulating pharmaceutical representatives and prohibiting them from engaging in deceptive or misleading

marketing (Council of the District of Columbia D.C. Official Code § 1-206.02(c)(1), 2008). Maine passed legislation prohibiting the inappropriate use of marketing messages to prescribers via electronic prescribing software (Maine Public Law Chapter 362, 2007).

Regulation of Retail Pharmacies

The bulk of prescription medications are dispensed via retail pharmacies. In fact, close to 3 billion prescriptions were filled in chain and independent retail pharmacies in 2008 (IMS Health, 2009). The retail pharmacies include companies most Americans are familiar with such as Walgreens, CVS, and Target, but they also include independent pharmacies such as Happy Harry's. For each state in which the pharmacy operates, the pharmacy must meet the states' individual rules and regulations governing pharmacy practice. For example, Walgreens must adhere to the state licensing and dispensing regulations for the 50 states in which it operates a pharmacy (Walgreens, 2009). The laws are designed to ensure that pharmacies are practicing an acceptable standard of care and to avoid incompetent or dangerous acts by pharmacies or pharmacists.

With so much at stake in terms of potential earnings and health care delivery, states have adopted policies to address the issue of unfair business practices. Unfair business practices often include issues of market advantage. Market advantage can be described as those situations which promote a competitive advantage of one product over another. States are addressing what might be construed as unfair business involving the nation's largest retailer. In 2006, Wal-Mart announced its $4 generic program which charges consumers $4

for a 30-day supply of selected medication. Several states (i.e., California, Colorado, Hawaii, Minnesota, Montana, Pennsylvania, Tennessee, Wisconsin, and Wyoming) proposed legislation aimed at "predatory pricing." The policies prohibit retailers from selling products below market prices. Unfortunately, the state policy has had unintended consequences. In particular, consumers now pay more for 14 generic drugs purchased at Target and about 55 generic drugs purchased at Wal-Mart (National Conference of State Legislatures). Additionally, industry experts argue that the $4 generic effect on patients overall was negligible for most of patients but has benefited those poor and uninsured patients the most.

Regulate Mail-Order pharmacies

Second only to retail pharmacies, mail-order pharmacies account for 16% ($101 billion) of the prescription drug sales in the U.S. (IMS Health, 2008). Mail-order pharmacies provide both convenience and cost saving opportunities for patients. For example, individuals who live in remote locations can secure prescription medications from a mail-order pharmacy. Additionally, their costs are substantially lower as a result of volume discount on medications from manufacturers, use of automated prescription filling technology, and filling more than one month supply of medication to patients (Enright, 1987; Wertheimer, Andrews, 1995). Patients typically benefit financially from the lower distribution and dispensing fees by paying for two months supply while receiving a three month supply of medicine. States have seen the financial benefits offered by mail-order pharmacies and have thus put in place legislation to encourage their use. For example, states like Maine and Colorado adopted legislation to allow Medicaid

recipients to use mail-order pharmacy (Chapter 237, 2008). In addition, Maryland established a $20 maximum copayment amount for those enrolled in the State Prescription Drug Plan (Chapter 28, 2006).

However, not all states are so receptive to the use of mail-order pharmacies. Historically, mail-order pharmacies were in competition with retail pharmacies. Contrary to retail allegations of the dangers associated with mail-order pharmacies, a study authorized under the Medicare Catastrophic Coverage Act of 1988, found no evidence suggesting that the quality of medications or care was inadequate. Additionally, scholars found that mail order customers were more satisfied with the pharmacy services than those of retail pharmacies (Johnson, et al. 1997). Nonetheless, retail pharmacies began to lobby states in an effort to impede the use of mail order pharmacies. As such, states such as Wisconsin have passed legislation requiring that all mail order pharmacies be licensed by the State Pharmacy Examining Board (Act 242, 2006). While similar to the requirement that retail pharmacies be licensed in the state in which they are operating a pharmacy, this legislation would require mail order pharmacies to be licensed in states where they will be mailing prescription medications. For example, if a mail-order pharmacy is physically located in Arizona but mails prescriptions to Wisconsin, the pharmacy must meet the licensing and regulation required by Wisconsin. Additionally, states have adopted legislation to protect the financial interests of state owned and operated pharmacies. For example, Maine has required that the all MaineCare beneficiaries have a local retail option to the

out-of-state mail order options. However, in Michigan legislation was adopted to remove legal barriers to mail-order companies operating in the state.

Regulate Internet Pharmacies

Use of the internet to purchase products has permeated the U.S. Thus, it should be no surprise that citizens have turned to the internet to purchase prescription medications. As with other products, the use of the internet has advantages of savings and convenience and disadvantages surrounding privacy, safety, and security. However, the fact that prescription medications are digested into the body, the safety concerns are somewhat different and potentially more dangerous than other internet purchases. While the Federal Food Drug and Cosmetic Act (FFDCA) regulates that a valid prescription must accompany all pharmacy dispensed medications, there are "rogue sites." According to the FDA, these rogue websites engage in illegal business practices such as selling counterfeit medications or dispensing without a valid prescription (Food and Drug Administration, 2001). The National Board of Pharmacies working with federal, state, consumers, and internet pharmacies developed the Verified Internet Pharmacy Practice Sites (VIPPS). In general, the VIPPS program is similar to a Good Housekeeping Award. Internet pharmacies who apply for VIPPS accreditation must meet state licensing requirements and the 18-point criteria based on quality, patient confidentiality, and pharmacy practice. Those meeting the requirement will receive VIPPS certification which can be placed on the website as an indicator to patients of the quality and status of the internet site.

Since 2003, states have adopted strategies to regulate this industry (National Conference of State Legislatures 2009). Pharmacies not only serve as dispensing centers but also provide consultative services to patients. It is due to the concern for patient safety that states such as New Hampshire, Arkansas, Idaho, and Louisiana, have adopted legislation requiring that a relationship between licensed practitioner and patient be established prior to transaction. Wisconsin requires that the pharmacy be licensed in the state by the State Pharmacy Examining Board (Act 242, 2006). In addition to regulating the pharmacies, Texas has created legislation to create a public awareness campaign to educate the public about the potential dangers of online pharmacies.

Regulate Wholesalers

Closely associated to the regulation of internet pharmacies is the states' desire to regulate pharmaceutical wholesalers. In the case of prescription drugs, the term wholesaler is not limited to manufacturer. Wholesalers are those entities that purchase directly from the manufacturer for resale to pharmacies and may include warehouses, manufacturers or repackagers (Frank, 2001). Prompted by both safety and unfair business practice concerns over prescription drug authentication, states are adopting legislation requiring wholesalers to ascertain the pedigree of prescription medications (Laven, 2006). In addition to the pedigree requirement, states like Colorado require wholesalers to complete a criminal history background check.

Regulation of Pharmacy Benefit Managers

In addition to pharmaceutical manufacturers, wholesalers, and retailers, pharmacy benefit managers (PBMs) play a role in the delivery of prescription drugs. In general, PBMs act in a fashion similar to managed care organizations, only without assuming the financial risk. While initially PBMs served primarily as claims processing services, PBMs expanded beyond claims processing to include formulary management, manufacturer rebate contracting, mail-order pharmacy, drug utilization review, medication compliance, and disease management programs. Employers would hire PBMs, as claims processors, to aggregate prescription drug claims from pharmacies, collect payment from the employer, and pay the pharmacy for those prescription drugs dispensed. In exchange for providing this administrative function, PBMs would receive an administrative fee or the difference between the two (i.e., spread). Figure 5 depicts the financial relationships between PBM, pharmacy and employers associated with claims processing. Beyond their claims processing role, PBMs serve as consultants in drug utilization review, medication compliance, and disease management programs. In their consultant role, PBMs take into account the clinical and economic considerations to achieve the employers' goal of effective and efficient use of financial resources allocated for prescription drugs.

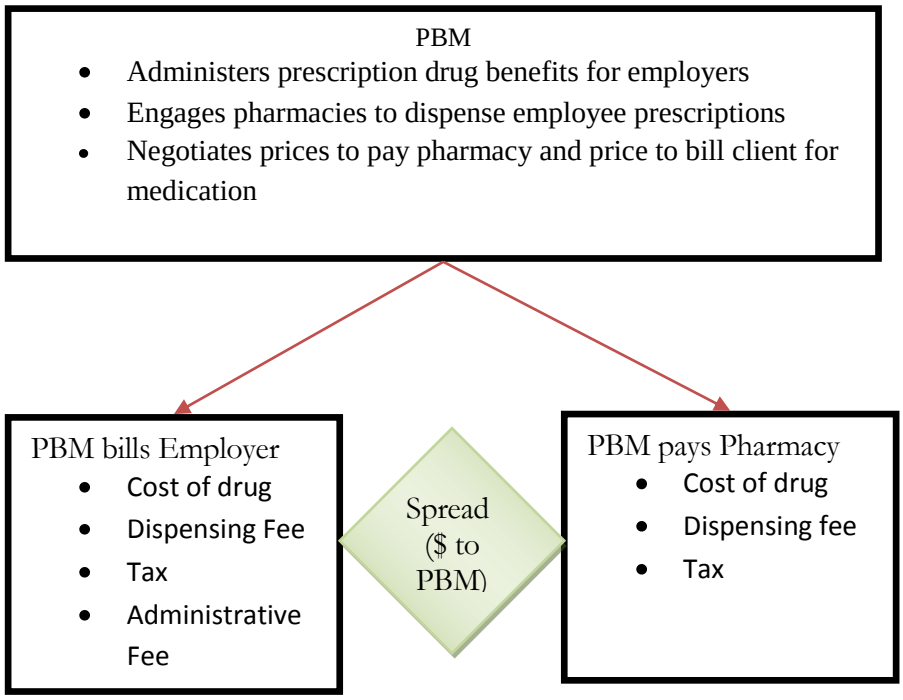

Figure 5: Illustration of PBM financial relationships between employer and pharmacy.

This graphic not only presents the roles of a PBM but also the relationship to those entities being paid by PBMs and those entities paying PBMs. The components included in the price billed by the PBM and the price paid by the PBM is identified in the bottom two boxes.

Undoubtedly PBMs provide a benefit in terms of cost savings; however, their financial arrangements with pharmaceutical manufacturers have come under scrutiny (Rentmeester and Garis, 2008). Through legislation, state legislatures have attempted to increase transparency into the financial arrangements of PBMs. Maryland increased the financial disclosure requirement of PBMs. Similarly, Louisiana's Pharmacy Patient Protection Act sought to increase disclosure by requiring PBMs to be licensed with the Department of Health and Hospitals and disclose financial affiliation with related pharmacy business. As expected, retail pharmacies were opposed to PBMs since most PBMs operate mail-order pharmacies. States such as Connecticut required PBMs to annually register with the state and obtain surety bond insurance.

Chapter Conclusion

As discussed in Chapter 3, state legislatures have utilized a variety of financial techniques to promote the well-being of residents related to prescription drugs. Similarly, state legislatures have made use of various public policies to address prescription drug unfair business practices concerns. Table **6**. indicates that only two states have adopted all four types of distribution policies, whereas, sixteen (30%) of states have adopted only one type of distribution policy. Figure 6 illustrates that once again, Maine has the most policies adopted. Additionally, there are many states who have failed to adopt any prescription drug policies to regulate those entities that distribute prescription medications.

For more than 200 years, the U.S. has embraced classical economics. During that time, the U.S. has largely applied the market self-regulation approach.

In essence, there is great faith in the market to correct itself when needed. In the case of prescription drugs, government has played a narrow role. Unlike the United Kingdom or Canada, there are no price controls, no national drug formulary and no universsal coverage of prescription drugs. It is the historic void of governmental involvement that heightens the intrigue over state actions. Why would states adopt policies seemingly counter to the underlying economic principles so prevalent in the U.S. DNA? What are the factors that would influence state policy adoption regulating prescription drug entities? It is the focus of this dissertation to explore such factors and their influence on prescription drug policy adoption.

John Kingdon suggests that problems that violate our societal values are likely to be construed as a problem needing attention (2003, 198). The strongest of those values include equity, individual responsibility, and faith in market solutions. In essence, those situations that are counter to the belief of fairness and equity might result in increased public concern to the level of government action. In the case of distribution policies, business actions perceived as unjust or providing unfair advantages to one group over another might result in adoption of public policy. However, undoubtedly there are situations when unfair business practices are at play yet no adoption of public policy adoption transpires. Thus, I hypothesize that the greater the issue salience, the greater the number of states adopting policies to address the issue of distribution.

Additionally, the state policies described in this chapter attempt to regulate entities within a powerful industry. The entities within this industry are represented

by one of the most influential interest groups in the nation. Thus, one would expect reasonable resistance to government regulation within this industry. Given the strength and influence of the pharmaceutical industry, it is a wonder any state policies attempting to regulate distribution would get adopted. While theory suggests that public concern and interest groups may influence the adoption of distributive policies, state legislators also answer to themselves and their political party. Thus to the extent that the policy proposals are consistent with the political ideology and the platform of the political party in control, one would expect government adoption of distribution policies. From how pharmaceutical representatives interact with physicians to the financial disclosure of PBMs, states' legislatures are introducing policies to regulate the dispensing of prescription medications. States with a conservative ideology are generally opposed to the intrusion of government into the market. Thus, I would expect that states with a liberal ideology to be more in favor of such policies.

	Pharmaceutical marketing and advertising	Retail	Mail-order	Internet	Wholesalers	PBM	Total by State
AL							0
AK							0
AZ				1	1		2
AR			1	1	1		3
CA	1			1	1	1	4
CO				1	1		2
CT						1	1
DE						1	1
DC							0
FL				1	1	1	3
GA				1	1		2
HI				1		1	2
ID				1	1	1	3
IL					1		1
IN							0
IA				1	1		2
KS				1		1	2
KY		1		1			2
LA	1			1		1	3
ME	1						1
MD			1	1	1	1	4
MA			1	1		1	3
MI			1				1
MN				1			1
MS				1			1
MO						1	1
MT					1	1	2
NE							0
NV				1	1	1	3
NH			1	1			2
NJ						1	1
NM				1			1
NY						1	1
NC				1	1		2
ND							0
OH							0
OK				1	1		2
OR						1	1
PA				1			1
RI				1			1
SC							0
SD				1	1	1	3
TN			1	1		1	3
TX				1	1		2
UT							0
VT				1	1		2
VA						1	1
WA						1	1
WV			1	1	1		3
WI							0
WY				1	1		2
Total	3	1	7	29	19	20	79

Table 8: States with Distribution Prescription Drug Policies

This table presents the state prescription drug policies adopted by each state between 1999-2008. One indicates the state adopted at least one prescription drug policy over the analytical period

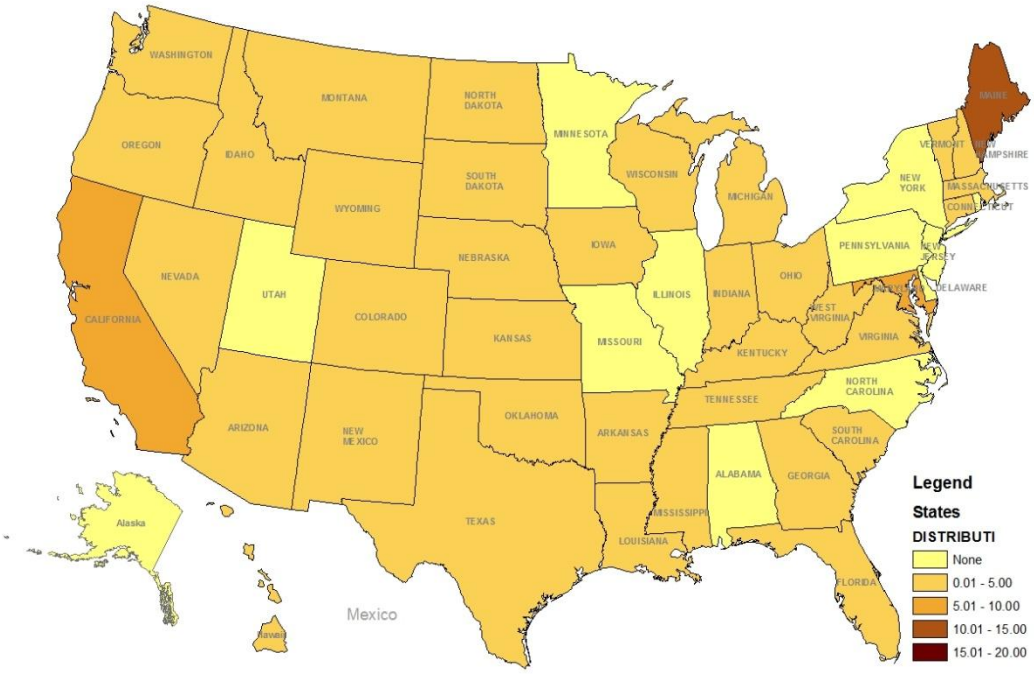

Figure 6: Geographic Variation of State Prescription Drug Distribution Policies
This map illustrates the total number of prescription drug distribution policies adopted between 1999-2008.

CHAPTER 6: *STUDY DATA AND METHODS*

"If we knew what it was we were doing, it would not be called research, would it?" -Albert Einstein

While prescription medications have become an integral part of health care services, acquisition, safety, and distribution surrounding these products have given rise to public concern. As discussed in the previous chapters, states have been innovative in adopting a myriad of public policies increasing access, ensuring safety, and safeguarding against unfair business practices. However, not all states have adopted prescription drug policies. Thus, the question still remains as to which factors affect whether or not a state adopts prescription drug policy.

The focus of this chapter is to present the methodological approach used to tackle the research question (i.e., what factors influence prescription drug policy?). First, a brief description of the data sources is presented. Second, covariate selection with specific research questions in terms of hypotheses is presented. Included in the third section is a discussion on the methodological approach to categorization of the prescription drug policies. Lastly, I illustrate the analytical models.

Data Source

This is a retrospective study comprised of a pooled cross-sectional time series using data from 1999 through 2008 where each case represents a state-year. Both practical and theoretical reasons guided the selection of this time period. From a theoretical standpoint the last ten years has been the most active in terms of prescription drug policy. The increased use, changes in approval process, and rising drug costs have put prescription medications on the public

agenda. From a practical standpoint, the National Conference for State Legislatures (NCSL) compiled data on prescription drug policy over the last ten years. According to their website, NCSL obtains information through 50 state website searches and through services provided via StateNet.[13] The data contained one observation for each state year, resulting in 500 observations over the ten year time period. In addition to the NCSL data, state legislative websites were reviewed to obtain legislative details (e.g., wording, date of approval, and sponsor).

Data from a variety of secondary data sources were used to obtain predictor variables. Appendix 1 is the full list of the data sources used in the analysis. The following sections provide detailed descriptions of the predictor and dependent variables used in the analysis. Data collection, time periods, and any data limitations data are also discussed.

Prescription Drug Policy Predictor Variables

Predictor variable identification and selection was based on research discussed in Chapter 2 (Walker, 1969; Mohr, 1969; Gray, 1973; Berry and Berry, 1990; Case, Hines, and Rosen, 1993; Mintrom, 1997; Berry and Baybeck, 2005; Gray, Lowery, and Godwin, 2007; Miller, 2005). The research suggests that state policy adoption is affected by the population composition, resource capacity, extraneous factors, and political and ideological influences. The twelve predictor variables selected for analysis include elderly, poverty, health status, urbanization, education, state wealth, and interest group activity, legislative professionalism,

[13] StateNet is a legislative and regulatory service provider. Information concerning StateNet can be found at www.statenet.com.

neighboring state policies, state ideology, political party control, and issue saliency. Table 2 depicts the covariates and the hypothesized effect on state prescription drug policy.

Population Composition – In theory, legislators are elected to represent the will of the people. Thus, one would expect demographics to matter. Specifically related to prescription drug policy, one would expect states with a disproportionate share of elderly, poor, sick, lesser educated, or those living in rural areas to influence policy adoption. The following section briefly presents the rationale for factor selection and the method of operationalization for variables related to the states' population:

State population over the age of 65: As discussed in Chapter 2, states with a disproportionate share of citizens over the age of 65 may have a greater need for pharmaceuticals. Research suggests a positive relationship between age and the use of prescription medications suggesting the greater the proportion of elderly individuals the greater the need for and utilization of prescription medications. Thus, lawmakers representing states with a greater percentage of elderly may be particularly concerned with the issues of pharmaceutical access and safety. However, the linkage between the percentages of those citizens over 65 and distribution policy becomes more difficult to establish. As discussed in Chapter 5, distribution policies are regulatory in nature and are aimed at the entities involved in distribution of prescription medications. One would not expect the adoption of distribution policies to be influenced by the percentage of elderly within a state. Rather for distribution policies, age may be proxy for public opinion.

Using U.S. Bureau of Census data from 1999 to 2008, age is operationalized as the percent of population age 65 and older. Figure 7 is a graphical presentation of the percentage of a state's population that is 65 years of age or older. All but three states had more than 10% of their population over the age of 65.

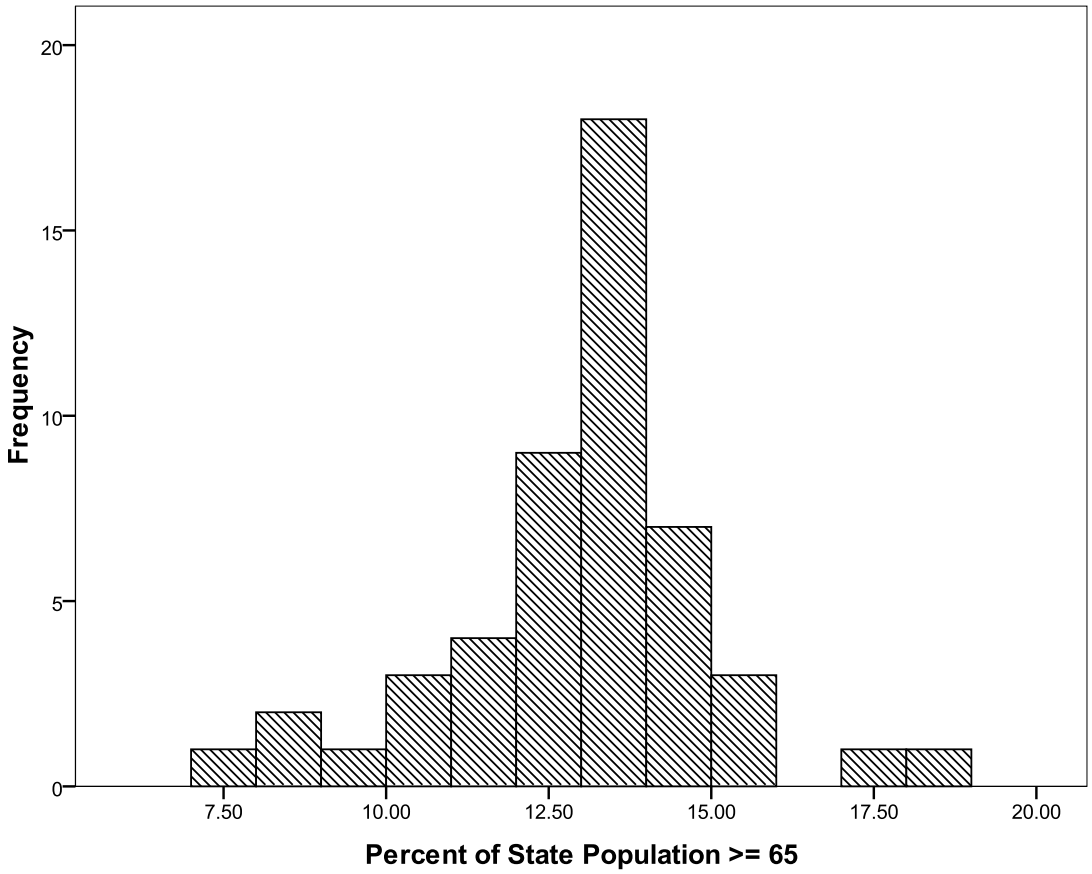

Figure 7: Histogram of State Population - Over 65
This graph presents the percentage of a state's population that is over the age of 65 in 2008.

State population in poverty: In general, the ability to pay for prescription medications has become more difficult as the price of prescription medications has continued to increase faster than the rate of inflation. Undoubtedly, those individuals with lower income will face more difficulty in paying for needed medications. As discussed in Chapter 2, legislators rely on indicators to ascertain which policies to address. Thus, a disproportionate share of the population in poverty may serve as an indicator to legislators of need for prescription medications. Lawmakers representing states with a greater proportion of citizens in poverty may be particularly concerned with the issues of pharmaceutical access and safety. However, one would not expect adoption of pharmaceutical distribution policies, discussed in Chapter 5, to be affected by an unequal representation of poverty. The distribution policies are aimed at regulating the distribution of prescriptions, regardless of economic status. Thus, I hypothesize that the greater the percentage of residents below the poverty level the greater the likelihood of prescription drug policies aimed at acquisition and safety but not those policies aimed at distribution. Poverty was operationalized as the percentage of individuals at the 100% Federal Poverty Level according to the U.S. Bureau of Census. Census data from 1999 to 2008 was downloaded from the U.S. Bureau of the Census website. Undoubtedly, the poverty rates have changed over the study period. Figure 8 is a histogram illustrating the number of state and their percentage of a state's population considered to be in poverty in 2008.

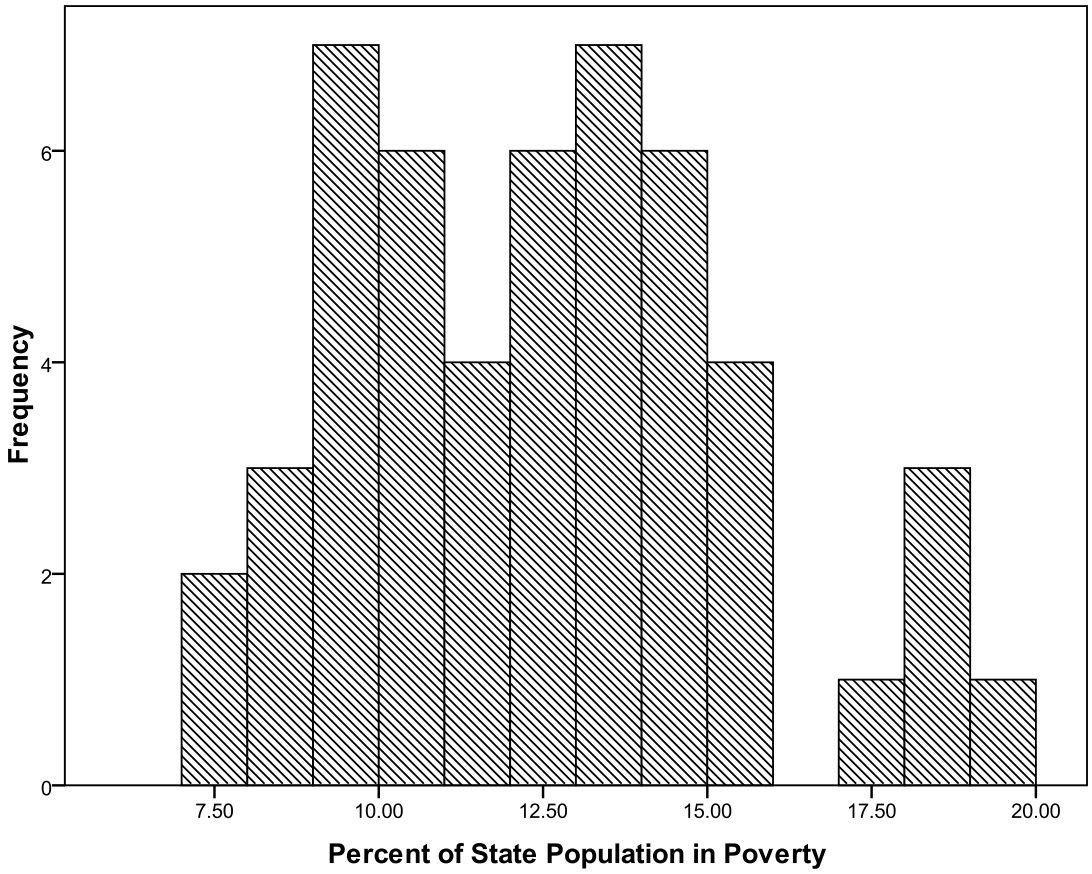

Figure 8: Percent of State Population below FPL
This graph illustrates the distribution of proportion of a state's population that are below the federal poverty level in 2008.

Lesser educated population: Similar to previously mentioned factors, the educational attainment of the population may serve as an indicator to legislator. In essence, states with a greater proportion of lesser educated citizens may signal a need for greater need for pharmaceuticals. As mentioned in Chapter 2, education is positively associated with good health. Thus, the supposition remains that states with a less educated population may have worse health and thus have greater need for pharmaceuticals and a greater need of protection against any dangers and injustice associated with prescription medications. Thus, I hypothesize that states with a greater proportion of citizens with at least a bachelor's degree the fewer prescription drug policies.

Educational attainment of the states' population was operationalized as the percent of the population over the age of 25 with a bachelor's degree (Wright, Erikson, and McIver, 1987). Educational attainment data was obtained from the U.S. Census Bureau website. Figure 9 presents the distribution of states and their proportion of population that have a bachelor's degree. In 2008, only Colorado, Connecticut, Massachusetts, and Maryland have greater than 35% of the population with a bachelor's degree.

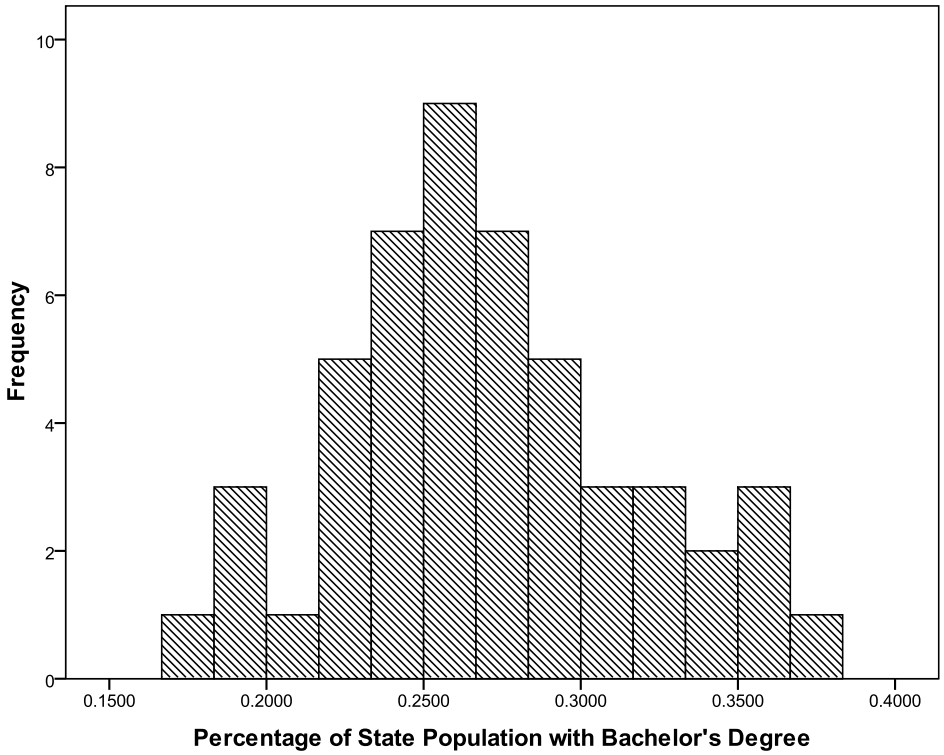

Figure 9: Histogram of State Proportion with Bachelor's Degree
This histogram indicates proportion of a state's population in 2008 with a bachelors degree ranges from the mid-teens to more than thirty percent.

Urban population: Similar to the effect that a state with a disproportionate share of elderly, poor, and less educated population may have on the need of pharmaceuticals, states with greater portion of citizens residing in rural areas may serve as an indicator of need. As discussed in Chapter 2, rural areas are characteristically older, sicker, and poorer and perhaps have a greater need of access to prescription medications. The distribution policies discussed in Chapter 5 may be of greater concern for rural states than for those with greater urbanization. For individuals in rural areas, the internet and mail-order pharmacies may serve as a cost-effective and convenient means to needed medications. Additionally, more retail pharmacies are located within urban areas than rural areas. Undoubtedly, the retail pharmacies do not embrace regulatory policies; consequently, states with larger urban areas may face greater resistance to distribution policies. Thus, state legislatures of a more rural state may have a greater number of acquisition, safety, and distribution prescription drug policies.

Consistent with the research of Wright, Erikson, and McIver (1987), urbanization was operationalized as the percent of the population residing in the State Metropolitan Statistical Areas (SMSA). Data on percent of state population living in urban areas was downloaded from the U.S. Bureau of the Census 2009 Statistical Abstracts website.

Health Status: As mentioned in Chapter 2, health status serves as an indicator of citizen need for prescription medications. Consistent with other factors selected for this analysis, states with a disproportionate population in poor health may have a greater need for pharmaceuticals. The essence of the

argument is based on the supposition that a healthier population would have less need for prescription medications. The diminished need may manifest itself into fewer prescription drug policies aimed at acquisition, safety, or distribution.

While individual health has been measured by the self-reported health status or the physician-reported number of chronic conditions, both focus on quantifying the health of the individual and are often used as a proxy for demand of services. In this analysis, health status is based on the National Center for Chronic Disease Prevention and Health Promotion's Behavioral Risk Factor Surveillance System (BRFSS).[14] The BRFSS data allows for the examination of self-reported health status representing the state's population across the study time period. States with a lower percentage of respondents within a state who responded that they are in "Good or Better" health may serve to indicate need of health services such as prescription medication.

Resource Capacity – In theory, state legislators are responsible for carrying out the will of the people; however, they must act within the confines of their state. In particular, state legislators are limited by financial resources and staffing with regard to what they can get done. Limited financial resources may restrict policy options and limited staffing available may reduce the amount of time spent on policy options. Thus, the supposition remains that the more resources available, both in terms of money and staff, the more likely legislators to adopt public policy.

[14] According to the CDC website the BRFSS is "The Behavioral Risk Factor Surveillance System (BRFSS) is the world's largest, on-going telephone health survey system, tracking health conditions and risk behaviors in the United States yearly since 1984." Telephone survey respondents are asked "Would you say that, in general, your health is Excellent, Very Good, Good, Fair or Poor."

The following section briefly presents the rationale for factor selection and the method of operationalization for variables related to the states' resource capacity.

Financial Capacity: A state's financial capacity may influence its willingness to adopt prescription drug policies. States with fewer dollars available may be more inclined to utilize the financial based policies discussed in Chapter 3 to address the access issue than states with greater resources. Safety and distribution policies which attempt to regulate the actions do not lend to the supposition that the wealth of a state would be a factor. In other words, one would not necessarily expect that a wealthy state is more likely to regulate the distribution of prescription medications, whereas the supposition remains that states with more money available may be more likely to adopt prescription drug policies to assist their population.

In this analysis, state financial capacity will be calculated as a ratio by taking the total state revenue minus the total state spending divided by total spending (Berry and Berry, 1990, 401). Thus for states where the total expenditure is less than total revenue, one would see a positive number. However, in cases where the state has spent more than was collected, one would see a negative number. The larger the gap between what was spent and what was collected the larger the ratio. As expected states differ not only in size but in budget, thus calculating financial capacity in such a manner allows for a comparable measure across states. The expenditure and revenue data was obtained from the U.S. Bureau of Economic Analysis, Survey of Current Business. The application of the formula below to calculate financial capacity will allow for the analysis of slack resources

on the adoption of state prescription drug policy. Below is the formula used to calculate the financial capacity of a state.

$$\textit{Financial capacity} = \frac{\textit{total state revenue} - \textit{total state spending}}{\textit{total state spending}}$$

Legislative Professionalism: According to Christopher Mooney (1985, 48) legislative professionalism "generally refers to the enhancement of the legislature's capacity to perform its role in the policy-making process with an expertise, seriousness, and effort comparable to other actors in that process." Prescription drug policy can be quite complicated, thus states with greater capacity in terms of expertise or staffing may be better suited to develop prescription drug policy, particularly those aimed at safety or distribution.

Research suggests a number of ways in which to operationalize legislative professionalism including state legislative compensation, days in session, operating budget per legislator, and the number of staff members per legislator (King, 2000; Grossback and Peterson, 2004; Berry, Berkman, and Schneiderman, 2000, Owings and Borck 2000). Consistent with King (2000) and Owings and Borck (2000) legislative professionalism is designed to measure the capacity of state legislators and one such way is by calculation of ratio of staff to legislator. As previously mentioned states differ not only in physical size but in representation, thus calculating legislative professionalism in terms of staffing per legislator allows for a comparable measure across states. Below is the formula used to calculate legislative professionalism.

$$\textit{Legislative Professionalism} = \frac{\textit{\# of staff}}{\textit{\# of state legislators}}$$

Extraneous Influence – In addition to considering who lives in the state and the resources available, state legislators may also be influenced by the actions or activities that occur outside of their state. With regard to prescription drug policy, which can be complex and time consuming, state legislators may look to neighboring states for ideas on successful policies. The following section briefly presents the rationale for including neighboring states as a factor and the method of operationalizing the influence of neighboring states'.

Neighboring State Policy Adoption: In the case of neighboring state influence, the adage "No man is an island" seems to apply. Whether motivated by constraints or competitive federalism, as discussed in Chapter 2, state legislators may look to neighboring states for public policy ideas (Berry and Berry, 1990; Canon and Baum, 1981). While in the case of prescription drug policy, Gray, Lowery, and Godwin's 2007 analysis did not find neighboring state adoption to explain state policy adoption, their analysis was limited to access prescription drug policies (i.e., Pharmacy Assistance Programs). Thus, this analysis examines the influence of neighboring states on state pharmaceutical policy adoption beyond access to include safety and distribution. A separate neighboring variable for each of the policy types (i.e., acquisition, cost, and safety) was created for each year in the analytic time period. For the purpose of this analysis, the neighboring states variable was calculated as the percentage of

neighboring states that had adopted the policy the year before (Berry and Berry, 1990). States differ not only in population size but also in the number of neighboring states, thus calculating neighboring state influence in terms of a percentage allows for a comparable measure across states. The variable can be interpreted as the greater the percentage the more neighboring states that have adopted the policy. The supposition being that a state with more neighbors who have adopted a policy may see the policy has having less risk or may face competition to enact a similar policy. Below is the formula used to calculate neighboring states.

$$\textit{Neighboring state} = \frac{\textit{\# of neighboring states with policy in preceding year}}{\textit{\# of neighboring states}}$$

Issues, Politics, and Ideology – Beyond the already mentioned influences of state population characteristics, financial and staffing resources, and neighbor influence, state legislators may also consider those factors related to the values, beliefs, and preferences of groups within the state. In particular, political parties, interest groups, and salient issues serve as indicators to state legislators of important issues. With regard to prescription drug policy, which can be complex and time consuming, state legislators may look to interest groups for policy information. Additionally, states legislators may rely on polls, surveys, or news media to ascertain the important public issues. The following section briefly presents the rationale and operationalization of interest group influence, political party control, and issue saliency.

Interest Group Influence: Historically, pharmaceutical manufacturers and physician groups have been among the most influential party on health care issues. Both have used their political influence to pressure elected officials. However, scholars indicate that even the most powerful interest groups (e.g., banking) do not always win when it comes to public policy adoption (Leech, et al, 2007). Thus, the question still remains whether interest groups affect adoption of prescription drug policy. As discussed in Chapter 2, interest groups may influence legislators through legislative testimonies, information gathering, and the most commonly associated activity of political contribution. The theory that interest groups influence state policy adoption hinges on the supposition that legislators will be positively influenced by either the information, testimony, or monetary support provided by the interest group.

As such scholars have utilized lobby registration data to identify which interest groups would be particularly interested in prescription drug policy (Gray, Lowery, and Godwin, 2007). In an effort to examine whether interest group influence affects state adoption of prescription drug policy, this dissertation will explore the impact by utilizing the amount contributed per legislator. While the amount spent does not assist in understanding the multiplicity of concerns, it does serve as a proxy for level of concern. The supposition is that the greater the amount spent on lobbying efforts the greater the area of concern. Amount spent between 1999 and 2008 was acquired from the National Institute on Money in State Politics, a nonpartisan, nonprofit organization who gather data on campaign contributions for all 50 states. The amount spent only included monies

associated with health care. While the National Institute on Money in State Politics provides useful information on the amount contributed by lobbying groups, it does not account for the non-financial contributions made by interest groups such as emailing, testifying at hearings, and media campaigns. The breadth and depth of interest group effect is an interesting topic for future analysis. The lobbying financial data adequately serves to measure interest group effect. Below is the formula used to calculate interest group influence.

$$\textit{Interest Group Influence} = \frac{\textit{total amount spent per year}}{\textit{\# of legislators}}$$

Issue Salience: One of the most thought provoking questions for a country often considered the beacon of democracy is whether or not citizen preference matters in terms of public policy. Scholars have long since indicated that issues matter, particularly in terms of agenda setting, policy options, and timeliness (Mayhew, 1974; Fenno, 1978; Dahl, 1969, Key, 1961). As discussed in Chapter 2, issues that are of concern to constituents are more likely to get on the public agenda. Additionally, salient issues may also influence policy solutions and the expediency with which the policy is addressed. The theoretical supposition rests on the assumption that public opinion serves as an indicator of issue preference. Thus, one may expect the issues important to citizens to be first and foremost in public policy adoption. At the state level, does public opinion make a difference in the actions of legislators with regard to policy adoption? In asking this

question, one must first consider how legislators would be made aware of citizen preferences.

On a national level public opinion polls are readily available to policymakers; albeit, a state level, public opinion polls are not quite as abundant (Turner et al, 2009; Rose, 2007). Thus, state lawmakers must undoubtedly rely on a variety of sources (e.g., press coverage, health assessment surveys, and national public opinion) to ascertain citizen policy preference (Weissert, 1991; Epstein and Segal, 2000; Turner et al, 2009). Upon closer investigation one quickly finds that, with the exception of the debate over the Medicare Modernization Act of 2003 (which grabbed national attention), prescription drug policy is not a typical subject matter for state public opinion polls nor is it a subject matter typically discussed in local news media outlets. With the exception of few states (e.g., Ohio, New Jersey, and New York) that in conjunction with universities have developed state level polling data repositories, health assessment surveys may be one of the few data options available to state lawmakers in their quest to discover the will of the people. According to the Center for Disease Control's (CDC) website, the Behavioral Risk Factor Surveillance System (BRFSS) has been utilized by states to "identify health issues at the local level." Additionally, Turner et al 2009 indicate the health assessment questionnaires are a viable option for operationalizing issue saliency. Thus, for the purpose of this analysis issue salience is based on the Behavioral Risk Factor Surveillance System Health Assessment Questionnaire. The BRFSS contains questions related to health status and the importance of

health insurance. In particular, the BRFSS survey reports the state percentage of respondents who indicate that securing health services was a concern for them during the past 12 months. While the BRFSS does not specifically ask the respondent what the most important issue facing their state is, the survey does provide legislators with insight into whether or not health services is an important issue. Legislators could easily interpret the response as an indicator that citizens view prescription drug policy as an important issue.

Ideology: As indicated in the discussion of issue salience, state legislators may not always have access to information indicating the public preference on a particular issue such as prescription drug policy. Absent citizen policy preference, state legislators may rely on the general political beliefs of the state citizenry when considering policy adoption. In general, conservatives are more likely to believe in individual responsibility with limited government involvement, whereas liberals are more likely to see individuals as constrained by their situation needing more government assistance. Thus, state legislators representing states with a greater proportion of citizens with liberal ideology will be more likely to adopt state prescription drug policies. Thus it is my hypothesis that liberal states are more likely to adopt the prescription drug acquisition, safety, and distribution policies described in Chapters, 3, 4, and 5.

Research indicates two primary approaches to measuring ideology. The first method comes from Erikson, Wright, and McIver's state citizen ideology measure. It was constructed from the CBS/NYT survey results from 1976 through 2006. The measure represents the average of the self-reported

ideological identification by state. The second method computes citizen ideology as a function of electorate support for the incumbent, electorate support for the challenger and the ideology of the incumbent and challenger (Berry, Ringquist, Fording, 1998). The state ideology is computed as an average across all districts. In essence, the two methods attempt to capture the conservative or liberalism ideology of a state, ranging from zero to one with one representing liberal. According to Berry, Ringquist, and Fording (1998) and Meinke, Staton, and Wuhs (2005) the use of Erikson, Wright, and McIver may not be the most appropriate for longitudinal data. Research indicates that ideology does vary over time. Thus, this analysis will utilize the updated Berry, Ringquist, Fording (1998) data to operationalize ideology (Brace et al., 2004). The selected data will allow for the evaluation of effect of ideology on prescription drug policy adoption. In essence, comparing the effect of states with a greater score (i.e., more liberal) on the adoption of prescription drug policy.

Political Party Control: Whether it is the statehouse or the White House, political parties undoubtedly seek to gain control. For it is believed that through the control of government, political parties have access to the distribution of public funding and input on key policy decisions (Ansolabehere and Snyder, 2003). Additionally, when a single party is in control of state government (i.e., legislature and governorship) scholars suggest that such a situation allows for a greater ability to handle political issues (Berry and Berry, 1990). In essence, to the extent that a unified controlled state government would be better able to handle obstacles, one would expect more policy adoption. Beyond the basic

supposition of one party in control, research suggests it matters which party is in control. In general, Democratic controlled states legislatures have been more supportive in terms of redistributive policies and regulatory policies than when their Republican counterparts are in control. Thus, in the case of prescription drug policy, one would expect more policy adoption in states with Democratic control as opposed to states with Republican or split control

In an attempt to capture the political party control of state government, political party control, in this analysis, has been measured as three separate dichotomous variables (i.e., Democratic, Republican, or Split). Specifically, if the Democratic Party had control of both the legislature and governorship a number 1 was assigned to the Democratic variable for that state-year. Subsequently, if the Republican Party had control of both the legislature and governorship a number 1 was assigned to the Republican variable for that state-year. In cases where there no political party controlled the legislature and governorship a number 1 was assigned to the Split, indicating a Split Party Control.

Classification and Creation of Dependent Variables

The objective of this analysis was to examine the factors that affect the adoption of state prescription drug policies. While the National Conference of State Legislatures (NCSL) provided the foundation of state prescription drug policies, further manipulation was required to create the dependent variable. First, the prescription drug policies from 1999 through 2008 were extracted from the NCSL website. A policy topic code was assigned to each policy by the NCSL. For example, state legislation where the text centered on drug discount programs was designated with a policy topic code of D. While the policy topic codes were useful in providing a guide to policy categorization, the policy description in conjunction with policy text was used to assign policies to a particular category (i.e., acquisition, safety, or distribution). Acquisition policies were those that mentioned an economic principle, Medicaid, or Medicare in an effort to increase access to prescription medications. Safety policies were those that mentioned the use of education, electronic prescribing, and databases to mitigate the possibility of misuse, abuse, adverse drug events, or medication errors. Distribution policies were defined as those policies that prohibited or restricted the marketing and advertising of prescription medications or in some other way regulated the prescription drug distribution entities. A policy that fit into multiple categories was assigned to both. For example, a law that contained text on the Preferred Drug list (i.e., Access) and text on PBM regulation (i.e., Distribution) were associated with both categories. As expected, there were state policies that did not fit into the classification schema and were categorized as *Other.*

Second, three dummy variables were created; (1) acquisition, (2) safety, and (3) distribution. For each state-year's dummy variable, a one was assigned if the policy passed by the legislature and was signed into law by the Governor.

Third, the three dependent variables, one for each of the categories (i.e., acquisition, safety, and distribution), were calculated as a sum of the dummy variables for each state-year. For each of the three policies for example, states with no policy will be assigned a zero; states with one policy related to financial of prescription drugs will be assigned a one; and states with two policies related to financial of prescription drugs will be assigned a 2; and so on.

Given the breadth and depth of prescription medication use, it is conceivable that states adopt policy changes beyond initial adoption. For example, states may periodically propose legislative modification related to the 340B Drug Pricing Program in an effort to expand the savings by adding state organization to the federally approved list. Doing so would not necessarily be considered a new policy adoption but rather a change to the original policy. For this reason, the three dependent variables include legislative adoptions regardless of whether they are merely a change or are newly created legislation.

Statistical Analysis

For the purposes of this analysis, the dependent variable, computed as the count of policy adoptions for a given type of prescription policy, lends itself to the specific event count regression approach negative binomial regression (King, 1988, 1989). The event count model allows for the examination of phenomenon where events occur over a period of time and are considered *rare* (Hamilton, 2003, Cameron and Trivedi, 1986; Box-Steffensmeier and Jones, 1987). The number of policy adoptions between 1999 and 2008 is a nonnegative integer, bounded at zero on the low end and unbounded high end. An event count model such as Poisson and negative binomial regression are the most appropriate for this type of data. However, the key assumption of a Poisson regression is that the variance is equal to the mean. Scholars suggest that using a Poisson regression model on over-dispersed data can result in inappropriately small standard errors and larger Z-values (King 1989; Long 1997). According to Boehmke (2005), heterogeneity and contagion are two motivations for overdispersion. Heterogeneity which can result from an "unobserved phenomena within a state influence the number of proposals reach the ballot" (Boehmke, 2005, 569). In the case of state prescription drug policy, legislator sponsorship may differ across each of the prescription drug policy types. Contagion refers to the situation where "the occurrence of an event in one time period increases the chance of additional events in the same time period." In prescription drug policy, contagion effect might occur where proponents of particular policy are particularly active in one year. Thus in the case where the

data is over-dispersed, a negative binomial regression is more appropriate (Long, 1997; Boehmke, 2005).

The independent variables included in the model were demographic factors (i.e., age, poverty, education, urbanization, and health status), external (i.e., neighboring policies) and political factors (i.e., ideology, political control and issue salience). SPSS version 17.0 in conjunction with Stata v8.2 was used for data and statistical analysis.

In this chapter, the methodological and analytical roadmap was presented with a brief summary of the hypothesized factors, their rationale for inclusion and how the factor was operationalized. Although linear regression and logit models are quite popular in the analysis of public policy, these models were not be the most appropriate. A negative binomial regression analysis was identified as the most appropriate method of analysis.

CHAPTER 7: *RESULTS AND DISCUSSION*

While Mark Twain conveys the opinion of many when it comes to quantitative analysis, and particularly statistics, it nonetheless remains a method often used in examining state public policy adoption. The previous chapters introduced the theoretical and methodological foundation for the analysis of state prescription drug policy adoption. The following chapter presents the results, starting first with descriptive statistics followed by the model results.

Descriptive Results

Over the ten year period, all 50 states adopted at least one of the prescription drug policies whether for acquisition, safety, or distribution. There were 500 observations in the analysis, one record for each year-state over the ten year analytical period. More states adopted acquisition policies than those aimed at safety or distribution. Coincidentally, there were twelve different states that did not adopt safety and twelve states that did not adopt a distribution policy. It is important to note that early in the study (i.e., 1999, 2000, and 2001), fewer states had adopted prescription drug policies; however, later in the study, not only were more states adopting policies but more policies were being adopted. Figures 10, 11, and 12 illustrate the geographic distribution in the year states first adopted prescription drug policies. In the case of acquisition policy, it is interesting to note that only Nebraska and Florida adopted their first prescription drug acquisition policy after the passage of MMA. Figure 11 reveals the fact that 12 states have not adopted prescription drug policy aimed at safety. Similarly, more than 10 states have failed to adopt prescription drug policy aimed at distribution. In

general, the maps illustrate there is not a geographic trend related to the policy adoption. There appears to be quite a bit of geographic variation with no specific pattern of policy adoption. The 2005 spike in the number of acquisition policies illustrated in Figure 13 would coincide with legislative activities related to the passage of Medicare and Modernization Act of 2003 (MMA). Under the MMA, those eligible for Medicare could enroll in Medicare Part D, which was designed to provide access to prescription medications for seniors. However, states had to adopt legislation to address the dual-eligibles as discussed in Chapter 3.

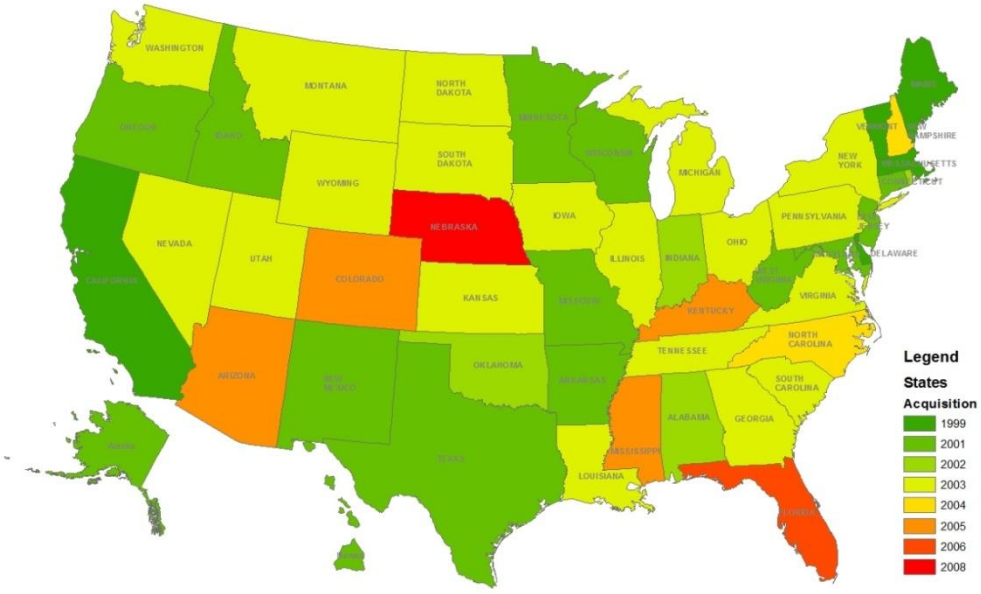

Figure 10: Year State First Adopted Acquisition Policy
This map illustrates that states were more active in policy adoption of acquisition policies earlier rather than in later years.

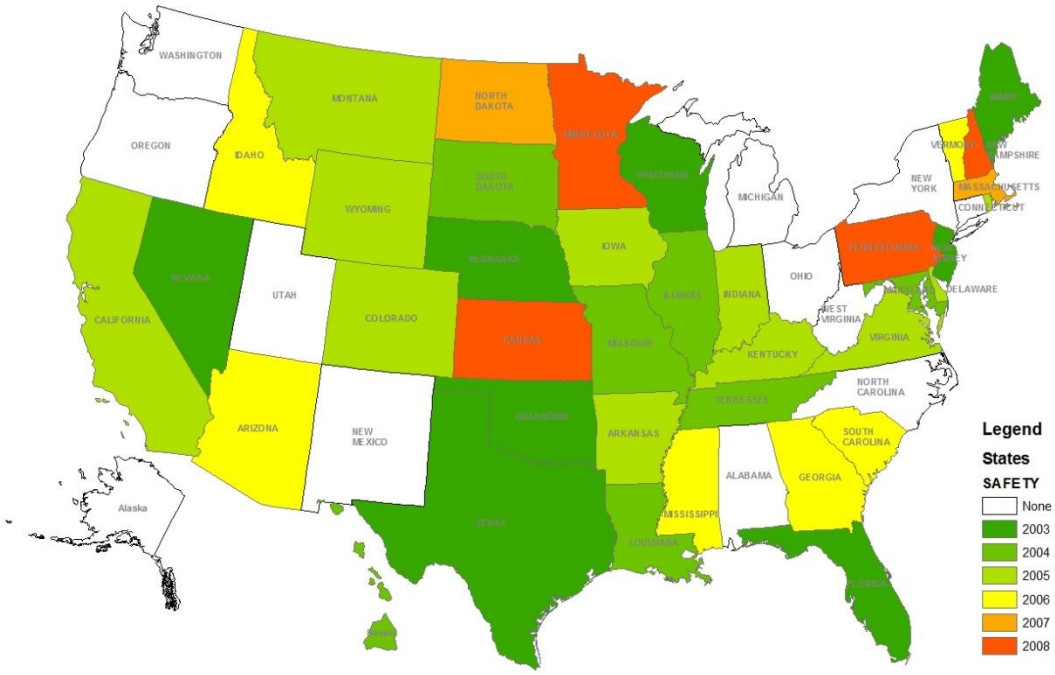

Figure 11: Year State First Adopted Safety Policy
This map illustrates that many states have not adopted prescription drug policy aimed at safety.

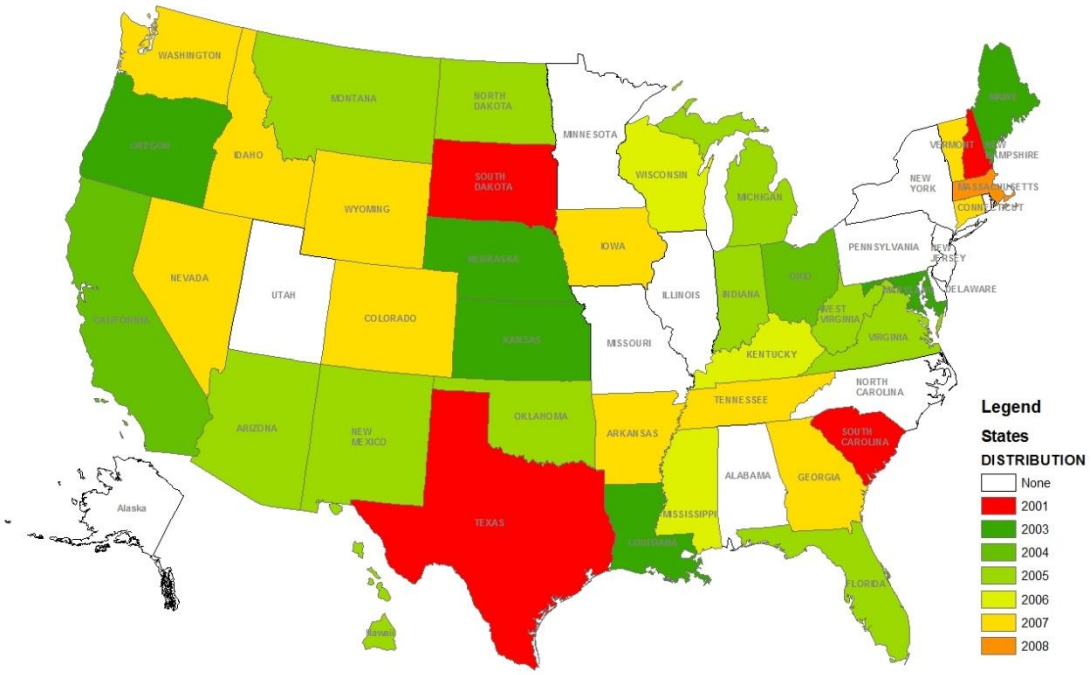

Figure 12: Year State First Adopted Distribution Policy
This map illustrate that a few early adopter of distribution policies and many states have yet to adopt a distribution targeted policy.

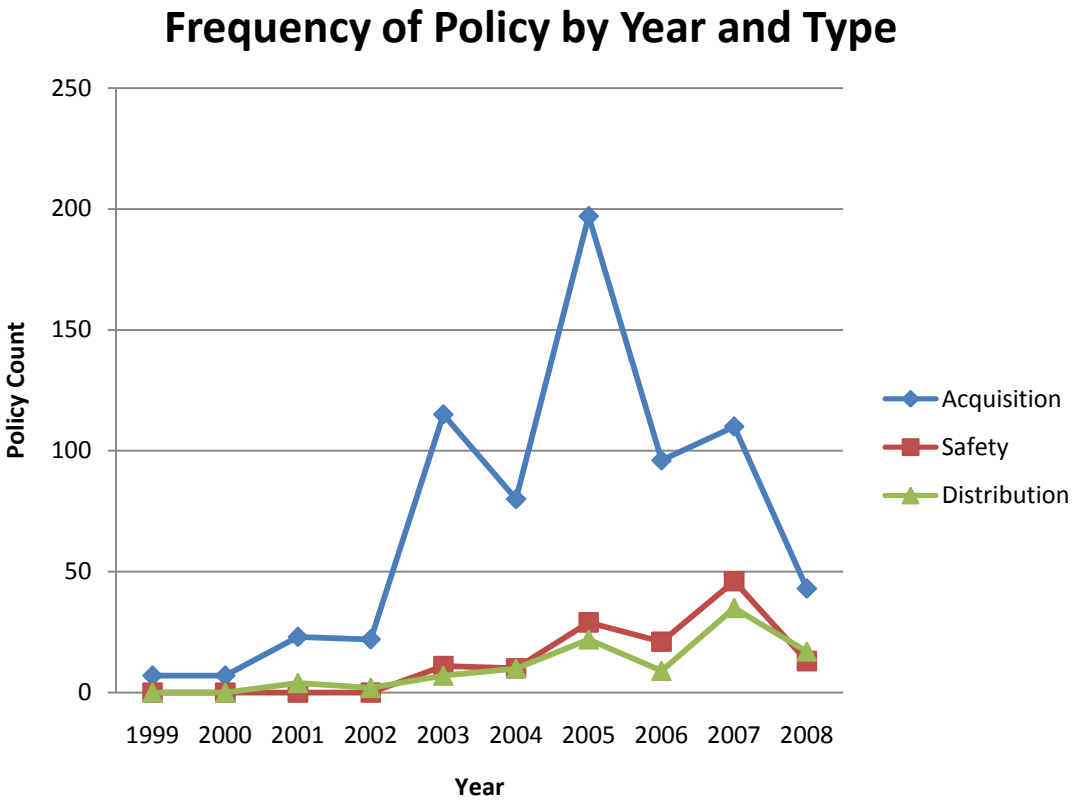

Figure 13: Policy Count by Year and Type
This chart illustrates that states have been more active on acquisition policies and were especially active during the period just before MMA went into effect.

Table 9 displays the descriptive results for the predictor variables. On average, 12% of the states' population was over the age of 65 and coincidentally 12% of the states' population was below the federal poverty level. The average percent of a state's population over the age of 25 with a bachelor's degree was 26%. According to the analytical description, more of a states' population live in urban areas than in rural areas. In fact, the results indicate that on average over two-thirds of a states' population live in urban areas. The BRFSS survey results indicate that on average the states' population report being healthy. The results indicate a wide variation in the number of staff per legislator, ranging from less than 1 to more than 20, with an average of approximately 5.

On average, interest groups contributed just under $10,000 per legislator, however the variation was quite large. Louisiana and Wyoming have the lowest reported contributions per legislator with less than $200 in some years. California has the highest reported contribution with more than $50,000 in 1999 and over $100,000 in 2008 per legislator. The average percent for neighboring states with policies is greater for acquisition policies than for safety and distribution: 39%, 16%, and 13% respectively. As expected, health care is an important issue. On average, health care is a problem for 61% of a state's population. Not surprisingly, the descriptive statistics indicate that states do not typically have large rate of slack resources. In fact, range indicates that some states have more expenditures than they do revenue streams. While the 2009 national Gallup polls suggest slightly higher rates than that presented in this analysis, the results from this analysis have a consistent pattern in that conservative ideology is more prevalent than that of

liberal ideology. According to the descriptive results, policymakers most often find themselves in state governments with split party control. Table 9 indicates that on average Democratic control of state legislatures occurs less often that of Republican or Split Control.

Factor	Mean	SD	Minimum	Maximum
	0.12	0.02	0.44	0.19
State population over the age of 65				
Proportion of Population below FPL (Poverty)	0.12	0.03	0.05	0.23
Proportion of opulation over 25 with Bachelor's Degree	0.26	.046	0.14	0.38
Proportion of population living in urban areas	0.73	0.17	0.30	0.99
Proportion of Population healthy	0.85	0.05	0.65	0.92
Financial capacity	0.05	0.16	-0.39	1.25
Staff per legislator	4.87	4.15	0.32	21.75
Neighboring States with Policy	0.39[a]	0.33[a]	0.00[a]	1.00[a]
Adoption	0.16[b]	0.22[b]	0.00[b]	1.00[b]
	0.13[c]	0.20[c]	0.00[c]	1.00[c]
Interest group financial support	$9,456	$13,783	$118	$110,552
Issue salience	0.86	0.42	0.71	0.95
Liberal political Ideology - % liberal	0.47	0.26	0.00	0.98
Democratic Party Control	0.19	0.39	0	1
Republican Party Control	0.37	0.48	0	1
Split Party Control	0.44	0.49	0	1

Table 9: Descriptive Statistics for Predictor Variables over All State Years (1999-2008) (n=500)

[a]Proportion of neighboring policies with acquisition policies
[b]Proportion of neighboring policies with safety policies
[c]Proportion of neighboring policies with distribution policies

Model Results

My hypotheses are based on the research premise that internal and external factors influence the actions of decision makers when it comes to prescription drug policy. A substantial amount of previous research is consistent with my hypothesis (Walker 1969; Gray 1973, Berry and Berry 1990; Gray, Godwin and Lowery 2007). The results of my research provide an addition to the previous scholarship indicating a relationship between these factors and state policy adoption.

In the empirical examination of factors effecting state adoption of prescription drug policies, I estimated a series of negative binomial regression models. The first model estimates the effect on policy adoption of acquisition policies with all factors included in the model. The second model includes the same factors but analyzes the effect on safety policy adoption, whereas the third model analyzes the effect on distribution policy adoption. The following section describes the results from each of the three models.

Acquisition

Prior to conducting the negative binomial regression, a histogram verified that the data was in fact non-linear and thus not appropriate for linear regression. Figure 14 illustrates that the count of prescription drug policies adopted over a ten-year period is skewed.

Table 10 displays the negative binomial regression model results for prescription drug policy adoptions aimed at acquisition. There are several important items to which one should pay particular attention. First, the log

likelihood of –726.83 was statistically significant indicating that the predictor variables are not equal to zero and the model is significantly different from zero. This result suggests that the model ”fits” in the sense that it explains variation in the dependent variable. Second, the likelihood ratio-test of alpha equal to zero indicates that the data is over-dispersed and thus supports the use of a negative binomial over a Poisson distribution. Figure 15 illustrates that the data fit a negative binomial distribution better than the corresponding Poisson distribution. The probability of a zero policies adopted increases from 0.25 using the Poisson regression model to 0.57 with the negative binomial regression model. In essence, Figure 15 illustrates that there is a larger probability for greater policy counts in the negative binomial regression than that of the Poisson regression.

Lastly, the results indicate that with the exception of the educational attainment variable, state composition variables did not influence the adoption of acquisition policies. In other words, the variables served to indicate need were not influential in the adoption of acquisition policies. The positive coefficient of educational attainment indicates that for every one percent increase in the percentage of the states' population over the age of 25 who have a bachelor's degree, the difference in the logs of expected counts of the response variables is expected to change by 7.91, while holding the other predictor variables constant.

Neighboring policy adoption and political ideology were statistically significant in the effect on acquisition policy adoption. The analysis appears to support the supposition that the policymaking of neighboring states makes a difference. The greater the percent of the states' neighbors who have adopted a

policy, the greater the number of acquisition policies. The positive coefficient of neighboring state policies indicates that for every one percent increase in the percentage of states' neighbors who have adopted an access policy, the difference in the logs of expected counts of the response variables is expected to change by 1.45, while holding the other predictor variables constant.

Consistent with the theory, the results indicate that ideology tends to correspond to higher counts of prescription drug policies aimed at access. Specifically, the results suggest a positive effect between political ideology and higher counts of state access prescription drug policies; the more liberal a state the more access policies it adopts. The positive coefficient of neighboring state policies indicates that for every one percent increase in the percentage of states' population that indicate liberal ideology, the difference in the logs of expected counts of the response variables is expected to change by 1.12, while holding the other predictor variables constant. Based on the negative binomial regression results, Figure 16 presents the factors that have an effect on state adoption of prescription drug acquisition policies.

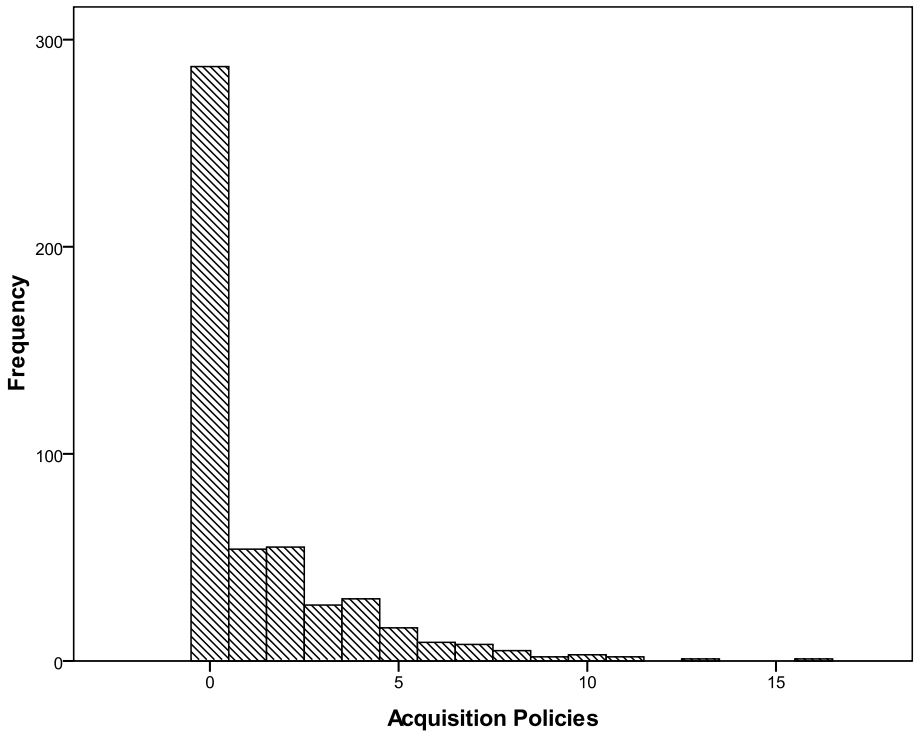

Figure 14: Histogram of State Prescription Drug Acquisition Policies
This graph illustrates the data are strongly skewed, not conducive for linear regression.

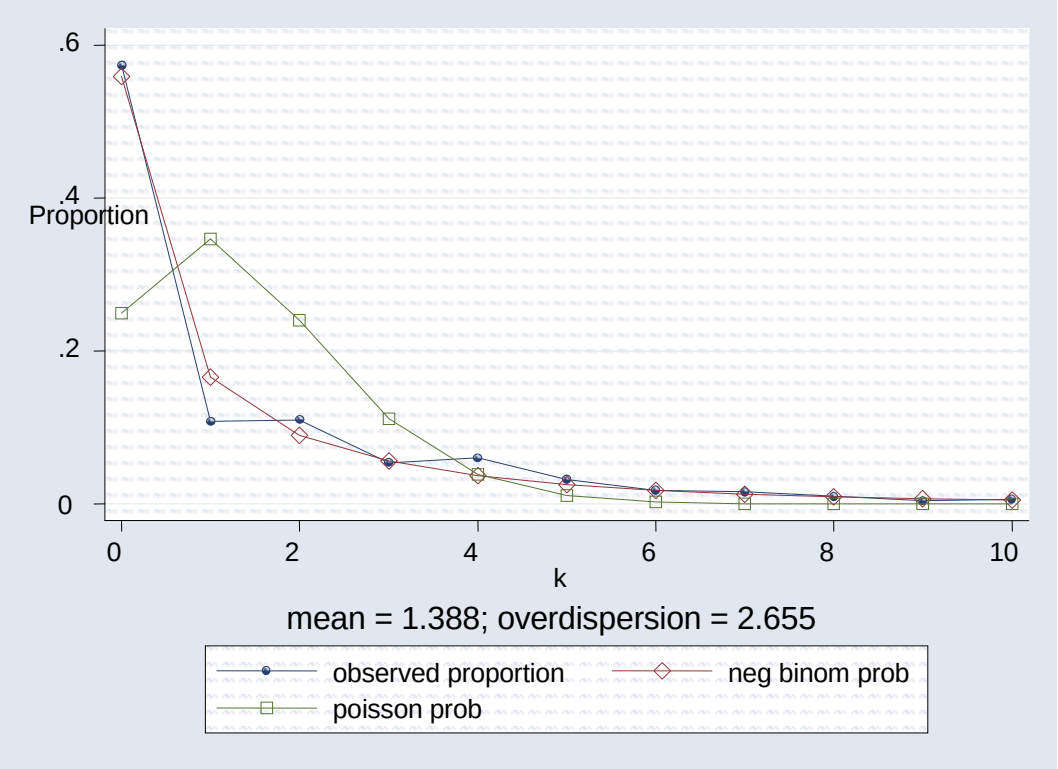

Figure 15: Negative Binomial Distribution for Acquisition Model
This graph illustrates the data fit a negative binomial distribution better than the poisson distribution.

Variable	Coefficient	Z value
Proportion of state population over the age of 65	3.33 (3.47)	0.96
Proportion of population below FPL (Poverty)	-1.05 (2.64)	-0.40
Proportion of population over 25 with Bachelor's Degree	7.91* (2.13)	3.71
Proportion population living in urban areas	-0.59 (0.57)	-1.05
Proportion population healthy	-3.41 (1.96)	-1.73
Financial capacity	0.26 (0.54)	0.49
Staff per legislator	0.00 (0.03)	0.26
Proportion of Neighboring States with Policy Adoption	1.47* (0.23)	6.37
Interest group financial support	0.00 (0.00)	1.42
Issue salience	-1.47 (1.96)	-0.75
% liberal political Ideology - % liberal	1.12* (0.46)	2.41
Republican Party Control	0.28 (0.32)	0.89
Split Party Control	0.02 (0.21)	0.11
Constant	-6.65 (2.25)	-2.95
Alpha	1.59 (0.21)	

Table 10: Results from Prescription Drug Acquisition Model, Negative Binomial Regression 1999-2008.

Note: *p<0.05 Standard errors in parenthesis.

Log-likelihood = -726.83

Chi-Square(13) = 99.37

N=500

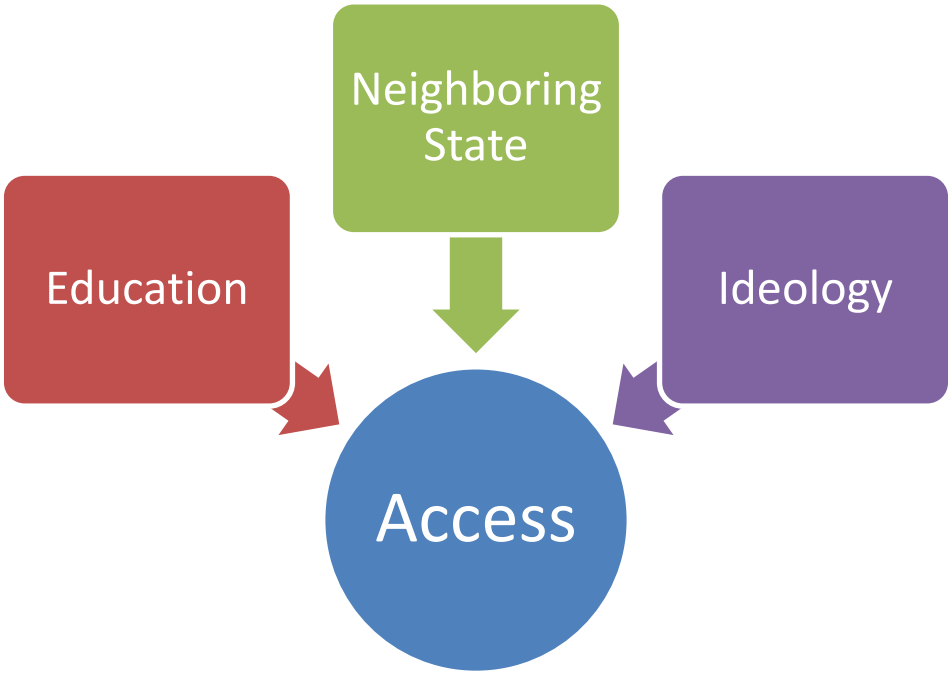

Figure 16: Predictor Variables of State Prescription Drug Acquisition Policies

Safety

As indicated in Figure 17 the distribution of state prescription drug policies aimed at safety is clearly skewed. Similar to the acquisition policies, the skewed data suggest the use of a negative binomial regression analysis.

Table 11 displays the results Z scores and coefficients from the negative binomial regression model for prescription drug safety policies. The log likelihood value of -289.47 was statistically further indicating the coefficients in the model are not equal to zero. This result suggests that the model is fit. Additionally, the likelihood ratio-test (LR) of alpha equal to zero indicates that the data is over-dispersed, supporting the use of a negative binomial over a Poisson distribution. Figure 18 indicates no benefit of the negative binomial distribution over the Poisson distribution for safety policies. The probability of a zero policies adopted increases from 0.78 using the Poisson regression model to 0.81 with the negative binomial regression model. In essence, Figure 18 illustrates that there is a larger probability, albeit only slightly, for greater policy counts in the negative binomial regression than that of the Poisson regression.

Similar to the adoption of acquisition policies, the model did indicate that of the population composite factors (i.e., elderly, poverty, educational attainment, health status, and urbanization) only education were statistically significant. The positive coefficient of educational attainment indicates that for every one percent increase in the percentage of the states' population over the age of 25 who have a bachelor's degree, the difference in the logs of expected counts of the response variables is expected to change by 7.87, while holding the other predictor variables

constant. In essence, the greater the proportion of state residents over the age of 25 with a bachelor's degree the greater the probability of states adopting a prescription drug policy aimed at safety. The proportion of as state's population with a bachelor's degree was not only consistently influential across all three models but it was the most influential.

The states' financial capacity also appeared to influence state policy adoption aimed at safety. The positive coefficient indicates that states with more *slack* resources adopted more safety prescription drug policies. The positive coefficient of financial capacity indicates that for every one percent increase in the ratio of expenditures to revenue, the difference in the logs of expected counts of the response variables is expected to change by 2.30, while holding the other predictor variables constant. In essence, the results suggest that the greater the state's slack resources the greater the number of safety policies adopted.

The model results related to the influence of neighboring states with policy adoptions is consistent with my hypothesis. The impact of neighboring policies indicated that an increase in the percentage of neighboring states adopting a prescription drug safety policy in the preceding year might result in an increase in the estimated incidence of safety prescription drug policy by a factor of 1.62. In essence, the results suggest that there a positive effect on the number of safety policies adopted the greater the proportion of surrounding states who have adopted prescription drug policy aimed at safety.

Additionally, the salience of an issue had an effect on the state prescription drug policy adoption; however, it was counter to my hypothesis. The negative

coefficient indicates that the greater the issue saliency the fewer policies adopted. While the results are counter to my hypothesis, it suggests that health care as an important issue results in fewer safety policy adoptions. One possible explanation may be that attention to a prescription drug safety issue lessens the likelihood that policies will actually be adopted. Figure 19 displays the negative binomial regression factors that influence adoption of safety policies.

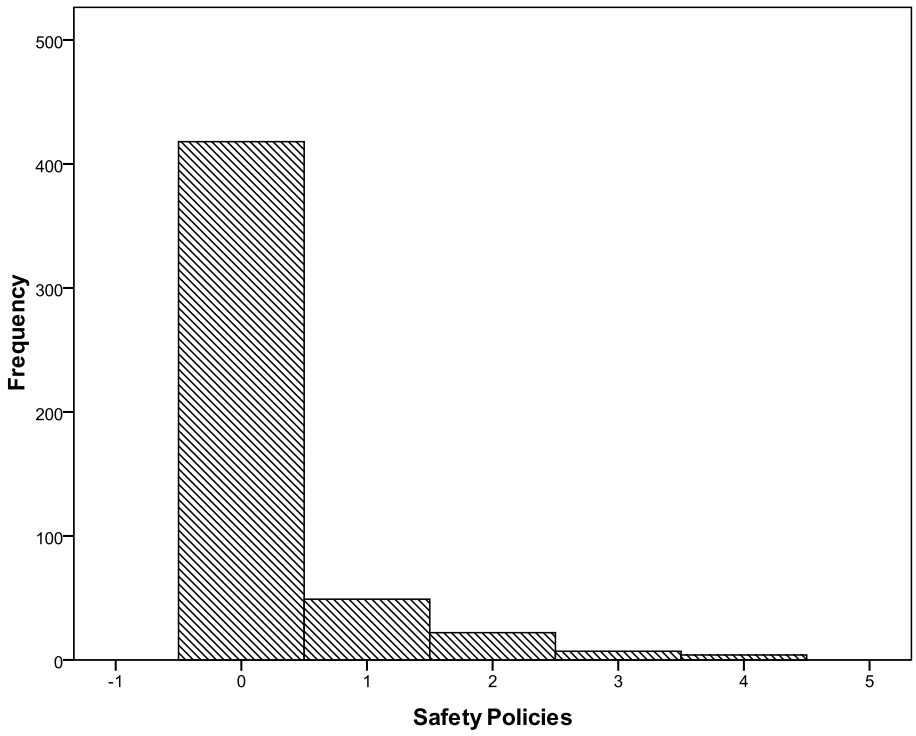

Figure 17: Histogram of Prescription Drug Safety Policies

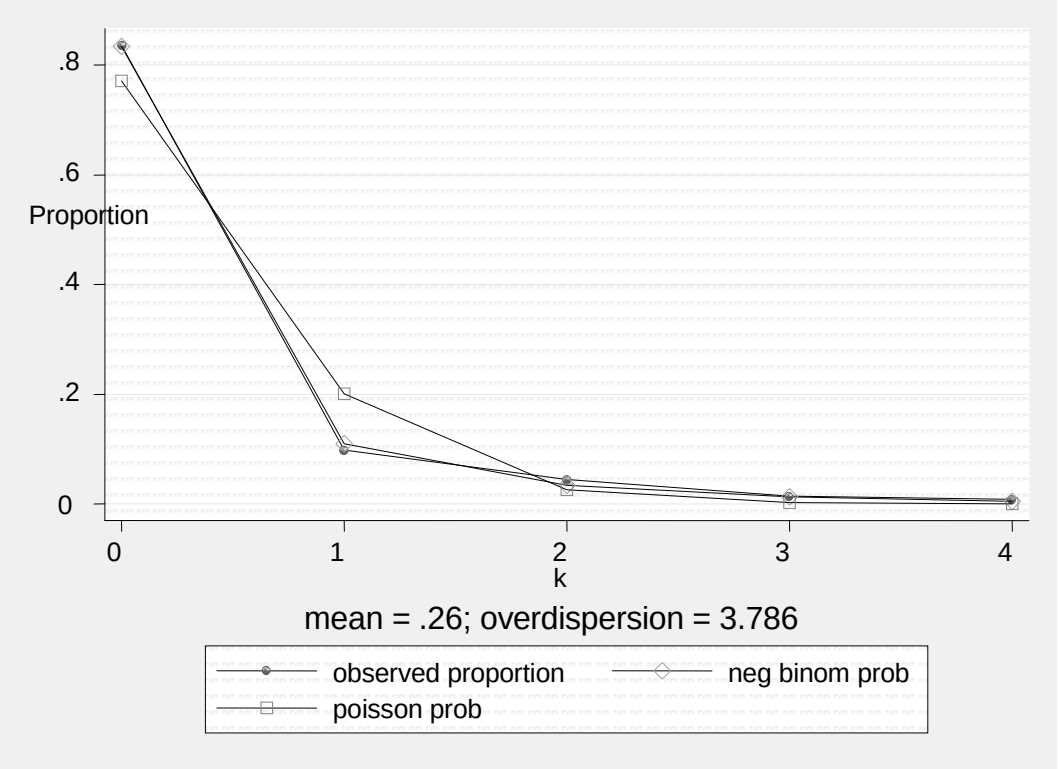

Figure 18: Negative Binomial Distribution for Safety Model
This figure displays the proportion of policies adopted is consistent for both the negative binomial and Poisson regression.

Variable	Coefficient	Z value
Proportion of state population over the age of 65	8.35 (5.93)	1.41
Proportion of population below FPL (Poverty)	0.58 (4.51)	0.13
Proportion of population over 25 with Bachelor's Degree	7.87* (3.64)	2.15
Proportion population living in urban areas	0.47 (0.95)	0.50
Proportion population healthy	-3.67 (2.18)	-1.69
Financial capacity	2.30* (0.90)	2.55
Staff per legislator	-0.05 (0.05)	-1.20
Proportion of Neighboring States with Policy Adoption	1.62* (0.56)	2.91
Interest group financial support	0.00 (0.00)	0.49
Issue salience	-8.66* (3.07)	-2.82
% liberal political Ideology - % liberal	-0.26 (0.74)	-0.37
Republican Party Control	-0.42 (0.50)	-0.84
Split Party Control	-0.44 (0.34)	-1.31
Constant	-1.87 (3.36)	-0,54
Alpha	2.29 (0.62)	

Table 11: Results from Prescription Drug Safety Model, Negative Binomial Regression 1999-2008.
Note: *p<0.05 Standard errors in parenthesis.
Log-likelihood = -289.47
Chi-Square(13) = 40.61
N=500

Figure 19: Predictor Variables of State Prescription Drug Safety Policies
This graphic presents the significant factors in the negative binomial regression analysis.

Distribution

Figure 20 displays the distribution of state prescription drug distribution policies. The histogram depicts the data is skewed to the right, thus supporting the use of a negative binomial regression.

The negative binomial regression model results for prescription drug policy adoptions are presented in Table 12. Based on the results, the log likelihood of -248.44 indicates a statistically significant model. This result suggests that the model is fit. While Figure 21 indicates no benefit of the negative binomial distribution compared to Poisson regression, the likelihood ratio-test (LR) of alpha equal to zero indicates that the data is over-dispersed. Thus, the use of a negative binomial was selected over a Poisson regression analysis.

Consistent with the access model, the negative binomial model using count of distribution policies indicates that educational attainment and neighboring policies influences policy adoption. A coefficient of 11.72 indicates that the educational variable has the stronger effect. The impact of educational attainment indicate that for every one percent increase in the percentage of the states' population over the age of 25 who have a bachelor's degree, the difference in the logs of expected counts of the response variables is expected to change by 11.72, while holding the other predictor variables constant.

The research appears to support the supposition that the policymaking of neighboring states makes a difference. The greater the percent of the states' neighbors who have adopted a policy, the greater the number of state prescription drug policies aimed at distribution. Specifically, the coefficients indicate that a one

unit increase in the percentage of neighbors with a distribution policy will have a 1.37 effect.

Also of considerable interest is the model results related to the influence of interest groups. Unlike the models for safety and access, the distribution model indicates that the financial contributions made by interest groups to policymakers matter when it comes to state prescription drug policy aimed at distribution. While the coefficient results (1.10) indicate a smaller effect than education, it is most interesting to note that the financial contribution was not a factor for the other two types of prescription drug policy. Figure 20 presents the factors that may influence state adoption of prescription drug distribution policies as indicated by the negative binomial regression results.

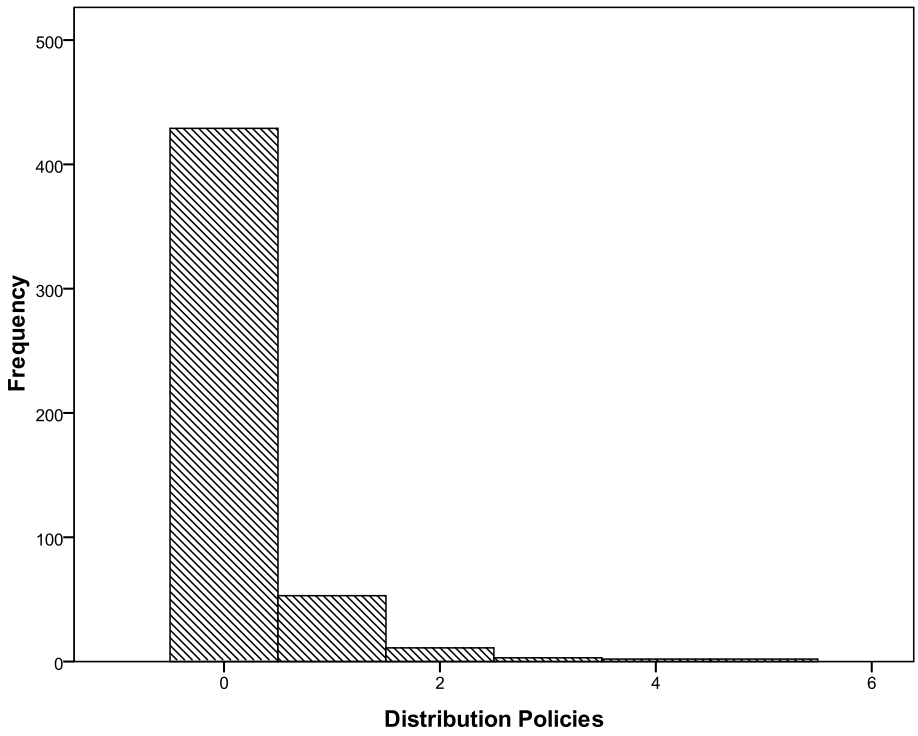

Figure 20: Histogram of State Prescription Drug Distribution Policies

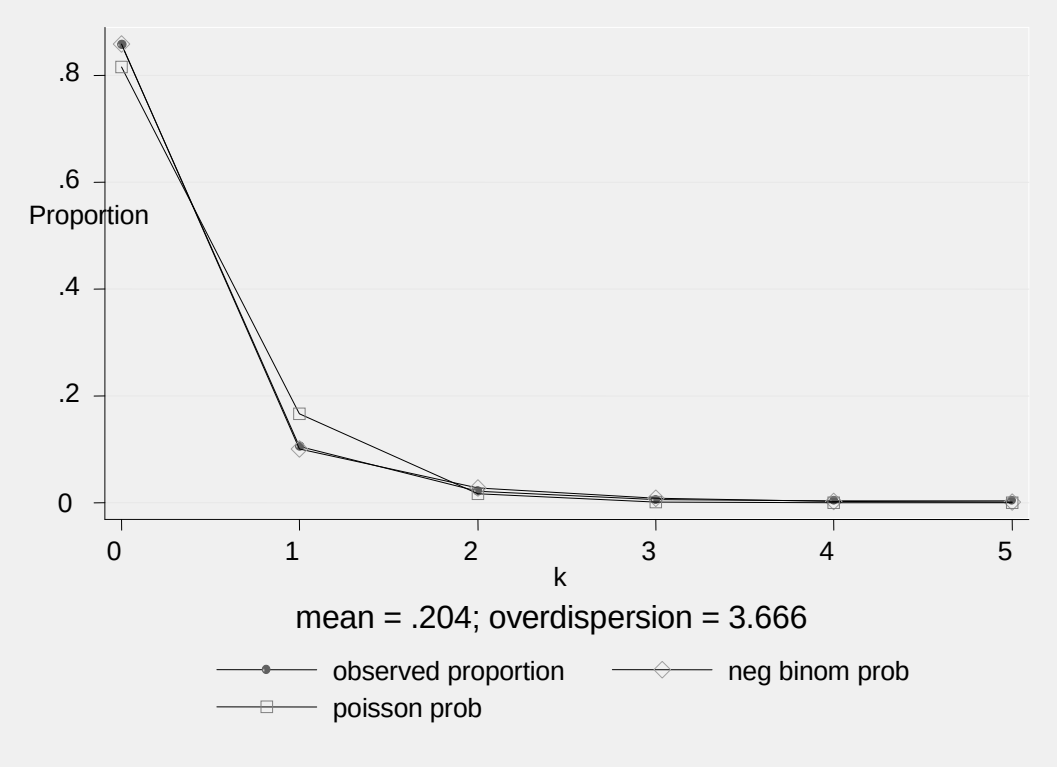

Figure 21: Negative Binomial Distribution for Distribution Model

Variable	Coefficient	Z value
Proportion of state population over the age of 65	12.52 (6.52)	1.92
Proportion of population below FPL (Poverty)	3.43 (5.10)	0.67
Proportion of population over 25 with Bachelor's Degree	11.72* (3.99)	2.93
Proportion population living in urban areas	-1.49 (0.99)	-1.50
Proportion population healthy	-1.52 (3.09)	-0.49
Financial capacity	1.10 (0.88)	1.26
Staff per legislator	-0.04 (0.05)	-0.88
Proportion of Neighboring States with Policy Adoption	1.37* (0.60)	2.28
Interest group financial support	0.00* (0.00)	2.38
Issue salience	-3.12 (3.62)	-0.86
% liberal political Ideology - % liberal	-0.30 (0.80)	-0.38
Republican Party Control	-0.63 (0.55)	-1.16
Split Party Control	-0.58 (0.35)	-1.67
Constant	-9.02 (4.10)	-2.20
Alpha	2.21 (0.68)	

Table 12: Results from Prescription Drug Distribution Model, Negative Binomial Regression 1999-2008.

Note: *p<0.05 Standard errors in parenthesis.

Log-likelihood = -248.44

Chi-Square(13) = 35.34

N=500

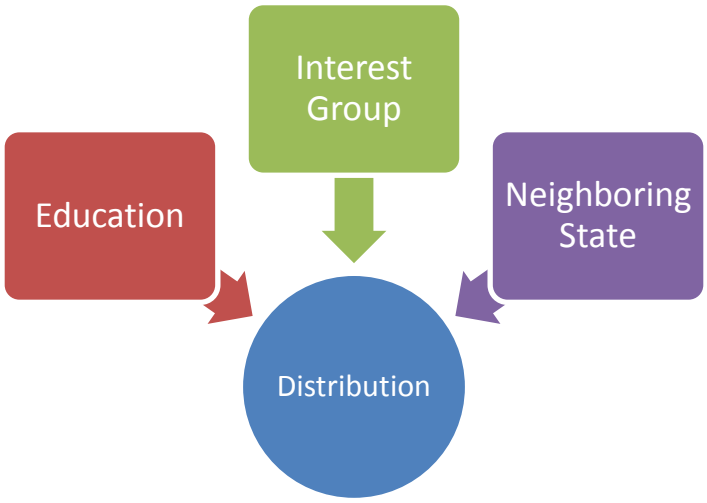

Figure 22: Predictor Variables of State Prescription Drug Distribution Policies

While each prescription drug policy type was explored separately, there are several important items to notice about the results. First, the proportion of a state's population with a bachelor's degree was not only consistently influential across all three models but it was the most influential. Additionally, across all three of the models, the state population composition variables, with the exception of educational attainment, were not significant. This was a surprising finding in that these factors served as indicators of need. As indicated by John Kingdon (2003), policymakers may rely on indicators as to what issues are of public concern. Thus as indicated in Chapter 2, one would suppose that states with a greater need (i.e., those with older, unhealthy, or poor) would have more policy adoptions. However, the results indicate that the factors used to proxy the potential need for pharmaceuticals were not influential in policy adoption. After further review, the result may be explained from the fact that prescription medications is a subset part of a larger health care issue and thus may not be influenced by the same factors as health care in general.

Second, in each of the three models, the policymaking of neighboring states made an impact. Thus the evidence does suggest that state legislators may rely on the policymaking of neighboring states to address the challenges of constraints (e.g., time and resources) or competitive federalism. As revealed in Chapter 2, prescription drug policy can be complex thus the legislators may look to their neighbor for assistance.

Third and most notable, is the fact that the pattern of influence of key variables across the three models is inconsistent. The theoretical supposition on which this analysis originated was that the prescription drug policies are not consistent and thus would be influenced by a variety of factors. These results provide evidence to support the theoretical foundation. As seen in Table 20, the significant factors do vary by prescription drug policy type. While two factors (i.e., educational attainment and neighboring state influence) are influential in two of the models, the factors that affect prescription drug policy do vary by policy. For example, financial capacity is only influential in safety policies. Additionally, the importance of the health care issue is only significant in the safety model. Political ideology is only a significant factor related to the adoption of acquisition policies, whereas interest group financial support per legislator is only a significant factor related to distribution policies.

Overall, the results suggest that the factors influencing adoption of state prescription drug policy do differ. Neighboring state policymaking, educational attainment, and political ideology affects prescription drug policy aimed at acquisition. While the hypothesis that political ideology mattered was true for acquisition policies, it was not influential in the adoption of distribution related policies. This was a surprising result in that one would expect the more conservative state ideology the less likely they would be to intervene in business in terms of adopting regulatory policies and less likely to provide government assistance in terms of access policies.

Variable	Acquisition Coefficient	Safety Coefficient	Distribution Coefficient
	3.33	8.35	12.52
Proportion of state population over the age of 65	(3.47)	(5.93)	(6.52)
Proportion of population below FPL (Poverty)	-1.05	0.58	3.43
	(2.64)	(4.51)	(5.10)
Proportion of population over 25 with Bachelor's Degree	7.91*	7.87*	11.72*
	(2.13)	(3.64)	(3.99)
Proportion population living in urban areas	-0.59	0.47	-1.49
	(0.57)	(0.95)	(0.99)
Proportion population healthy	-3.41	-3.67	-1.52
	(1.96)	(2.18)	(3.09)
Financial capacity	0.26	2.30*	1.10
	(0.54)	(0.90)	(0.88)
Staff per legislator	0.00	-0.05	-0.04
	(0.03)	(0.05)	(0.05)
Proportion of Neighboring States with Policy Adoption	1.47*	1.62*	1.37*
	(0.23)	(0.56)	(0.60)
Interest group financial support	0.00	0.00	0.00*
	(0.00)	(0.00)	(0.00)
Issue salience	-1.47	-8.66*	-3.12
	(1.96)	(3.07)	(3.62)
% liberal political Ideology - % liberal	1.12*	-0.26	-0.30
	(0.46)	(0.74)	(0.80)
Republican Party Control	0.28	-0.42	-0.63
	(0.32)	(0.50)	(0.55)
Split Party Control	0.02	-0.44	-0.58
	(0.21)	(0.34)	(0.35)
Constant	-6.65	-1.87	-9.02
	(2.25)	(3.36)	(4.10)
Alpha	1.59	2.29	2.21
	(0.21)	(0.62)	(0.68)

Table 13: Results from the Negative Binomial Models
Note: This table presents a side-by-side comparison of the coefficients for all three negative binomial regression models. *p<0.05. N=500.

Limitations

The study has several limitations. The first is the commonly accepted limitation associated with data availability. Undoubtedly, the invention of the internet has made data more readily available than at any other point in time; however, researchers still face data limitations. Although there were obvious situations (i.e., issue salience and interest groups) where ideal datasets were not readily available, it is the belief of this researcher that the measurements used serve as an adequate indicator to measure the intended construct.

Second, while regression analysis assists researchers in examining the dependence of one variable on another it does not abdicate causation. In essence, the presence of a relationship between X and Y variables does not necessarily mean that X caused Y. In the case of state prescription drug policy, the statistical significance of certain factors (e.g., ideology, education, interest group support) does not indicate that these factors cause state legislators to adopt policies, but simply that there is a relationship and to some degree influence. The limitation in the ability to substantiate causality has a direct impact on how the results may be applied.

While my dissertation provides insight into the variation of factors influencing state prescription drug policy adoption, it does not provide indication to the substantive question related to policy outcomes. Understanding what factors are present in policy adoption are informative for activities of agenda

setting, policy options and their expediency, appears to omit the major component of whether or not the policy was successful.

CHAPTER 8: *CONCLUSION AND FUTURE RESEARCH*

"It was the best of times, it was the worst of times, it was the age of wisdom, it was the age of foolishness, it was the epoch of incredulity, it was the season of Light, it was the season of Darkness…" Charles Dickens from a Tale of Two Cities

Although written some time ago, Dickens' quote seems as fitting to the prescription drug world of today as it did in describing England and France during the 18th century. The availability of new therapies, lower cost generics, and innovative biotechnological medications has made this a provocative time in health care. Specifically, over the past decade, new and lower cost prescription medications have assisted patients in their quest for health and save overall health care dollars. For example, evidence suggests consistently taking one's medication can reduce overall medical costs (American Diabetes Association, 2007; American Heart Association, 2009; Sokol et al, 2005). However, the rising drug costs, drugs removed from the market and pharmaceutical manufacturer profits have spawned greater government attention to the issue or prescription drug policy. The focus of this dissertation was to gain a better understanding as to what factors are influential in states adopting pharmaceutical policies.

Future Research

While the analysis of prescription drug policy adoption expands on the current state policy adoption literature, the analysis presented here could be expanded to explore the impact of predictor variables. The variables selected for this analysis were consistent with those used in seminal state policy adoption literature. In addition, analysis could be expanded to analyze policies categorized as *Other*.

Future research could benefit from further exploration beyond that dependent on quantitative analysis. According to William W. Watt, "Don't put your faith in what statistics say until you have carefully considered what they do not say." As such, one might explore a mixed-method approach using qualitative data of interviewing state legislators on the issue of prescription drug policy. In terms of statistical research, future research might explore the use of Cox regression or more sophisticated statistical techniques such as those indicated in the Box-Steffensmeier and Jones 2004 article.

Related to the affect of neighboring states on prescription drug policy, future research might include analysis of policies resulting from federal government legislative activity. For example, there was significant activity after the passage of the Medicare Modernization act; presumably in reaction to the federal policies. However, not all states adopted MMA related policies, thus it would be interesting to look at difference between the two.

Conclusions and Policy Implications

While political science scholars have spent over 40 years expanding on the seminal work of Walker (1969) and researchers have investigated a variety of policy areas, the results from this analysis indicate there is always room for more analysis on state policy adoption (Walker 880-99;Mohr 111-26;Gray 1174-85;Berry and Berry 395-415;Case, Hines, and Rosen 285-307;Mintrom 41-59;Berry and Baybeck 505-19). This dissertation expands on the existing literature by examining the variation of factor influence within one particular policy area. Specifically, this dissertation explored the idea that factors influential in state policy

adoption were not consistent within one policy area, but rather the influential factors are as varied as the policies themselves.

While the analysis is limited to the last decade of state prescription drug policies, the research and subsequent findings expand on the innovation and diffusion literature. The research is of particular importance in our understanding of factors present in state policy adoption of a particular health care issue. In particular, the study contributes to our understanding of what factors are influential in the area of state prescription drug policies aimed at acquisition, safety, and distribution.

Consistent with previous research of Gray, et al (2007), this analysis establishes that organized interests had little effect on the passage of prescription policy adoption related to acquisition (i.e., Pharmacy Assistance Programs). However, the results from this dissertation indicate that the findings of interest group influence should not be applied to all prescription drug policies but rather judiciously depending on the policy objective. In the case of state prescription drug distribution policies, whose objective is to regulate distributors, the findings suggest that interest group contributions to state legislators were influential when related to distribution policies but not influential in acquisition and safety related policies.

The study further supports the existing theory that neighboring state policymaking influences state policy adoption. While previous scholars have explored the impact of neighboring policy adoption, this research broadens our application the neighboring state effect to additional policy topic areas.

Metaphorically speaking, the results indicate that what is going on next door matters. Specifically, the policymaking of neighboring states was influential in all three types of prescription drug policy.

One of the most provocative questions, not only political scientists but for citizens as well, is whether or not public opinion matters. Does the public preference influence the policies adopted by lawmakers? In the 2009 health care reform debate many would argue the fact that public opinion matters, but on the issue of state prescription drug policy it was only influential in the case of safety policies. One could speculate that news coverage may be greater on prescription drug safety issues as opposed to distribution or acquisition. However, without specific public opinion data or data on state news coverage it is difficult to ascertain why issue saliency was a factor for safety as opposed to acquisition or distribution policies.

While the passage of the Patient Protection and Affordability Act of 2010 is undoubtedly a monumental event, much of what had already been accomplished in terms of access to health care has come at the state level. For an example of state activism on the issue of health care, one need only look at the number of prescription drug policies aimed at acquisition to get a sense of the work done at the state level. As presented in this dissertation, states vary in their policies adopted and the factors influencing those adoptions. As the federal government begins implementation, the results presented in this dissertation suggest that the institutional, demographic, political party control and public preference may influence how the policy is implemented at the state levels.

APPENDIX 1: VARIABLE DESCRIPTION AND SOURCES

Variable	Description	Source
State	Two digit state abbreviation	
Year	1999-2008	
Predictor Variables		
Need: Elderly	Percent of state population over 65 yrs of age	U.S. Bureau of the Census (various years)
Need: Poverty	Percent of state population below the federal poverty level	U.S. Bureau of the Census (various years)
Need: Education	Percent of state population over the age of 25 with a Bachelor's degree	U.S. Bureau of the Census (various years)
Need: Urbanization	Percent of state population living in metropolitan statistical area	U.S. Bureau of the Census (various years)
Need: Health Status	Percent of survey respondents who indicated "Good Health" on the BRFFs survey	Center for Chronic Disease Control
Capacity: Fiscal	Percentage of total state revenue minus the total state spending	U.S. Bureau of the Census (various years)
Capacity: Professionalization	Number of staff per legislator	National Conference of State Legislatures (various years)
Neighbor Adoption	Number of neighboring states with policy in preceding year	National Conference of State Legislatures (various years)
Interest Group	Dollar amount spent per legislative seat in 2004	Follow the money.org
Issue Salience	Percent of respondents who indicated health care is an important issue	Center for Chronic Disease Control
Ideology	Citizen ideology ranging 0 to 1 with 1 being liberal	Berry, Ringquist, Fording and Hanson
Party Control	Split political party	National Conference of State Legislatures (various years)
Dependent Variables		
Access policies	Count of prescription drug policies aimed at access	NCSL
Safety policies	Count of prescription drug policies aimed at safety	NCSL
Distribution policies	Count of prescription drug policies aimed at distribution	NCSL

Reference

2003. Pharmaceutical Research and Manufacturers of America, petitioner v. Peter E. Walsh, Acting Commissioner, Maine Department of Human Services. In *PharmaceuticalResearch and Manufacturers of America v.Walsh*, Supreme Court of the United States.

Advisory Commission on Intergovernmental Relations (ACIR). 1985. The Question of State Government Capability. Washington, DC: Government Printing Office.

Aids Foundation of Chicago. 2009. "Couldn't Trek to Springfield? Be an Armchair Advocate for 2009 HIV/AIDS Lobby Days!" 2010. Available from http://www.aidschicago.org/events/lobby_day_2009.php.

Albin PS, and Stein B. 1977. The Impact of Unemployment on Welfare Expenditures. *Industrial & Labor Relations Review* 31 (1): 31.

Ansolabehere S, and Snyder JrJM. 2003. Party Control of State Government and the Distribution of Public Expenditures.

Balla SJ. 2001. Interstate Professional Associations and the Diffusion of Policy Innovations. *American Politics Research* 29 (3): 221-245.

Baumgartner FR, and Jones BD. 1993. *Agendas and instability in American politics*. Chicago: University of Chicago Press.

Baumgartner FR, and Leech BL. 2001. Interest Niches and Policy Bandwagons: Patterns of Interest Group Involvement in National Politics. *The Journal of Politics* 63 (4): 1191-1213.

Berry FS, and Berry WD. 1990. State Lottery Adoptions as Policy Innovations: An Event History Analysis. *The American Political Science Review* 84 (2): 395-415.

Berry WD, Ringquist EJ, Fording RC, and Hanson RL. 1998. Measuring Citizen and Government Ideology in the American States, 1960-93. *American Journal of Political Science* 42 (1): 327-348.

Berry WD, Berkman MB, and Schneiderman S. 2000. Legislative Professionalism and Incumbent Reelection: The Development of Institutional Boundaries. *American Political Science Review* 94 (4): 859-874.

Berry WD, and Baybeck B. 2005. Using Geographic Information Systems to Study Interstate Competition. *American Political Science Review* 99 (4): 505-519.

Bingham RD. 1976. *The Adoption of Innovation by Local Government*. Lexington, MA: Lexington Books.

Blendon RJ, and et al. 2008. Health Care in the 2008 Presidential Primaries. *New England Journal of Medicine* 358 (4): 414-422.

Boehmke FJ, and Witmer R. 2004. Disentangling Diffusion: The Effects of Social Learning and Economic Competition on State Policy Innovation and Expansion. *Political Research Quarterly* 57 (1): 39-51.

Boehmke FJ. 2005. Sources of Variation in the Frequency of Statewide Initiatives: The Role of Interest Group Populations. *Political Research Quarterly* 58 (4): 565-575.

Box-Steffensmeier JM, and Jones BS. 1997. Time is of the Essence: Event History Models in Political Science. *American Journal of Political Science* 41 (4): 1414-1461.

Brace P, Arceneaux K, Johnson M, and Ulbig SG. 2004. Does State Political Ideology Change over Time? *Political Research Quarterly* 57 (4): 529-540.

Brown JG. 1998. Audit of the Utilization of the Public Health Service 340B Drug Pricing Program. U.S. Department of Health and Human Services.

Buntin J. 2009. "Minding the Detailers." 2010. Available from http://www.governing.com/article/minding-detailers.

Bunting BA, and Cranor CW. 2006. The Asheville Project: Long-Term Clinical, Humanistic, and Economic Outcomes of a Community-Based Medication Therapy Management Program for Asthma. *Journal of the American Pharmacists Association* 46 (2): 133-147.

Cameron AC, and Trivedi PK. 1986. Econometric Models Based on Count Data: Comparisons and Applications of Some Estimators and Tests. *Journal of Applied Econometrics* 1 (1): 29-53.

Campbell JL. 2002. Ideas, Politics, and Public Policy. *Annual Review of Sociology* 28: 21-38.

Canon BC, and Baum L. 1981. Patterns of Adoption of Tort Law Innovations: An Application of Diffusion Theory to Judicial Doctrines. *The American Political Science Review* 75 (4): 975-987.

Carpenter D, Chernew M, Smith DG, and Fendrick AM. 2003. Approval Times For New Drugs: Does The Source Of Funding For FDA Staff Matter? *Health Affairs* w3: 618.

Carpenter DP. 2004. The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy. *Health Affairs* 23 (1): 52-63.

Carter LE, and LaPlant JT. 1997. Diffusion of Health Care Policy Innovation in the United States. *State and Local Government Review* 29 (1): 17-26.

Case A, Hines JR, and Rosen HS. 1993. Budget Spillovers and Fiscal Policy Interdependence: Evidence from the States. *Journal of Public Economics* 52 (3): 285-307.

Casey MM. 2001. Are rural residents less likely to obtain recommended preventativve healthcare services? *American Journal of Preventative Medicine* 21 (3): 182-188.

Centers for Medicaid and Medicare Services. 2004. Summary of H.R. 1 Medicare Prescripton Drug, Improvement and Modernization Act of 2003, Public Law 108-173.

-----. 2008. 2008 Actuarial Report on the Financial Outlook for Medicaid., 1-40.

Centers for Medicare & Medicaid Services. 2008. "National Health Expenditure Table." 2008. Available from http://www.cms.hhs.gov/NationalHealthExpendData/.

Congressional Budget Office. 2006. Research and Development in the Pharmaceutical Industry.

Cox E, Behm A, and Mager D. 2007. "2005 Generic Drug Usage Report." 2008.

Cranor CW, Bunting BA, and Christensen DB. 2003. The Asheville Project: Long-Term Clinical and Economic Outcomes of a community Pharmacy Diabetes Care Program. *Journal of the American Pharmaceutical Association* 43 (2): 173-184.

Cunningham PJ, Miller C, and Cassil A. 2008. Living on the Edge: Health Care Expenses. ed Center for Studying Health System Change, 1-14. Center for Studying Health System Change.

Dahl RA. 2005. *Who governs?democracy and power in an American city*. New Haven: Yale University Press.

Damico AJ, Conway MM, and Damico SB. 2000. Patterns of Political Trust and Mistrust: Three Moments in the Lives of Democratic Citizens. *Polity* 32 (3): 377-400.

Daniels N. 2001. Justice, Health and Healthcare. *The American Journal of Bioethics* 1 (2): 2-16.

Doron G. 1992. Policy Sciences: "The State of the Discipline.". *Policy Studies Review* 11: 303-309.

Downs A. 1972. Up and Down with Ecology - The 'Issue-Attention' Cycle. *Public Interest* 28: 38-50.

Downs GW, and Mohr LB. 1976. Conceptual Issues in the Study of Innovation. *Administrative Science Quarterly* 21: 700-714.

Downs GW. 1976. *Bureaucracy, Innovation, and Public Policy*. Lexingon, Mass.: Lexington Books.

Dye TR. 1984. Party and Policy in the States. *The Journal of Politics* 46 (4): 1097-1116.

E-Health Initiative. 2004. Electronic Prescribing: Toward Maximum Value and Rapid Adoption. Washington, D.C.: eHealth Initiative.

Elaam L. 2005. Do State Medicaid Preferred Drug Lists Affect Patient Safety? *Psychiatric Services* 56 (8): 1012-1013.

Enright SM. 1987. Mail-order pharmaceuticals. *American Journal of Hospital Pharmacy* 44: 1870-1873.

Epstein L, and Sigel J. 2000. Measuring Issue Salience. *American Journal of Political Science* 44 (1): 66-83.

Erikson RS. 1971. The Relationship Between Party Control and Civil Rights Legislation in the American States. *Policy Studies Journal* 7 (Summer): 753-761.

Express Scripts. 2007. "2006 Drug Trend Report." 2008. Available from http://www.express-scripts.com/ourcompany/news/industryreports/drugtrendreport/2006/.

Fenno RF. 1978. *Home style*
House Members in their districts
10. Boston: Little, Brown.

Frank RG. 2001. Prescription Drug Prices: Why Do Some Pay More Than Others Do? *Health Affairs* 20 (2): 115-128.

Garrison LP, Jr., and Wilensky GR. 1986. Cost containment and incentives for technology. *Health Affairs* 5 (2): 46-58.

Glabman M. 2002. "Lobbyists That the Founders Just Never Dreamed of." 2010. Available from http://www.managedcaremag.com/archives/0208/0208.lobbying.html.

Grabowski HG, and Vernon J. 1983. *The Regulation of Pharmaceuticals*. Washington, DC: American Enterprise Institute.

Grady DO. 1987. State Economic Development Incentives: Why Do States Compete? *State and Local Government Review* 19 (3): 86-94.

Gray V. 1973. Innovation in the States: A Diffusion Study. *The American Political Science Review* 67 (4): 1174-1185.

Gray V, Lowery D, and Godwin EK. 2007. Public Preferences and Organized Interests in Health Policy: State Pharmacy Assistance Programs as Innovations. *Journal of Health Politics, Policy and Law* 32 (1): 89-129.

Grogan CM. 1994. Political-Economic Factors Influencing State Medicaid Policy. *Political Research Quarterly* 47 (3): 589-622.

Grossback LJ, and Peterson DAM. 2004. "Understanding Institutional Change: Legislative Staff Development and the State Policymaking Environment." 2009.

Guadagnino C. 2005. "Pa. launches academic drug detailing." 2009. Available from http://www.physiciansnews.com/spotlight/1205.html.

Hall RL, and Van Houweling RP. 2006. Campaign Contributions and Lobbying on the Medicare Modernization Act of 2003. Paper presented at American Political Science Association, 31 2006.

Hamilton LC. 2003. *Statistics with Stata*. Belmont, California: Duxbury Thomson Learning.

Heaney MT. 2008. Brokering Health Policy: Coalitions, Parties, and Interest Group Influence. *Journal of Health Politics, Policy and Law* 31 (5): 887-944.

Hellerstein JK. 1998. The Importance of the Physician in the Generic versus Trade-Name Prescription Decision. *The RAND Journal of Economics* 29 (1): 108-136.

Hilts PJ. 2003. *Protecting America's health the FDA, business, and one hundred years of regulation*. New York: Alfred A. Knopf.

Holahan J, Berenson RA, and Kachavos PG. 1990. Area Variations in Selected Medicare Procedures. *Health Affairs* Winter.

Huddle tS. 2008. Drug Reps and the Academic Medical Center: a case for management rather than prohibition. *Perspectives in Biology and Medicine* 51 (2): 251-260.

Illinois Pharmacists Association. 2010. "IPhA Mission Statement." 2010. Available from http://www.ipha.org/about/missionStatement.php.

IMS Health. 2008. "Channel Distribution by U.s. Sales." 2009. Available from http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/2008_Channel_Distribution_by_U.S._Sales.pdf.

Iowa Drug Card Program. 2009. "Iowa Drug Card Program." 2009. Available from http://www.iowadrugcard.com/index.php.

Johnson JA, Coons SJ, Hays RD, Sabers D, Jones P, and Langley PC. 1997. A comparison of Satisfaction with Mail versus Traditional Pharmacy Services. *Journal of Managed Care Pharmacy* 3 (3): 327-337.

Kaiser Family Foundation. 2004. "FDA Delays Response to Vermont Lawsuit Over Reimportation of Prescription Drugs." 2009. Available from http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=26586.

-----. 2007. "Prescription Drug Trends." 2008. Available from http://www.kff.org/rxdrugs/upload/3057_06.pdf.

-----. 2008. "Few Options for State to Control Medicaid Spending in Declining Economy." 8 A.D. Available from http://www.kff.org/medicaid/upload/7769.pdf.

-----. 2009. "Massachusetts Health Care Reform: Three years later." 2009. Available from http://www.kff.org/uninsured/upload/7777-02.pdf.

Karch A. 2007. Emerging Issues and Future Directions in State Policy Diffusion Research. *State Politics and Policy Quarterly* 7 (1): 54-80.

Kesselhelm AS, and Choudhry NK. 2008. The International Pharmaceutical Market as a Source of Low-Cost Prescription Drugs for U.S. Patients. *Annals of Internal Medicine* 148 (8): 614-618.

Ketchum JD, and Ngai J. 2008. How Similar Are States' Medicaid Preferred Drug Lists? *Am. J. Manag. Care* 14 (11 Spec No): SP46-SP52.

Key VO. 1961. *Public opinion and American democracy*. New York: Knopf.

King G. 1989. Variance Specification in Event Count Models: From Restrictive Assumptions to a Generalized Estimator. *American Journal of Political Science* 33 (3): 762-784.

King JD. 2000. Changes in Professionalism in U.S. State Legislatures. *Legislative Studies Quarterly* 25 (2): 327-343.

Kingdon JW. 2003. *Agendas, Alternatives, and Public Policies*. New York: Longman.

Krause B. 2004. "State Purchasing Pools for Prescription Drugs: What's Happening and How Do They Work?" 2008. Available from http://www.nga.org/cda/files/0408PRESCRIPTION.pdf.

Lasswell HD. 1951. The Policy Orientation. In *Communication Researchers and policy-making*, ed S Braman, 85-104. Boston: MIT Press.

Laven DL. 2006. Prescription Drug Wholesalers: Drug Distribution and the Inspection Process (A Florida Perspective). *Journal of Pharmacy Practice* 19 (4): 196-214.

Leavitt MO. 2007. Electronic Prescribing Report to Congress., 1-35.

Leech BL, Baumgartner FR, Berry JM, Hojnacki M, and Kimball DC. 2007. Does Money Buy Power? Interest Group Resources and Policy Outcomes. Paper presented at Midwest Political Science Association, 12 2007.

Lichtenberg FR. 2002. Benefits and costs of newer drugs: an update. *Health Economics* 28 (4-5): 485-490Benefits and costs of newer drugs: an update.

Lindblom C. 1959. The Science of Muddling Through. *Public Administration Review* 19: 79-88.

Long JS. 1997. *Regression models for categorical and limited dependent variables*. Thousand Oaks: Sage Publications.

Longest BB. 2001. *Contemporary health policy*. Chicago, Ill: Health Administration Press.

Lowi TJ. 1964. Review: American Business, Public Policy, Case-Studies, and Political Theory. *World Politics* 16 (4): 677-715.

Manning J. 4 A.D. "State questions FDA drug seizures." 2009. Available from http://www3.jsonline.com/bym/news/sep04/258631.asp .

Marmor TR. 2000. *The politics of medicare*. New York: A. de Gruyter.

Mayhew DR. 1974. *Congress: the electoral connection*. New Haven: Yale University Press.

McCool DC. 1995. *Public Policy: Theories, Models, and Concepts*. Englewood Cliffs, NJ: Prentice-Hall.

McMillan ML, and Amoako-Tuffour J. 1991. Demands for Local Public Sector

Outputs in Rural and Urban Municipalities. *American Journal of Agricultural Economics* 73 (2): 313-325.

Meinke SR, Staton JK, and Wuhs ST. 2005. "Supplemental Materials: State Delegation Selection Rules for Presidential Nominations, 1972-2000.".

Mertz K. 2007. "An "Oldie but Goodie": The 340B Program." 2008. Available from http://www.ncsl.org/programs/health/shn/2007/sn491b.htm.

Miller Edward Alan. 2005. State health policy making determinants, theory, and methods: A synthesis. *Social Science & Medicine* 61: 2639-2657.

Mintrom M. 1997. The State-Local Nexus in Policy Innovation Diffusion: The Case of School Choice. *Publius: The Journal of Federalism* 27 (3): 41-59.

Mohr LB. 1969. Determinants of Innovation in Organizations. *The American Political Science Review* 63 (1): 111-126.

Murawski MM, and Abdelgawad T. 2005. Exploration of the impact of preferred drug lists on hospital and physician visits and the costs to Medicaid. *Am. J. Manag. Care* 11 Spec No: SP35-SP42.

National Association of Chain Drug Stores Foundation. 2006. NACDS Annual Report 2006.

National Conference of State Legislatures. 2009. "Pharmaceuticals." 2009. Available from http://www.ncsl.org/IssuesResearch/Health/tabid/160/Default.aspx.

National Governors Association. 2004. State Purchasing Pools for Prescription Drugs: What's Happening and How Do They Work?, 1-9. Washington, D.C.: National Governors Association Center for Best Practices.

Nice DC. 1984. Interest Groups and Policymaking in the American States. *Political Behavior* 6 (2): 183-196.

Nivola PS, and Rosenbloom DH. 1986. *Classic readings in American politics 1*. New York: St. Martin's Press.

Northington Gamble V, and Stone D. 2006. U.S. Policy on Health Inequities: The Interplay of Politics and Research. *Journal of Health Politics, Policy and Law* 31: 93-126.

Nownes AJ. 2006. *Total lobbying what lobbyists want (and how they try to get it)*. Cambridge: Cambridge University Press.

Oliver TR, Lee PR, and Lipton HL. 2004. A Political History of Medicare and Prescription Drug Coverage. *Milbank Quarterly* 82 (2): 283-354.

Olson MK. 2004. Perspective: Explaining Reductions In FDA Drug Review Times: PDUFA Matters. *Health Affairs* 10.1377/hlthaff.w4 (s1).

Ormond BA, Zuckerman S, and Lhila A. 2000. Rural/Urban Differences in Health Care Are Not Uniform across States. New Federalism: National Survey of America's Families, Series B, No. B-11. Assessing the New Federalism: An Urban Institute Program To Assess Changing Social Policies., 1-8. Urban Institute, 2100 M Street, N.W., Washington DC 20037. Tel: 202-833-7200; Fax: 202-429-0687; e-mail: paffairs@ui.urban.org; Web site: http://www.urban.org.

Owings S, and Borck R. 2000. Legislative Professionalism and Government Spending: Do Citizen Legislators Really Spend Less? *Public Finance Review* 28 (3): 210-225.

Peterson PE, and Rom MC. 1990. *Welfare magnets a new case for a national standard*. Washington, D.C: Brookings Institution.

Pincus T, Esther R, DeWalt D, and Callahan L. 1998. Social conditions and self-management are more powerful determinants of health than access to care. *Annals of Internal Medicine* 129 (5): 406-411.

Poisal JA, and Murray L. 2001. Growing Differences Between Medicare Beneficiaries With And Without Drug Coverage. *Health Affairs* 20 (2): 74-85.

Poisal JA, Truffer C, Smith S, Sisko A, Cowan C, Keehan S, Dickensheets B, and the National Health Expenditure Accounts Projections Team. 2007. Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact. *Health Affairs* 26 (2): w242-w253.

Pracht EE, and Moore WJ. 2003. Interest Groups and State Medicaid Drug Programs. *Journal of Health Politics, Policy and Law* 28 (1): 9-39.

Preskorn SH. 2002. Drug approvals and withdrawals over the last 60 years. *Journal of Psychiatric Practice* 8 (1): 41-50.

Reforming States Group. 2003. State Initiatives on Prescription Drugs: Creating a More Functional Market. *Health Affairs* 22 (4): 128-136.

Remler D, and Atherly A. 2003. Health status and heterogeneity of cost-sharing responsiveness: how do sick people respond to cost-sharing? *Health Economics* 12 (4): 269-280.

Rentmeester CA, and Garis RI. 2008. Rebates and Spreads: Pharmacy Benefit Management Practices and Corporate Citizenship. *Journal of Health Politics, Policy and Law* 33 (5): 943-963.

Reynolds GH, 2009. Tax Day Becomes Protest Day. *The Wall Street Journal*, 17 July.

Roe CM, and McNamara A. 2002. Gender- and age-related prescription drug use patterns. *Annals of Pharmacotherapy* 36 (1): 30-39.

Rogers EM. 2003. *Diffusion of innovations*. New York: Free Press.

Rose G. 2007. The Power of Polls: A primer for generating, analyzing and using poll information., 1-2.

Rosenau PV, Lal LS, and Glasser JH. 2010. U.S. pharmacy policy: a public health perspective on safety and cost. *Social Work Public Health* 24 (6): 543-567.

Rosenthal A. 1996. State Legislative Development: Observations from Three Perspectives. *Legislative Studies Quarterly* 21 (2): 169-198.

Rosenthal MB, Berndt ER, Donohue JM, Frank RG, and Epstein AM. 2002. Promotion of Prescription Drugs to Consumers. *New England Journal of Medicine* 346 (7): 498-505.

Rubenstein S, 2007. Pill Push: Industry Fights Switch to Generics for Epilepsy. *Wall Street Journal Online*, 2 October.

Sabatier PA. 1999. *Theories of the policy process*. Boulder, Colo: Westview Press.

Satterthwaite SB. 2002. Innovation and Diffusion of Managed Care in Medicaid Programs. *State and Local Government Review* 34 (2): 116-126.

Schattschneider EE. 1986. The Scope and Bias of the Pressure System. In *Classic Readings in American Politics*, eds PA Nivola and DH Rosenbloom, 247-260. New York: St. Martin's Press.

Scholz L. 2008. The 340B Drug Pricing Program State Optimization of 340B. Paper presented at Promoting Integrity, Access, & Value, 23 2008.

Shipman CR, and Volden C. 2008. The Mechanisms of Policy Diffusion. *American Journal of Political Science* 52 (4): 840-857.

Silow-Carroll S, and Alteras T. 2004. Stretching State Health Care Dollars: Pooled and Evidence-Based Pharmaceutical Purchasing. ed Common Wealth Fund, 1-30. Common Wealth Fund.

Sokol MC, McGuigan KA, Verbrugge RR, and Epstein RS. 2005. Impact of medication adherence on hospitalization risk and healthcare cost 3. *Med Care* 43 (6): 521-530.

Stafford RS. 2008. Regulating Off-Label Drug Use -- Rethinking the Role of the FDA. *The New England Journal of Medicine* 358 (14): 1427-1429.

Starr P, and American Council of Learned Societies. 1982. *The social transformation of American medicine*. New York: Basic Books.

State of Illinois Office of the Auditor General. 2006. Management Audit of the Flue Vaccine Procurement and I-SaveRx Program., 1-30. Springfield, IL: Office of the Auditor General.

State of Kansas. 2004. "I-Save Rx Program." 2009. Available from http://www.kansas.gov/healthykansasrx/isaverx.shtml.

State of Maine. 2009. "State of Maine." 2009. Available from http://www.maine.gov/dhhs/mainerx/.

Thompson CA. 2005. Oklahoma allows limited medication recycling. *American Journal of Health-System Pharmacy* 62 (14): 1437.

Tiebout CM. 1956. A Pure Theory of Local Expenditures. *The Journal of Political Economy* 64 (5): 416-424.

Turner S, O'Connor P, and Rademacher E. 2009. Inform, Influence, Evaluate: The Power of State Public Opinion Polls. *Health Affairs* 28 (1): 273-276.

U.S.Department of Health and Human Services Health Resources and Services Administration. 1993. "Pharmaceutical Pricing Agreement (PPA)." 2009.

U.S.Food and Drug Administration. 2008. "Approved Drug Products With Therapeutic Equivalence Evaluations." 2008. Available from http://www.fda.gov/cder/ob/default.htm.

USA Today/Kaiser Family Foundation/Harvard School of Public Health. 2008. "The Public on Prescription Drugs and Pharmaceutical Companies." 2009. Available from http://www.kff.org/kaiserpolls/upload/7748.pdf.

Walgreens. 2009. Walgreens Announces Executive Change.

Walker JL. 1969. The Diffusion of Innovations among the American States. *The American Political Science Review* 63 (3): 880-899.

-----. 1983. The Origins and Maintenance of Interest Groups in America. *The American Political Science Review* 77 (2): 390-406.

Wang JJ. 2000. "Unopened, Unused Prescription Drugs Destroyed at Taxpayer Expense." 2009. Available from http://www.law.uh.edu/healthlaw/perspectives/Food/001129Unopened.html.

Wapner J. 2009. "Hurdles Facing Unused Prescription Drug Repositories." 2009. Available from http://www.scientificamerican.com/article.cfm?id=spreading-the-health.

Washington State Department of Revenue. 2007. Tax Facts 2007. Washington State Department of Revenue.

Weaver JL. 1976. The Elderly as a Political Community: The Case of National Health Policy. *The Western Political Quarterly* 29 (4): 610-619.

Weissert CS. 1991. Issue Salience and State Legislative Effectiveness. *Legislative Studies Quarterly* 16 (4): 509-520.

Weissert CS, and Weissert WG. 2006. *Governing health the politics of health policy*. Baltimore: Johns Hopkins University Press.

Wertheimer AI, and Andrews KB. 1995. The economics of mail service pharmacy. *Pharmacoeconomics* 7 (2): 111-117.

Wilson JQ. 1973. *Political organizations*. New York: Basic books.

Woloshin S, Schwartz LM, Tremmel J, and Welch HG. 2001. Direct-to-consumer advertisements for prescription drugs: what are Americans being sold? *The Lancet* 358 (9288): 1141-1146.

Wright GC, Jr., Erikson RS, and McIver JP. 1985. Measuring State Partnership and Ideology with Survey Data. *Journal of Politics* 47 (2): 469.

-----. 1987. Public Opinion and Policy Liberalism in the American States. *American Journal of Political Science* 31 (4): 980-1001.

Yackee JW, and Yackee SW. 2006. A Bias Towards Business? Assessing Interest Group Influence in the U.S. Bureaucracy. *Journal of Politics* 68: 128-139.

Zaltman G, Duncan R, and Holbek J. 1973. *Innovations and organizations*. New York: Wiley.