ESSAYS ON THE PERSISTENCE OF CAPTURE THEORY: THE FOOD AND DRUG ADMINISTRATION

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A Dissertation

Presented to

The Faculty of the Department

of Political Science

University of Houston

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In Partial Fulfillment

Of the Requirements for the Degree of

Doctor of Philosophy

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By

Sophiya Das

December, 2018

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ABSTRACT

What determines the decisions taken by the Food and Drug Administration? Does the agency have the public interest in mind? Or is it captured by the numerous interest groups that attempt to influence the regulations? Multiple theories have been developed to understand the motivation behind the decisions taken by the regulatory agencies. Despite this, scholars have remained divided among different school of thought. This study is an attempt to provide clarity to this debate. The results of this study show the working of the Capture Effect in the Food and Drug Administration. In order to test this theory, I analyze three unique channels of influence utilized by the regulated pharmaceutical entities. Existing studies that have denied the presence of capture have looked at only the internal dynamics of the FDA. They have not incorporated the role of government in the whole process. The first paper addresses this gap and examines the impact of campaign contributions on the bills sponsored by the members of Congress. The result reveals a positive and significant effect of campaign contributions on bill sponsorship. The second paper examines the direct effect of lobbying on the drug applications approved by the Food and Drug Administration. The analysis reveals that lobbying contribution and certain lifesaving drugs (i.e., cancer and HIV medication) are a deciding factor in the drug approval process. In my third paper, I incorporate the role of institutions in the channels of influence utilized by the regulated companies. The analysis reveals that pharmaceutical company is successful in influencing the FDA when it lobbies both during the rulemaking phase and executive branch review of the rules.

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DEDICATION

This work is dedicated to my father for his heavenly blessings.

Introduction

The usage of prescription drugs and over-the-counter medications have increased exponentially over the years in the United States. These medications are utilized to alleviate ailments, as well as help individuals lead a healthy and long life by enhancing the quality of living. In United States, more than 3 billion prescriptions were dispensed in the year 2002 (Ceccoli 2004). Due to such increased utilization of medications in the country, there has been a rise in the growth of the pharmaceutical industries. This in turn has increased the importance of the Food and Drug Administration (FDA) which regulates the entry of drugs into the market. Under the existing laws, before any drug can be marketed, they have to be approved by the FDA on grounds of safety and effectiveness.

With the increasing growth and competition in the pharmaceutical industry, these companies have to compete for survival. They spend millions of dollars on R&D to develop one drug. The only way for them to survive is to achieve FDA's seal of approval and earn profitability after they are marketed. However, due to stringent regulations, often these drug applications fail to get the needed approval and end up in losses. In order to avoid this adverse outcome, the drug and medical device companies engage in alternative avenues to convince and make FDA officials more responsive towards them. When the decisions taken by the regulator reflects the well-being of the regulated companies instead of the consumers/general public, the regulator is said to have been captured.

Over the years, scholars have been divided regarding the motivation behind the decisions taken by the FDA. There are three major school of thought – Public Interest Theory; External Signals Theory; and Capture Theory.

Public Interest Theory **-** This theory belongs to the oldest school of thought. The Food and Drug Administration was created with the "mission to promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use" (Hickman 2003, 1). Like most public bureaucracies, FDA's role was considered highly normative. As Carpenter (2010, 4) notes "public interest was less a body of theory and a more descriptive label used by critics of an earlier era's scholarship". According to Ceccoli (2004), regulation in public interest was required particularly in cases where market failures occurred and inefficiencies arose as a result of natural monopolies. The major drawback of this theory is that it completely ignores the numerous roles played by different actors and interest groups in the public policy. Similar conclusions have been reached by multiple studies (Carpenter 2010; Ceccoli 2004; and Kalt and Zupan, 1984). Because of the naivety and the limited applicability of this theory, it has been rendered obsolete in the literature.

External Signals Theory **–** Another competing school of thought includes studies done by Carpenter (2010); Olson (1997) and Quirk (1980). They focus on the external environment surrounding the agency, which plays a very important role in the expansion of power of a regulatory agency. The external environment is composed of public support and political influence.

"The external signals theory suggests that regulatory agencies seek positive feedback from outside groups. In contrast to positive feedback, adverse feedback from outside groups often creates hassles for the agency" (Olson 1995). The main aim of the FDA is to get positive feedback from the bigger firms as these firms will have a greater impact because of their political influence (Olson 1997). The agency tries to maintain the political support in order to

survive and maintain their budget. Hence the agency might take decisions that favor the bigger firms (Quirk 1980).

Capture Theory – The regulator is said to be captured by the regulated entities when "there are certain inherent features of the regulatory process and environment that determine the fundamental nature of the regulatory process and guarantee the dominance of the regulated group in influencing regulatory decisions" (Berry 1984). This competing school of thought was an extension of the public interest theory and was propagated by Stigler (1971) and Peltzman (1976). These scholars spread the idea of self-interest or capture effect[1].

Existing scholarly literature on capture theory is done in terms of distribution of benefits and burdens of regulation in the society (Stigler 1971, Posner 1971, Peltzman 1971), internal dynamics of the regulatory agencies (Bernstein 1955, Downs 1967) and repeated interaction of the regulator with the regulated firms (Wilson 1989).

Distribution of benefits and burdens of regulation - According to Stigler (1971), regulated actors may use the state's power (i.e., the ability to coerce the industries into regulation) to increase its profitability through subsidies, tariffs and price fixing. Posner (1971) and Peltzman (1976) extends Stigler's analysis and argue that "most laws are passed at the behest of special interests and that these laws actually accomplish what they are designed to accomplish".

Internal Dynamics of the regulatory agencies - Like every other regulatory body, the Food and Drug Administration also had to go through a period of gestation (Bernstein 1955) before becoming powerful. In other words, it had to cross the "initial survival threshold" (Downs

[1] Note: In this dissertation the term 'capture theory' and 'capture effect' has been used interchangeably. They mean the same.

1967) before achieving influence over the regulated firms. Crossing the initial survival threshold takes a lot of effort for an agency. Therefore, when it crosses this threshold and matures, there is a tendency for the agency to avoid any dramatic changes. "It becomes more positive and calculated in its approach as the environment surrounding it becomes more stable than before when it was newly created. There is a desire to avoid conflicts and to enjoy good relations with the regulated groups" (Bernstein 1955). Hence it can be concluded that the internal dynamics of a regulatory agency eventually leads to its capture by the regulated firms.

Repeated interaction of the regulator with the regulated firms - In the case of Food and Drug Administration, the only way to get information regarding a particular drug is by contacting the regulated firms. If the number of interaction is numerous, a relationship develops that goes beyond the formal agency-firm relationship (Wilson 1989). Repeated interaction between the agency and the regulated firms may make FDA officials sympathetic towards the regulated agencies.

This dissertation aims to settle the scholarly debate (regarding the motivation behind regulatory agency's decisions), and contends that although the FDA was created in order to protect the public, it has been captured by the regulated companies. "Since regulation generally imposes significant costs and constraints on private actors, the regulated actors has an interest in developing a mutually beneficial relationship with the regulatory agency" (Ceccoli 2004, 29). Such mutually beneficial relationship can take multiple forms (e.g. favorable policies protecting the regulated entities in exchange of lobbying money). The results in this paper shows that the decisions taken by the FDA reflects the direct impact of lobbying and campaign contributions made to the agency, Congress and the Executive. The unique contribution of this study is that it analyzes the direct (i.e., effect of lobbying on the FDA) as well as indirect (i.e.,

impact of campaign contributions on bill sponsorship) channels of influence utilized by the regulated pharmaceutical companies. Besides lobbying and campaign contributions, influence can also be exercised through the rulemaking process. The final paper analyzes the combined impact of influence when a regulated entity lobbies the executive during the OIRA review of rules as well as comments during the notice-and-comment period.

Laws that Strengthened the Role of the FDA: Increased Clout of the Regulated Companies

Like most regulatory agencies, the FDA was borne out of public outcry and was motivated by the "duty to protect consumers from monopolistic abuse" (Bo 2006). Following are the three major laws that strengthened the role and the power of the FDA over the years.

Pure Food and Drug Act (1906)

The Pure Food and Drug Act was passed following the public uproar created by Upton Sinclair's *Jungle.* Before this law, there were no regulations regarding the sale of pharmaceutical products to the public. Many drugs were sold with false or misleading information to the consumers. Through this law, it "sought to prevent misbranding and adulteration of drugs using the court system to punish violators" (Ceccoli 2004, 56).

Although this law was meant to protect the consumers, drug manufacturers worked towards the passage of this law. In line with Stigler's idea (1971) of regulatory capture, the regulated drug companies used this law to further their own advantage. They utilized this law to "secure advantage over domestic competitors and to expand markets to interstate and foreign commerce" (Wood 1985, 403).

Food, Drug and Cosmetic Act (1938)

The Food, Drug and Cosmetic Act substantially increased the role of FDA in drug regulation. This law was passed following the major drug disaster *Elixir Sulfanilamide* which killed hundreds of children. This law endowed the FDA with sole authority to reject ex-ante marketability of any new pharmaceutical product (Carpenter 2010). The new drugs that entered the market had to show the proof of "safety" during their evaluation. Although this law greatly expanded the power of FDA, it had a loophole: "If the FDA failed to provide its approval to the product within two months, it was granted automatic approval" (i.e., most drugs were cleared without major objections by the FDA) (Ceccoli 2004). It also did not specify the kinds of test required for approval, as a result "drug officials could block the marketing of a new drug formally or delay it by requiring additional data" (Junod and Beaver 2008, 1).

Kefauver-Harris Drug Amendments (1962)

The Kefauver-Harris Drug Amendments further strengthened the role of FDA in the regulatory process. Similar to previous regulations, this law was passed following the *Thalidomide disaster* in Europe which led to fetal deformities in pregnant women. Although the drug had not been introduced in the U.S., the drug manufacturer had sent samples to thousands of U.S. physicians, who in turn gave the samples to their patients without informing them that it was an experimental drug. This led to the birth of more than a dozen thalidomide babies in the U.S. (Junod and Beaver 2008). Because of the widespread public outrage created by this accident, the 1962 Amendments significantly strengthened the role of FDA over the drug approval process. Two major provisions that directly affected the drug innovation process included – i). Proof of efficacy requirement for approval of new drugs; and ii). Establishment

of FDA regulatory controls over the clinical (human) testing of new drug applications (Grabowski and Vernon 1983).

Although the 1938 Food, Drug and Cosmetic Act and the 1962 Kefauver Amendments significantly expanded the power of the Food and Drug Administration over production and marketability of the drugs, the regulated entities also increased their involvement and influence over the agency. Following are some of the reasons for greater influence exercised by the regulated pharmaceutical entities over the FDA, making it susceptible to capture:

FDA is a part of the larger bureaucracy – FDA is controlled by the Congress (through oversight, budget appropriations or personnel appointments). Therefore regulated entities can indirectly exercise influence over FDA when they lobby or make campaign contributions through Political Action Committees (PAC) to the members of Congress. "A PAC is either the separate, segregated campaign fund of a sponsoring labor, business, or trade organization, or the campaign fund of a group formed primarily or solely for the purpose of giving money to candidates" (Sabato 1984, 7). PAC's are often part of the lobbying strategy of an organization. Contributions made through these strategies help in buying access to the legislators. And for the legislators, these contributions are means to an end: reelection (Sabato 1984). "The dependence of parties upon the contributions of substantial business interests puts them at the mercy of this group when it comes to formulation of policies" (Overacker 1932, 197). The legislators return this favor by voting favorable for the industry. In the year 2016, Pharmaceutical/Health Product PAC's contributed $19,054,270 to the Federal candidates which shows an increment over the contributions made in the previous years 2014 and 2012 ($16,212,112 and $15,730,007 respectively).

Existing literature which measures the impact of campaign contributions on Congress are based on roll-call votes (Bronars and Lott 1997; Stratmann 2001; Chappell 1981; Kau et al. 1982; and Fleisher 1993). In my first essay, I argue that roll-call vote is not a proper measure of legislator's preference as it does not allow any discretion for the legislator. Roll-call votes make it mandatory for the legislators to take positions while non roll-call votes are more voluntary and discretionary. Hence, non roll-call position taking "are important signaling devices that provide valuable information to the interest groups looking for ways to spend their resources" (Rocca and Gordon 2010). I show the presence of capture effect by analyzing the impact of campaign contributions received during 112 and 113 congressional session on the bills sponsored by the members of Congress. I selected bill sponsorship as a measure for legislator's preference because it entails time as well as cost for the legislator. As member of Congress may serve more than one term in office, there might be a difference in time between their receipt of contribution and bills sponsored. In order to account for this discrepancy, I also looked at the joint impact of contributions over two congressional session. Methodologically, I utilized probit regression analysis as each individual bill was coded dichotomously. If the bills reflected the presence of capture, it was coded as 1; 0 otherwise.

After the Kefauver-Harris Drug Amendment was passed in 1962, the FDA and the drug companies barely spoke to each other. It was believed that if there were open communication between the regulator and the regulated entity, then the agency won't be able to remain neutral in its decisions. Overtime, this caused delays in the approval of drugs and the agency decided that "if there were standards for safety and efficacy that new drugs needed to meet, and if the FDA had recommendations on how to meet those standards, then telling the drug companies what those standards and recommendations were would not be some sort of unethical collusion

that would cause unsafe drugs to be slipped onto the pharmacy shelves" (Hawthorne 2005, 147). After FDA started publicizing its requirements, it opened up channels of communication between the regulator and the regulated pharmaceutical companies.

Most the existing literature which tests the presence/absence of capture theory does so by looking at the indirect impact through the Congress. There has not been any systematic study that looks at the direct impact of lobbying on the regulator. The second essay of this dissertation analyzes the direct impact of lobbying done by the regulated pharmaceutical industry on the New Drug Applications approved by the FDA. For this essay, I collected data on Type 1 approvals only, i.e., first time approvals of the New Molecular Entity.

FDA can be influenced in more than one way – There are ways (other than lobbying or campaign contributions) that help the regulated industry capture the regulator. Since the regulation of medicines is highly technical and complex, legislators "delegate important decisions" to the regulatory agency. This is done primarily due to agency's expertise and other informational advantages that the agency possesses (Ceccoli 2004, 23). Therefore, the burden of implementation of a regulation falls on the agency (i.e., the FDA) – referred to as the rulemaking process. During the rulemaking process, public participation takes place during the notice and comment period. After the comment period closes, final regulation gets published in the Federal Register. In my third essay, I measure commenter influence on the final regulations by analyzing the commenter recommendations that were followed in the final rule.

The Executive branch also plays a role during the rulemaking process. The OMB reviews the rules multiple times during this whole process and may recommend changes. During the OMB review, interested parties may contact the officials through in person meetings, oral communications and letters. This opens up channel of influence by the regulated

parties. Existing scholarly research on the mechanisms of influence during the rule making process and OMB review of regulations have been kept independent. It is surprising to see that there has not been a single study which looks at the impact on the final rules when a regulated entity tries to influence the policy output through more than one channel. This final essay addresses this missing piece and looks at the joint impact of influence on the final rule when the interest groups participates both during the rulemaking process as well as during OMB review of the rules.

Table 1.

Description of Channels and Process of Influence utilized by the Regulated Companies

Channels of Influence	Process of Influence	Chapters
Indirect	Campaign contribution on bill sponsorship	Chapter 1
Direct	Lobbying contribution on drug applications approved by the FDA	Chapter 2
Both	Combined influence of comments during the rulemaking phase and communication during OIRA review on final rules	Chapter 3

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CAMPAIGN CONTRIBUTIONS: ANOTHER WAY TO CAPTURE THE FOOD AND DRUG ADMINISTRATION

Abstract: This paper provides evidence for the presence of Capture Theory that has previously been denied in the literature. In order to measure the responsiveness of the regulator, i.e., the Food and Drug Administration (FDA), I examined campaign contributions provided by the Pharmaceutical and Health Products Political Action Committees (PACs) to the House and Senate members for 112 Congress, and the bills (dealing with regulation of drug industry, medical devices and clinical labs) sponsored by these members. As the members may serve more than one year in office, there is a possibility that they receive contributions in the first year and introduce bills in the next. This paper addresses this issue and aggregated results for both 112 and 113 congresses are also analyzed. In both the cases, I find statistically significant relationship between campaign contributions and the bills (providing favorable regulation) sponsored signifying the presence of Capture Effect.

Existing literature on regulatory policies try to address one fundamental question – What factors determine the decisions taken by the regulatory agencies? – Do the decisions reflect the well-being of the consumers (Public Interest) or the well-being of the regulated firms (Capture Effect)? While there are numerous regulatory agencies, this paper focuses on one specific agency – The Food and Drug Administration.

The Food and Drug Administration (FDA) was created in order to protect the interests of consumers (Quirk 1980). However, overtime there have been some inconsistencies in the drug approval process. It has been observed that some drugs receive quicker approvals and enter the market faster than others (Dranove and Meltzer 1994). Some scholars argue that the reason for this inconsistency is the working of the "capture effect" (Stigler 1971; Wilson 1989), while some say that quicker approvals is not a result of the capture but instead "greater experience which makes the firms proficient in their application" and hence quicker approvals (Carpenter 2004; Carpenter 2010; and Olson 1997). These studies which show the presence or absence of Capture Effect focuses on either of the two elements – either the FDA or the pharmaceutical companies. These studies do not address the role of the government or Congress which plays a crucial role in the whole regulatory process. As a result, it is correct to point out that the existing studies are disconnected pieces of a puzzle. This paper addresses this loophole and contributes to the existing literature by connecting the role of the regulatory process with the Congress.

As the pharmaceutical companies cannot influence the behavior of the FDA directly, the best way for the regulated firms to get favorable response is by enacting legislations that would give less power to the FDA and more leniency to the regulated companies in the drug approval process. In order to have leverage in the enactment of legislations, the pharmaceutical

company's Political Action Committees (PACs) contribute money to the members of the Congress who are responsible for introduction of bills. Every election cycle these companies donate millions of dollars in order to get favorable legislations which would help them in earning profits through quicker drug approvals. In the year 2016, Pharmaceutical/Health Product PAC's contributed $19,054,270 to the Federal candidates which shows an increment over the contributions made in the previous years 2014 and 2012 ($16,212,112 and $15,730,007 respectively) (Source: Opensecrets.org).

Hence campaign contribution is one way through which the FDA may be captured by the pharmaceutical companies. By testing the impact of campaign contribution on the bill sponsored by the member of Congress, I can show the presence of Capture Effect. In order to do so, I have collected data on the amount of campaign contribution received by members of House and Senate and the details of each bill (dealing with regulation of drug industry, medical devices and clinical labs) introduced in 112 Congress.

Stratmann (1995) notes that the timing of the contributions is important for the congressional voting behavior as there can be a cumulative effect. It is important to address the past as well as the present cycle. As the members serve more than one year in office, it is possible that they receive contributions in the first session and introduced bills in the next. In order to address this issue, I have collected data on campaign contributions and bills sponsored for the 113 Congress as well. For showing the cumulative effect, the second half of the paper has combined data for both 112 and 113 Congresses.

Both the individual analysis (112 Congress) and the combined analysis (112 and 113 Congresses) show that campaign contributions have a positive and significant impact on the bills sponsored by the members of the House and Senate. The unique contribution of this paper

is that it shows Capture Effect not only persists through the internal workings of the FDA or the pharmaceutical companies but also through the Congress indirectly. This paper addresses the loophole that exists in the literature regarding the relationship between the regulatory process and the government.

Existing Studies

Existing literature that have tried to determine the motivation behind the decisions taken by the regulatory agencies are either answered by Public Interest theory or Capture Effect. Such studies (Olson 1997; Dranove and Meltzer 1994) focus on one key element – Review time (i.e., the time period when a New Drug Application is submitted to its approval) of the FDA. Olson (1997) shows the relation between firm specific characteristics and review times. Similarly, Kaitin et al. (1991) showed the impact of "therapeutic novelty of drugs on the review times, whereby drugs that were therapeutically novel received faster approval compared to less novel drugs". Determining the presence or absence of capture effect based on only review times seems problematic as it is focused on only the internal workings of the Food and Drug Administration. It ignores the major role played by the government in the regulatory process. This study tries to remove this gap by showing how capture effect holds not only through the regulatory agency but also indirectly through the Congress.

PAC Contributions and Roll Call Votes

The pharmaceutical companies attempt to influence FDA by providing campaign contributions either independently or through Political Action Committees (PAC's) to the members of Congress. These contributions are made to ensure that those legislations are passed which reduces the control of FDA in the drug approval process, and provides competitive

advantage over other regulated companies through quicker approvals. This paper focusses on the first aspect. i.e., reducing control of the FDA over the drug approval process. The main motive behind getting quicker approval is to earn profit and recover the development costs of the drug, as quicker approval implies quicker marketing. "The average cost entailed in the discovery and development of a prescription medicine is $231 million" (Vagelos 1991).

Studies that have shown the influence of campaign contribution are based on the roll-call votes of the members of Congress (Bronars and Lott 1997; Stratmann 2001; Chappell 1981; Kau et al. 1982; and Fleisher 1993). Such studies provide mixed results about the influence of these contribution on the voting patterns of the members of Congress. Luke and Krauss (2004) note a "significant positive relationship between campaign contributions from the tobacco industry and votes by the members of Congress on tobacco related legislation in 1997 through 2000". Frendreis and Waterman (1985) also established a "strong relationship between PAC contributions and Senate votes on 1980 bill for deregulating the truck industry". Similar conclusion has been reached by Silberman and Durden (1976, 318), where they found "positive and significant influence of contributions from the AFL-CIO political action committee on the legislator's voting pattern on the 1973 legislation to amend the Fair Labor Standards Act" in the 93rd Congress. On the same issue of minimum wage legislation, positive impact of campaign contributions from the labor union and small business has been shown by Kau and Rubin (1981). Welch (1982, 482) examines "the effect of 1974 campaign contributions on the 1975 congressional vote on milk price supports. And the results reveal a greater probability of voting for higher milk price supports for congressmen who received contributions from dairy PAC's than those who did not (by almost seventy-seven percent)". Chappell (1981) also showed a "positive influence (low significance) of maritime interest

group campaign contribution on votes by the U.S. House on the maritime bill in 1977". On the issue of national defense, Fleisher (1993) shows a "statistically significant (marginally) impact of PAC contributions from defense contractors on the pro defense roll-call votes of the U.S House members of the 100th Congress when the ideological predispositions of the members are controlled". Evans (1986, 114) analyzes "the impact of campaign contributions on the House votes on two policies – the Chrysler loan guarantee program and the windfall profits tax program. Although she finds no direct effects between the two, they appear to make a difference at the margins – when legislators may have no strong preferences and where PAC's make a strong commitment of resources". The same result has been reached by Stratmann (2001) where "the voting behavior (on agricultural policy) of eight out of ten legislators is determined by the contributions received".

On the other hand, there are multiple studies (Wright 1985; Bronars and Lott 1997; Chappell 1982; Kau et al. 1982; and Chappell 1979) which show the limited influence of PAC contributions on the voting behavior of the Congressmen. Wright (1985) analyzed "five powerful PAC's and the results indicate the limited nature of PAC's influence on roll calls due to complex organizational arrangements". Grenzke (1989, 19) provides little evidence about "contributions from 120 PAC's affiliated with 10 largest interest groups generally do not maintain or change House members' voting patterns". Bronars and Lott (1997) test the "vote buying theory by examining the changes in the voting pattern of the politicians when they receive campaign contributions versus when they are in their last term and are not receiving any money through contributions". This comparison was made with those politicians who never received any money through contributions. The result of this paper lends support to the ideological sorting theory. In contrast to Silberman and Durden (1976)'s findings, Chappell

(1982, 80) shows that "campaign contributions do not have any significant impact on the congressional votes." The decision to vote is mostly decided by non-economic factors. The tendency to vote according to the non-economic factors has also been shown by Kau et al. (1982). Chappell (1979, 132) also showed "mild support for the hypothesis that campaign contributions from interest groups influence congressmen's decisions about how to vote on the House floor. The voting behavior were more determined by other non-economic factors like party affiliation, ideological preferences, and the interests of the constituents".

PAC Contributions and Bill Sponsorship

As pointed out by Fleisher (1993, 392), "existing studies of different PAC's across a range of issues have produced a confusing, inconsistent set of conclusions: some studies report a significant relationship between contributions and votes, and others do not". The same ambiguous impact on contributions on legislative votes have been reached by Chappell (1981) and Chappell (1979). One of the reasons for this murky relationship is because of the focus on roll-call votes for measuring a legislator's preferences. In order to truly measure the preferences of the members of Congress, it is important to take into consideration some other component (other than roll call votes) which provides legislators the discretion of not taking any position if they so wish. As pointed out by Highton and Rocca (2005), roll-call vote is not the only way through which the members of Congress can take positions. Roll-call votes makes it mandatory for the legislators to take positions while non roll-call voting are more voluntary and discretionary. Hence, non roll-call position taking "are important signaling devices that provide valuable information to interest groups looking for ways to spend their resources" (Rocca and Gordon 2010, 389).

Ways for non-roll call position taking includes bill sponsorship, bill co-sponsorship, interviews, floor speeches, press conferences and many other ways. Out of all the ways, bill sponsorship is the reliable way to know about the preferences of the members of Congress. Besides having "policy and position taking importance" (Rocca and Gordon 2010), bill sponsorship also entails costs (resource cost, opportunity cost and political costs) and is time consuming (Schiller 1995). Some studies utilize co-sponsorship as a way to measure legislators' preferences. However, co-sponsorship is not a credible option as the legislators do not need to undertake any costs associated with the introduction of the bill. "Although bill co-sponsorship may have policy implications, it is relatively costless activity" (Rocca and Gordon 2010, 391). Co-sponsorship rarely plays a role in the legislative success of a bill. This has been shown by Wilson and Young (1997, 26) where they analyze if "cosponsorship signals anything important about the content of legislation and whether it affects the bill's passage". The results reveal that the number of cosponsors in a bill does not have any effect on the final passage of the bill. In other words, cosponsorship is ineffective.

The timing of the contribution is another important factor that affects the voting behavior of the legislators. Traditional scholars have assumed that PAC makes contribution first, and if the candidate gets elected, he/she votes favorably for the contributors in the next cycle (Mueller 1989). As most states in United States do not have term limits on the members of Congress, the legislators can serve more than one term. Hence in order to clearly understand the working of capture effect, it is important to consider the cumulative impact of the contributions on bill sponsorship. Stratmann (1995, 127) analyzes "two time periods to find the cumulative effect of campaign contributions for ten roll call votes for various farm commodities in 1981 and 1985. His finding suggest that campaign contributions from not only

one period, but from at least two periods, are important for legislative voting" (Stratmann 1995, 135).

Based on this argument, the two main hypotheses in this paper are:

1. If capture theory holds in the case of Food and Drug Administration, then an increase in the campaign contributions will have a positive and significant effect on bills sponsored (dealing with regulation of pharmaceutical industry) by the members of Congress.
2. As the members of Congress may serve more than one term in office, it is possible that contributions received and bills sponsored may be spread over more than one term. Therefore if capture effect holds, then there should exist cumulative (over two sessions of Congress) positive relation between contributions and the bills introduced (dealing with FDA regulation).

Empirical Analysis

Data and Variables

The main objective of this paper is twofold: (i). to show the presence of Capture Effect between regulated pharmaceutical firms and the FDA through Congress; and (ii). to test the cumulative impact of contributions on bills sponsored over multiple congressional sessions.

The primary independent variable is the campaign contributions provided by the Pharmaceuticals/Health Products PACs to the members of Congress. The main dependent variable is bills sponsored (dealing with regulation of drug industry, medical devices and clinical labs) by the members[2]. In other words, two separate datasets we combined so that it is

[2] Check methodology note for the coding scheme of this variable in the Appendix

possible to connect contribution received by a specific member to the bills that he/she sponsored. The data for the campaign contribution is collected from the opensecrets website. And the data on the bill sponsorship is obtained from Policy Agendas Project under the Congressional Bills Project[3]. This dataset provides details of all the bills that have been sponsored in the Congressional session[4].

The analysis includes both members of House of Representatives and the Senate. To measure the individual impact of a single term, election cycle 2012 (112 Congress) is considered. For measuring the cumulative impact, election cycles 2012 and 2014 (i.e., 112 and 113 Congresses) are considered.

There are some important control variables that are included in the regression analysis. The importance of ideology or party affiliation has been discussed in multiple studies (Luke and Krauss 2004; Fleisher 1993; Evans 1986; and Kau and Rubin 1979). Luke and Krauss (2004) note "significant differences in the voting behavior between members of Democratic and Republican parties in the tobacco-related bills between 1997 and 2000. Their results also reveal a difference in the voting patterns based on the PAC contributions received by the members in different states". The independent member's party affiliation was coded based on the affiliation of the party they formed caucus with[5].

Another important dimension to consider is the role of parties and party structure when analyzing the effect of campaign contribution on bill sponsorship. As this paper integrates the

[3] E. Scott Adler and John Wilkerson, Congressional Bills Project: (2012 and 2014), NSF 00880066 and 00880061.

[4] For the empirical analysis in this paper, only those bills are included in the dataset which are coded as 321 (Regulation of drug industry, medical devices, and clinical labs) or 335 (Prescription drug coverage and costs) under the major topic code 3 (Health) in the Policy Agendas Project.

[5] Coding Scheme for Party Affiliation is as follows: 1 = Democrats, 2 = Republicans

role of Congress in the regulatory process, it is important to take into consideration the details of the committee and the relation of the legislator to any significant committees. I created an index (Leadership Index) that takes into account all these factors (i.e., chamber that requested the bill; if the bill was reported by a House or a Senate committee; if the legislator is the chair, ranking member, leader of any committee/subcommittee or a member of the majority party). This variable is coded dichotomously.

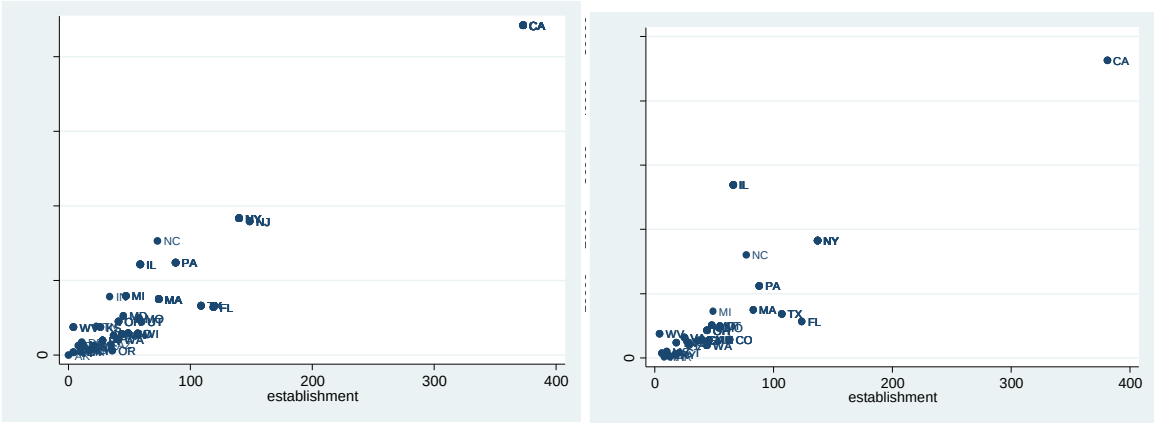
The importance of company location has have been shown by Porter (2000) whereby "location determines the competitive strategy for the company. A company choses to establish in a place where it can achieve competitive advantage through its influence on firm productivity and especially on productivity growth" (Porter 1996). Productivity of a company may be determined as a function of the number of employees and the number of establishments. The influence of number of establishments and employees have also been explained by the Social Impact Theory (Latane 1981) whereby the "impact of a source of influence on the target is a function of strength, immediacy and the number of sources present". In this case, the source is the number of pharmaceutical establishments and target is the bills. The importance of "increased proximity leading to closer monitoring and better information" have been shown to play an important role in cases of banks or mutual fund managers (Giroud 2013). Distance has been shown to have an impact on "cooperation and persuasion" (Bradner et al. 2002).

As different states tend to have varying number of pharmaceutical companies, there can be state level variation on bill sponsorship due to difference in demographics. In order to avoid any bias that can result from such state level variation, control for number of establishments based on number of employees is included in the regression analysis. This data

is collected from the Bureau of Labor Statistics[6]. Figure 1 shows the graph of the distribution of number of establishments and employees for each state in the dataset. It can be noticed from this figure that California (CA) is an outlier.

Figure 1

Distribution of Establishments and Employees for 112 and 113 Congresses



In order to show the impact of PAC contributions on bill sponsorship, it is important to take into consideration the number of cosponsors in a bill. A single member of Congress can sponsor and cosponsor multiple bills at the same time. As cosponsoring is a costless activity (Rocca and Gordon 2010), on one hand a member of Congress can sponsor a bill providing lenient regulation for the drug industry. And on the other hand, cosponsor another bill that provides more power to the regulatory agency. Therefore it is important to control for the number of bills cosponsored by the members of Congress.

The literature on the position taking by the member of Congress highlights the role of gender (Highton and Rocca 2005; Thomas 1994; Canon 1999; Thomas and Welch 1991; and Bratton and Haynie 1999). These studies have shown that women's issue might be an important

[6] Coding Scheme for state level demographic is as follows: 1= When the number of establishment with 20 employees or more>= number of establishment with less than 20 employees; 0 = When the number of establishment with 20 employees or more < number of establishment with less 20 employees

consideration for the women legislators. For example, women may take different position on the issue of abortion. This study controls for the gender[7] of members of Congress in order to avoid any bias.

The analysis in this paper is divided into two parts. The first part analyzes the capture effect of campaign contributions on bills sponsored by the members of Congress in 112 congressional session. The second part shows the cumulative impact of contributions for 112 and 113 congressional sessions on the bills sponsored over both the sessions.

Findings

112 Congress

For 112 and 113 sessions of Congress, the data on campaign contribution is collected for 2012 and 2014 election cycles respectively. As the dependent variable. i.e., bills sponsored is dichotomous, probit regression is utilized. Table 1 provides descriptive statistics for the variables.

Table 1.

Descriptive Statistics for 112 Congress

Variable	Observation	Mean	Standard Deviation	Min.	Max.
Bills	**145**	**0.33**	**0.47**	**0**	**1**
Contribution	**145**	**63052.71**	**67169.37**	**0**	**304227**
Co-Sponsor	**145**	**14.78**	**31.31**	**0**	**240**
Party	**145**	**1.48**	**0.50**	**1**	**2**
Gender	**145**	**0.17**	**0.38**	**0**	**1**
Establishment Size (Employment)	**145**	**0.49**	**0.50**	**0**	**1**
Leadership Index	**145**	**0.72**	**0.45**	**0**	**1**

[7] Coding Scheme for Gender is as follows: 1 = Female, 0 = Male

There are 145 observations in the dataset. The mean number of bills sponsored and the amount of PAC contributions are 0.33 and $63,053 respectively. The maximum amount of contribution for the time period of the dataset is $304,227. The maximum number of bills cosponsored by the members of Congress is 240.

Table 2 shows the impact of campaign contribution on bills sponsored for single session of Congress (112) (Model 1). I have done two robustness checks for this analysis: a). As California is an outlier in 112 Congress, I utilized probit regression without the outlier (Model 2); b). Generalized poisson regression[8] (Model 3). For generalized poisson regression, the coding strategy of dependent variable is changed from dichotomous to count (i.e., instead of coding the bills as 0 or 1, the dependent variable is changed to total number of bills sponsored by each member of 112 Congress). This is done in order to make sure that there is no bias in the coding procedure of the dependent variable.

In models 1 and 2, an increase in campaign contribution increases the predicted probability of bill sponsorship, satisfying the first hypothesis. The other variables fail to achieve statistical significance. To better assess the results, I looked at the substantive significance of the contribution variable in the model[9]. The result reveals that when campaign contribution moves from minimum to maximum value, it increases the probability of bill sponsorship by 57%.

In the generalized poisson regression model (Model 3), members of congress who received campaign contributions sponsored bills 1.00 times the rate of those members who did not receive any contributions. Similar to the probit model, other variables fail to achieve

[8] Generalized poisson regression is used as the data is underdispersed [(i.e., the variance (0.67) <Mean (1.45)]
[9] Refer to Table 3 in the Appendix

statistical significance. As each bill has different number of cosponsors and leadership index, when the dataset was converted from dichotomous to count, these variables were eliminated.

Table 2.

Regression Analysis for 112 Congress

Variables	**Probit (Model 1)**			**Probit (without outlier) (Model 2)**			**Generalized Poisson Regression (Model 3)**	
Bills	**Coef.**	**p-value**	**Std. Err.**	**Coef.**	**p-value**	**Std. Err.**	**p-value**	**IRR (s.e.)**
Contribution	5.27e-06	0.004	1.85e-06	4.10e-06	0.030	1.88e-06	0.000	1.000 (8.80e-07)
Co-Sponsor	-0.0007	0.851	0.004	0.0003	0.933	0.004	--	--
Party	0.143	0.612	0.281	0.048	0.869	0.293	0.771	1.038 (0.133)
Gender	-0.457	0.186	0.346	-0.259	0.472	0.360	0.311	0.848 (0.138)
No. of Establishments (Employment)	0.124	0.602	0.237	0.211	0.402	0.252	0.096	0.825 (0.095)
Leadership Index	0.482	0.150	0.335	0.464	0.188	0.353	--	--

Causal Relationship between Campaign Contribution and Bill Sponsorship

This paper attempts to show the working of capture effect in the case of the Food and Drug Administration, indirectly through Congress. In order to do so, I evaluate the impact of campaign contribution on bill sponsorship. However there are some studies that indicate an inverse causal relationship between contributions and bills sponsored, i.e., they show that bill sponsorship has an impact on campaign contribution. They argue that votes or expectations of votes affects the amount/choice contribution by the PACs (Grenzke 1989; Wright 1985; Grier

and Munger 1986; Evans 1986; and Gopoian 1984). Therefore in order to successfully prove my hypotheses, I will have to address the issue of endogeneity.

Role of Party in the Legislative Process

The role and importance of parties in the legislative process is highly contested in the existing literature. There are two major school of thought that attempt to explain the role of party and party structure in Congress. On one hand, scholars such as Cox and McCubbins (1992), Sinclair (1998) and Rohde (1991) stress on the strong role of political parties and their leaders in the legislative process. They argue that members of Congress maintain leadership and organizational form in order to solve the collective action problem. According to Sinclair (1998), party exercises its influence on its members through the determinants of legislative preferences of the members of Congress (i.e., their views on good public policy, their aim of getting reelected to office, and the preferences of the career-relevant actors). The party can also influence the behavior of the members through side payments (e.g., getting suitable committee assignment if a member votes in a particular way) or through party reputation (i.e., "if a member's future electoral prospects are, in part, dependent on the party's record, she has an interest in that record being one that helps her rather than hurts her and so an interest in delegating to leaders sufficient resources to enable them to facilitate the production of a favorable record or, at least, avoid a bad one") (Sinclair 1998, 5). The importance of party reputation has also been emphasized by Cox and McCubbins (1992). They also focus on the determinants of legislative preferences of the legislators, particularly reelection in order to maintain the party position. In their theory of party cartel, "parties are cartels of legislators, policed by their leaders" (1992, 547). In other words, in order to solve the collective action

problem and make sure that the members remain with the party position, the majority party has the means to achieve it.

Another important dimension of this literature is the agenda setting power of the majority leadership. The leader of the majority party "uses procedural strategies to affect legislative outcomes" (Sinclair 1998, 8). The scarcity of floor time combined with the veto power of the Speaker, provides the leader of the majority party with the power to set the floor agenda and avoid certain proposals from the agenda.

On the other hand, competing school of thought that denies the role of parties in the legislative process is led by Krehbiel (1993), Mayhew (1991) and rational choice theorists (Shepsle and Weingast 1994). They argue that parties do not play any significant role in either congressional structure or legislative process. Mayhew (1991) posits that legislative productivity is not impacted by the divided government. Krehbiel (1993) is the most influential proponent of this school of thought. In his paper, he stressed the importance of legislator's preferences over party. Unlike Sinclair's (1998) premise where determination of legislative preferences of the members of Congress is the key behind the increased role of party and leadership, Krehbiel (1993) assumes that "member's legislative preferences are stable and a function of constituency preferences and personal policy views, but not of party influence" (Sinclair 1998, 6). Krehbiel's (1993, 240) preference-based spatial theory argues that "legislators vote for the policy alternative nearest their ideal policies". His central argument is significant party behavior, i.e., "behavior that is consistent with known party policy objectives but that is independent of personal preferences" (Krehbiel 1993, 240).

Most studies on the relationship between roll call votes and PAC contribution utilize some sort of instrument. Table 4 shows the list of studies that have previously utilized

instrumental variables. Following the footsteps of these existing studies, I will utilize instrument to solve the endogeneity problem. An instrument helps to isolate the effects of contribution from the bills sponsored. Following the argument regarding the role of party in the legislative process from the previous paragraph, I will utilize party affiliation of the members of Congress as the instrument for the analysis. Party affiliation has a causal effect on PAC contributions (correlation 0.34). Brunell (2005) shows that the PACs do not randomly make contributions to the legislators. Party affiliation is an important indicator of the stand of a member on the issue. "PACs treat party affiliation as an important signal in distributing money" (Grier and Munger 1986, 357).

Figure 2 shows that the amount of campaign contribution made by the Pharmaceutical/Health Products PAC's to the Federal Candidates for 16 years (2000-2016). It can be noticed that candidates from the Republican Party receive more money in contributions than the Democrats.

Table 4.

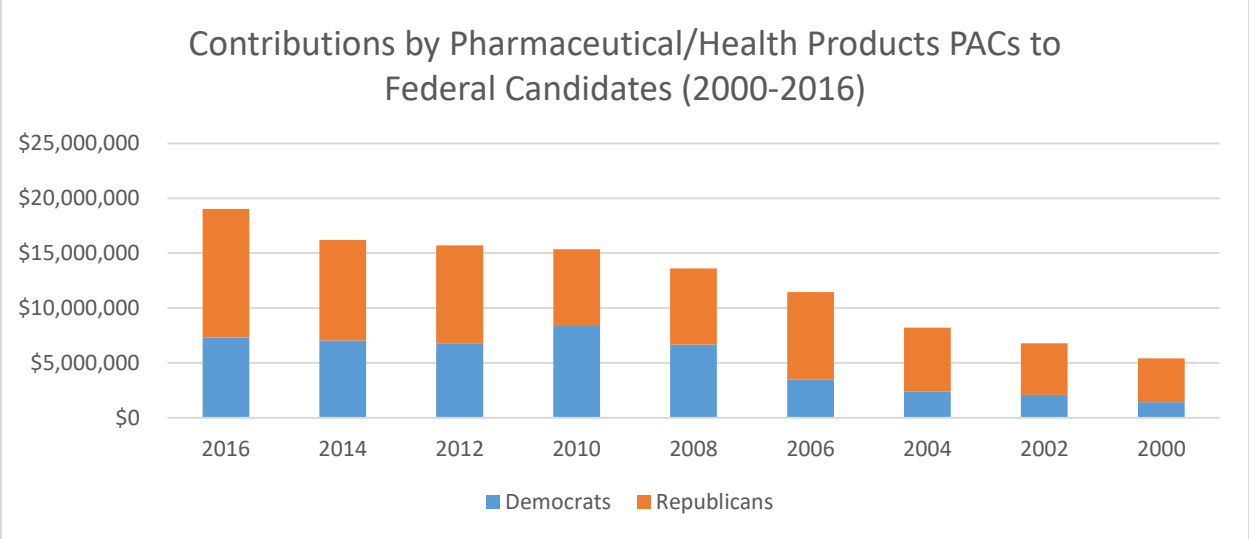
Roll Call Voting Studies that utilize Instrumental Variables

Study	*Issues Covered*	# *Votes*	*IV?*
Silberman, Durden (1976)	minimum wage	2	No
Chappell (1981)	cargo preference	1	Yes
Kau, Rubin (1981)	various economic	8	Yes
Kau, Kennan, Rubin (1982)	various economic	8	Yes
Chappell (1982)	variety	7	Yes
Welch (1982)	dairy subsidy	1	Yes
Evans (1986)	tax, Chrysler	8	No
Kau, Rubin (1984)	variety	10	Yes
Peltzman (1984)	variety	333	No
Feldstein, Melnick (1984)	health care	1	No
Coughlin (1985)	domestic content	2	No
Johnson (1985)	bank, real estate	9	Yes
Wright (1985)	variety	5	No
Wayman (1985)	arms control	19	No
Frendreis, Waterman (1985)	trucking	4	No
Schroedel (1986)	banking	3	No
Wilhite, Theilmann (1987)	labor	2	Yes
Tosini, Tower (1987)	trade (textiles)	1	No
Jones, Keiser (1987)	labor	1	No
Saltzman (1987)	labor	1	Yes
MacArthur, Marks (1988)	domestic content	1	No
Grenzke (1989)	variety	30	Yes
Vesenka (1989)	agriculture	14	No
Neustadl (1990)	labor, business	2	No
Wright (1990)	tax, agriculture	2	No
Langbein, Lotwis (1990)	gun control	6	No
Durden et al. (1991)	strip mining	3	No
Mayer (1991)	aircraft carriers	1	No
Stratmann (1991)	agriculture	10	Yes
Rothenberg (1992)	MX missile	8	No
Langbein (1993)	gun control	6	No
Marks (1993)	trade	5	No
Nollen, Quinn (1994)	trade	6	No
Stratmann (1995)	agriculture	10	Yes
Bronars, Lott (1997)	variety	35	No
Stratmann (2002)	banking	2	No

Source. Ansolabehere et al., 2003 (Table 1)

Figure 2.

Contributions made to Democrat and Republican Candidates by PACs



Data Source. Opensecrets.org

Table 5 represents the data for donations from the pharmaceutical/medical devices PACs to the candidates in the House and the Senate for the dataset. I calculated the distribution of contribution based on party affiliation of the members of congress. The table shows the number of donation to candidates, their average dollar amount of the donations as well as the minimum and maximum contributions. For 112 Congress, Pharmaceutical PACs made almost equivalent number of contributions to the Democrat as well as Republican members (75 and 70 respectively). However, there is huge difference in the average amount contributed. The members of Republican party received more than double the amount compared to the member in Democratic party ($86,576.5 vs $41,097.2). Furthermore, the maximum amount received by the Republican is higher than the Democrats ($304,227 vs $201,330).

Table 5.

PAC contribution to the members of the House and Senate

Party	N	Average	Minimum	Maximum
Democratic	75	$41,097.2	$0	$201,330
Republican	70	$86,576.5	$0	$304,227

In Table 6, I use party affiliation as an instrument to address the issue of endogeneity. Campaign contribution variable has a positive relationship with bill sponsorship, however it loses the statistical significance. The other variables (co-sponsors, gender, number of establishments and leadership index) do not achieve statistical significance.

Table 6.

Probit Analysis for 112 Congress

Variables	Probit (Party as instrument)		
Bills	**Coef.**	**p-value**	**Std. Err.**
Contribution	9.60e-06	0.26	8.55e-06
Co-Sponsor	-0.001	0.75	0.004
Gender	-0.44	0.22	0.36
No. of Establishments (Employment)	0.45	0.87	0.28
Leadership Index	0.38	0.42	0.47

Cumulative Impact

Members of Congress without term limits can serve more than one term. As Stratmann (1995) observes, in order to clarify the relationship between campaign contributions and legislative activity, it is important to consider at least two sessions. This argument is based on the fact that sometimes PACs make contributions to the legislators in order to get favorable votes in return. Hence, it can be stated that PACs contribute to the members of Congress in

112 congressional session thinking that they will get favorable policies either in 112 or 113 sessions. Keeping this argument in mind, the second analysis looks at the PAC contributions received during 2012 and 2014 election cycles on the bills sponsored during both the sessions.

Table 7.

Descriptive Statistics for multiple Congress (112 and 113)

Variable	Observation	Mean	Standard Deviation	Min.	Max.
Bills	**251**	**0.32**	**0.47**	**0**	**1**
Contribution	**251**	**56858.62**	**61968.75**	**0**	**304227**
Co-Sponsor	**251**	**8.54**	**24.86**	**0**	**240**
Party	**251**	**1.47**	**0.50**	**1**	**2**
Gender	**251**	**0.17**	**0.37**	**0**	**1**
Establishment Size (Employment)	**251**	**0.49**	**0.50**	**0**	**1**
Leadership Index	**251**	**0.80**	**0.40**	**0**	**1**

Table 7 provides descriptive statistics for the variables. There are 251 observations in the dataset. The mean number of bills sponsored and the amount of PAC contributions are 0.32 and $56,858.62, respectively. The maximum amount of contribution for the time period of the dataset is $304,227. The mean number of bills cosponsored by the members of Congress is 8.5. As the dependent variable. i.e., bills sponsored is dichotomous, probit regression is utilized. Table 8 shows the result of the probit analysis for multiple congressional sessions.

Table 8.

Probit Analysis for 112 and 113 Congress sessions

Variables	**Probit**		
Bills	**Coef.**	**p-value**	**Std. Err.**
Contribution	2.87e-06	0.049	1.46e-06
Co-Sponsor	-0.0002	0.948	0.003
Party	0.313	0.101	0.191
Gender	-0.473	0.065	0.256
No. of Establishments (Employment)	0.122	0.474	0.171
Leadership Index	0.211	0.365	0.233

Table 8[10] shows the relationship between independent variables (i.e., contribution, cosponsor, party, gender, number of establishments and leadership index) and the dependent variable (i.e., bills sponsored). An increase in the campaign contribution significantly increases the predicted probability of bill sponsorship. The other variables (co-sponsors, gender and number of establishments) do not achieve statistical significance.

Based on this result, it can be implied that when members of Congress receive contribution from interested parties, they return the favor by sponsoring bills either in the same congressional session or in the next. This shows the presence of capture effect, satisfying the second hypothesis. The other variables fail to achieve statistical significance. As the number of co-sponsors increase, it decreases the predicted probability of bill sponsorship. In order to better interpret the result of this probit analysis, I looked at their substantive significance[11].

[10] There are some members who received contributions in both 112 and 113 Congress. It should be noted that although the observations appear twice in such cases, they are linked to separate contribution values for each separate bill. Therefore they are treated as separate observations.

[11] Refer to Table 9 in the Appendix

The result reveals that when campaign contribution moves from minimum to maximum value, it increases the probability of bill sponsorship by 34%.

Similar to the analysis in the first half of the paper, I addressed the issue of endogeneity by utilizing instrumental variable. I used the same instrument (party affiliation).

Table 10.

Probit Analysis for multiple Congress sessions

Variables	**Probit (Party as instrument)**		
Bills	**Coef.**	**p-value**	**Std. Err.**
Contribution	9.90e-06	0.02	4.23e-06
Co-Sponsor	-0.002	0.67	0.004
Gender	-0.46	0.09	0.27
No. of Establishments (Employment)	0.07	0.70	0.18
Leadership Index	0.17	0.50	0.25

As in Table 9, the same significant statistical relation can be observed between campaign contribution and bill sponsorship in Table 10. By using party affiliation as an instrument, I am able to address the problem of endogeneity. The other variables (co-sponsors, gender, number of establishments and leadership index) are not statistically significant.

Conclusion

Capture theory suggests that "there are certain inherent features of the regulatory process and environment that determine the fundamental nature of the regulatory process and guarantee the dominance of the regulated group in influencing regulatory decisions" (Berry 1984, 254). The concept of "capture" of the regulator by the regulated firms can be traced back to Stigler's idea of "Economic Regulation" (Stigler 1971) which seeks to explain the

distribution of benefits and burdens of regulation in the society. Through his work, he shows that an industry may use the state's power (i.e., the ability to coerce the industries into regulation) to increase its profitability through subsidies, tariffs and price fixing. This view which revealed the utilization of regulation for industry's benefits instead of consumers bore the seeds of capture theory.

The primary question that this paper attempts to answer is – Does Capture Effect persists in the case of Food and Drug Administration? And the results in this paper provide a convincing answer. The pharmaceutical companies are successful in capturing the Food and Drug Administration with a particular tool at their disposal - campaign contributions - which they provide to the members of Congress. Previous scholars who have studied the working of capture effect have relied on either the internal mechanism of the FDA (i.e., the time taken to review the drug applications) or the regulated pharmaceutical companies (i.e., the amount of money spent on research and development). They have ignored the role of government, particularly the Congress, in the whole process. This paper incorporates the role of Congress in the regulatory debate.

The pharmaceutical/health industry PACs donate millions of dollars to the members of Congress. With the help of these monetary contribution, they are able to campaign for their seats. However, this is not a one way favor. These PACs donate money so that the members pass laws and regulations that are in favor of the industry, once they are elected. This paper tested the role of PAC contribution on the bills sponsored by the members of Congress. The results reveal that there is a positive and significant relation between these two variables, showing the presence of capture. The same effect holds when multiple congressional sessions

are considered. PAC contributions made during 2012 and 2014 election cycles also revealed a positive and significant impact for bills sponsored in 113 Congress.

Future research might include collecting data for more than two congressional sessions. Doing so will help in producing more generalizable results.

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APPENDIX

Methodology Note:

In this paper, the impact of capture effect is analyzed by reading the details of each individual bill. Bills that show the presence of capture effect are coded as 1 and those bills which do not show capture effect are coded as 0.

Examples of bills that were coded as 1 include the following:

a). To amend the Federal Food, Drug, and Cosmetic Act to authorize a 6-month extension of certain exclusivity periods in the case of approved drugs that are subsequently approved for a new indication to prevent, diagnose, or treat a rare disease or condition, and for other purposes.

b). To amend title V of the Federal Food, Drug, and Cosmetic Act to provide for extensions of marketing exclusivity periods for drugs in certain combinations of such drugs, and for other purposes.

Explanation – FDA describes exclusivity as "exclusive rights granted by the FDA upon approval of a drug". New drug innovations get periods of exclusivity which prevents the submission or approval of generic drug applications. This was done in order to maintain a balance between new drug innovation and generic drug competition. By increasing the exclusivity period, companies with new drug innovations continue to be the sole profit earners which might discourage a generic drug company to invest in developing similar drug that can be provided to the patients at a lower cost.

c). A bill to clarify the orphan drug exception to the annual fee on branded prescription pharmaceutical manufacturers and importers.

Explanation – This bill will provide exception to the orphan drug industry to the annual non-deductible fee which is allocated according to the market share of the sale of branded prescription drugs during the previous calendar year. Therefore enactment of this bill means more money for the orphan drug industry.

d). To amend the Internal Revenue Code of 1986 to repeal the medical device tax, and for other purposes.

Explanation – If the medical device tax is repealed, then the medical device companies pay less in taxes which implies more earnings.

Those bills that were coded as 0 do not indicate any profit or advantage that could be earned by the medical device/pharmaceutical industry instead it focusses on the well-being of the patients/consumers. These bills are self-explanatory in nature. Following are the examples of such bills:

a). To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of drugs.

b). To amend the Federal Food, Drug, and Cosmetic Act to improve humanitarian device regulation.

c). To amend the Federal Food, Drug, and Cosmetic Act to preserve the effectiveness of medically important antibiotics used in the treatment of human and animal diseases.

d). To amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration with improved capacity to prevent drug shortages.

Table 3.

Substantive significance of campaign contribution on bill sponsorship for 112 Congress

Variable (Change in Contribution)	Change	p-value
+1	0.000	0.003
+delta	0.571	0.000
Marginal	0.000	0.003

Table 9.

Substantive significance of campaign contribution on bill sponsorship for combined Congress

Variable (Change in Contribution)	Change	p-value
+1	0.000	0.046
+delta	0.341	0.037
Marginal	0.000	0.046

IMPACT OF LOBBYING ON DRUGS APPROVED BY THE FOOD AND DRUG ADMINISTRATION

Abstract: This paper provides evidence of Capture Theory or Institutional Corruption in the case of Food and Drug Administration. Institutional responsiveness is measured by analyzing the direct impact of lobbying contributions on the number of New Drug Applications (NDA) approved by the Food and Drug Administration (FDA). As the size of the pharmaceutical organization may have an effect on the amount of money spent on lobbying, an index (through factor analysis) is generated to account for the size. The results show a statistically significant relation between money spent on lobbying the Food and Drug Administration and the number of drugs that enter the market.

Duchenne Muscular Dystrophy is a muscular degenerative disease caused by rare genetic disorder. This condition is typically common in boys and causes muscular weakness. This illness makes it difficult to walk and may also cause intellectual disability. There is no cure for this disease. However, there are available medicines/therapies for alleviating the symptoms.

Sarepta Therapeutics submitted the drug application for intravenous injection Eteplirsen (NDA 206488) which offered a cure for this disease. The advisory committee met on January 2016 to discuss the issues surrounding the drug. The committee meeting was attended by patients and their families, academics, researchers, doctors and industry representatives. During this meeting testimonies were also given by patients which were very encouraging, and they stressed on the positive impact on all aspects of their lives after taking the medicine. However there was a flaw between these extremely positive testimonies and the data provided with the application to the Food and Drug Administration. The clinical data showed a worsening of conditions.

On September 19, 2016 this drug was approved under priority review by then FDA Commissioner Robert Califf, even though there was mismatch between the clinical data which lacked any support for clinical benefit and positive patient testimonies. Before becoming the Commissioner of the agency, Califf was responsible for running clinical trials for drug companies. The effect of such revolving door is common amongst all regulatory agencies, however, it is much more pronounced in the case of FDA. When there is a rotation of appointment between the regulator and the regulated agencies, it leads to decisional biases causing capture. Revolving appointments is one of the direct channels of influence utilized by the regulated pharmaceutical companies. When the lobbying organizations hired by the

pharmaceutical company approaches the regulator, who was previously part of their company, it is much easier to influence their decisions as they might be sympathetic to their cause.

This chapter extends the debate behind the guiding principle of the decisions made by regulatory organizations. The Food and Drug Administration was established in order to protect the health and well-being of the people from drugs that were either unsafe or ineffective. Over the years, the interest groups have targeted the agency directly or indirectly in order to influence its decisions. The money spent on lobbying such regulatory organizations helps them to achieve policies and legislations that protects them, and provides financial advantages. For example in the case of Food and Drug Administration, "the federal government actively provides drug firms with very profitable patent protection and market exclusivity from new products, while refusing to set any controls on prices as a condition for those advantages" (Jorgensen 2013, 562). With the growing influence of the pharmaceutical companies over the FDA, the idea of public good has been undermined. Instead, the "pharmaceutical firms have learned how to make huge profits with drugs that do not much improve public health and that sometimes are unsafe or are prescribed without need" (Jorgensen 2013, 562).

There are numerous ways to influence a government agency's behavior. The most common way of influence is though exchange of favors. This type of influence is practiced indirectly through the Congress and involves vote buying. There has not been any systematic study measuring the agency responsiveness to direct lobbying efforts by the regulated parties on the regulator (i.e., the FDA). This paper addresses this missing piece in the literature, and provides a direct measure of agency responsiveness of FDA. It analyzes the relationship

between lobbying contributions made by the pharmaceutical companies and the number of New Drug Applications (NDA) approved for each of these companies over 2008-2016.

The following section provides an overview of the existing literature on the role of political money on government institutions. Section I provides an overview of the literature. Section II provides the description of the data utilized for the study in this paper. Section III provides the analysis of this paper. The final section IV concludes this paper.

I. Overview: How much influence is too much influence?

The relationship between pharmaceutical companies and the FDA is more complicated than it seems. "From industry's point of view, it is more a combination of grudging acceptance, plus fear, plus desire for a gold star that can be used in marketing plus the natural tendency of anyone to gripe about whoever is in a position of authority over them" (Hawthorne 2005, 124). From the point of view of the FDA, it is supposed to protect the health of the public, keeping in mind that Congress controls the purse strings of the agency. Therefore, in order to have an influence over the regulations, the companies spend millions of dollars in campaign contributions or lobbying.

The literature[12,13] on the impact of political money on the government institutions is rife with the idea of 'dependence corruption' or 'institutional corruption'. This sort of corruption exists "whenever an institution deviates from its intended purposes because of some third party actors". In the case of the healthcare industry, these third party actors might include drug firms, medical device companies, special interests, medical facilities, and insurers. These

[12] "Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda". Paul D. Jorgensen. 2013

[13] "Conflicts of Interest, Institutional Corruption, and Pharma: An Agenda for Reform". Marc A. Rodwin. 2012

companies spend millions of dollars on the research and development of drugs. Therefore, their core motive is to reap a return on their investment. Before marketing any drug in the United States, it needs to get the approval of the FDA. Therefore, they lobby the FDA in order to get a quicker approval of their New Drug Applications (NDAs).

Although the pharmaceutical industry does want to influence the FDA, they also want to protect the consumers to some extent. Abraham (2002) observes that "pharmaceutical companies want the safety and efficacy standards of regulators to be high enough to avoid frequent drug disasters, which bring the industry into disrepute, but not so high that they threaten their commercial viability". For example, a manufacturer can lose on average over US $1 million for each day's delay in gaining marketing approval from the U.S. Food and Drug Administration. On the other hand, patients and doctors want to protect the interests of the consumers, irrespective of the interests of the pharmaceutical manufacturers. Therefore, whenever a government entity tries to pass laws dealing with the health of the patients, the pharmaceutical companies try to have a say in it. And "the more the pharmaceutical industry influences the perspective of the regulatory agency - so it comes to adopt their interests over and above those of patients – the more the agency could be said to be captured" (Abraham 2002, 1498).

The idea of the working of the capture effect in the case of FDA was truly noticed when it approved Menaflex on December 20, 2008. "Menaflex is a rubbery material designed to repair the cushioning between the knee bones. The drug application for Menaflex was first submitted for approval in 2004. After the clinical trial ran into difficulty, the manufacturer ReGen Biologics INC resubmitted the product for special fast track approval process. After rejection for the device in 2005, ReGen enlisted three Democratic members (Sen. Frank

Lautenberg, Sen. Robert Menendez and Sen. Steve Rothman) from its home state of New Jersey to influence the evaluation process" (Report 2004, 2). In December 2007, the Senators contacted the FDA enquiring about the delay. Finally, in December 2008 Menaflex was approved. According to the opensecrets website, the three senators received a total of $26,000 combined from the ReGen executives.

In the above case study, it was noticeable that particular members of Congress were chosen in order to influence the approval process. There can be multiple factors guiding the choice of the Senators. In this case, it was because the headquarters of the ReGen was in the same state as the senators. Other cases might involve certain senators/congressmen-women sympathetic towards certain disease because of family reasons. Nancy Reagan was very active in scientific research involving human embryonic stem cells. Her involvement was believed to stem from her husband's ailment of Alzheimer's disease. Similarly, Peter Deutsch, former member of Congress from Florida "who is genetically at risk for skin cancer, testified at an FDA advisory committee meeting on a skin cancer drug. So as the drug wends its way through the FDA's review, for six months or more, a top official from that company might call the interested lawmaker to mention that a promising cure has been sitting around at the FDA for a long time going nowhere" (Hawthorne 2005, 144-7). When there is communication about particular drugs, the FDA cannot ignore it mainly because of the control of FDA's budget by the Congress.

Scholars researching on the relationship between the regulator and the regulated firms have looked at it indirectly (i.e., through the Congress). They have either looked at the control exercised by the Congress on the regulatory agencies through the budget. Or at the effect of campaign contributions on the roll-call votes of the members (Bronars and Lott 1997;

Stratmann 2001; Chappell 1981; Kau et al. 1982; Fleisher 1993; Luke and Krauss 2004; Frendreis and Waterman 1985; Silberman and Durden 1976; and Kau and Rubin 1981). They have not addressed the direct effect of lobbying on the federal agencies. "In addition to campaign contributions to elected officials and candidates, companies, labor unions, and other organizations spend billions of dollars each year to lobby Congress and federal agencies. Some special interests retain lobbying firms, others have lobbyists working in-house"[14]. According to Hawthorne (2005, 145), "the trade organization of the pharmaceutical industry, Pharmaceutical Research and Manufacturers of America (PhRMA) spend some $150 million a year in lobbying, including nearly $5 million just to lobby the FDA". However, there has not been any study to show this direct influence of lobbying on any federal agency. In order to understand the principles guiding the decisions of the FDA, it is important to take into consideration the indirect as well as the direct channels of influence utilized by the regulated companies on regulator due to the following reasons:

1. Even though a member of Congress receives donations from pharmaceutical companies, it is difficult to clearly establish the reason for his/her vote choice on a bill. It could be possible that the member's vote choice would have been the same irrespective of the political money they received. Based on this argument, it is wrong to conclude the working of public interest/capture theory based on the voting patterns of the congressional representatives.

[14] Source: OpenSecrets.org. https://www.opensecrets.org/lobby/index.php (Last visited: August 24, 2018)

2. It is difficult to establish the direction of the causality between campaign contributions and the roll-call votes. It might be possible that pharmaceutical companies pay contribution money to a candidate only after they have voted on a bill.

Based on the above argument, it follows:

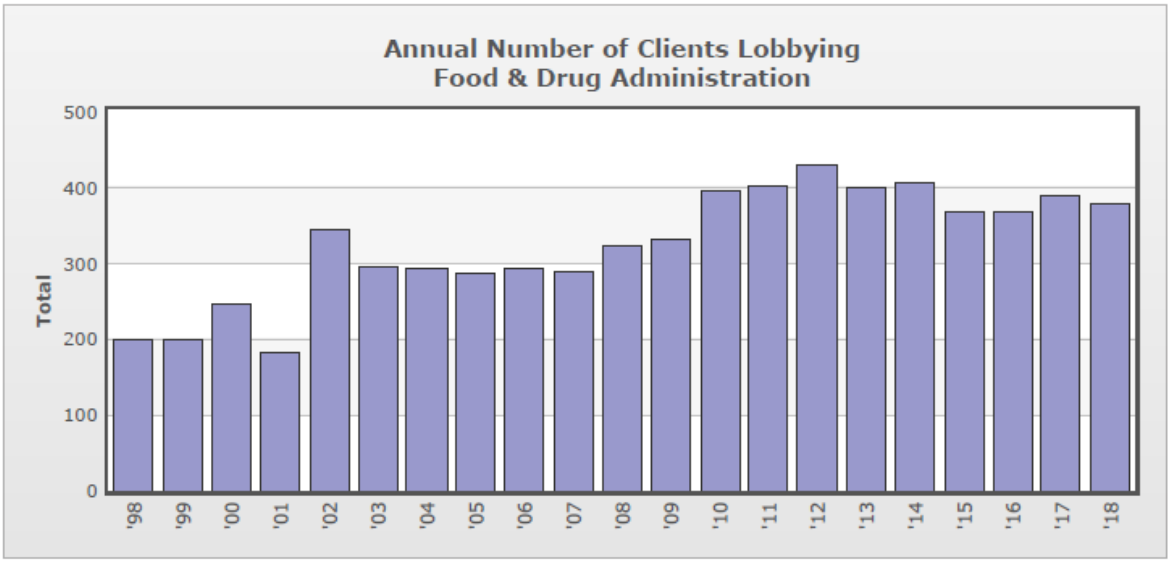
Hypothesis: If the FDA is captured by the regulated pharmaceutical companies, there will be positive and significant relationship between direct lobbying money spent on FDA and the number of NDAs approved by the agency. By eliminating the role of Congress from the equation, we can see the direct working of the Capture Theory.

II. Data Description

The main independent variable is the amount of money spent by the pharmaceutical companies on lobbying the FDA. The data on lobbying contributions for this paper is collected from the opensecrets website. As there are different amounts of money contributed by different companies, the lobby data has been scaled by 1 million. Figure 1 shows the annual number of clients that lobbied the FDA from 1998 – 2018. It is observable that the number of clients has increased steadily over the past decade.

Figure 1.

Annual Number of Clients Lobbying the FDA (Source: OpenSecrets.org[15])



The main dependent variable for this paper is the number of drug applications approved by the FDA over the period of 2008-2016. This data is collected from the FDA website. The FDA maintains a database showing 'Drug Approval Reports by month'. There can be multiple types of approvals. For the purpose of this chapter, I only look at the 'Original New Drug Approvals by Month'.

The Center for Drug Evaluation and Research (CDER) assigns a classification code to the NDA based on the characteristics of the product in application. "The NDA classification code provides a way of categorizing new drug applications. The code evolved from both a management and a regulatory need to identify and group product applications based on certain characteristics, including their relationships to products already approved or marketed in the United States"[16]. In this paper, I am looking at only Original NDAs which received a *Type I* (first time) approval. This approval type includes New Molecular Entities (NME's). "An NME

[15] Link to the figure: https://www.opensecrets.org/lobby/agencysum.php?id=135 (Last visited: August 25, 2018)
[16] Manual of policies and procedures, Center for drug evaluation and research, NDA Classification codes

is an active ingredient that contains no active moiety that has been previously approved by the Agency in an application submitted under section 505 of the Act or has been previously marketed as a drug in the United States"[17]. Figure 2 depicts the number of NDAs which received Type I approval over 2008-2016. Year 2015 received maximum approval of Type 1 NDAs (35) followed by year 2012 (33).

Figure 2.

Number of NDAs approved between years 2008-2016

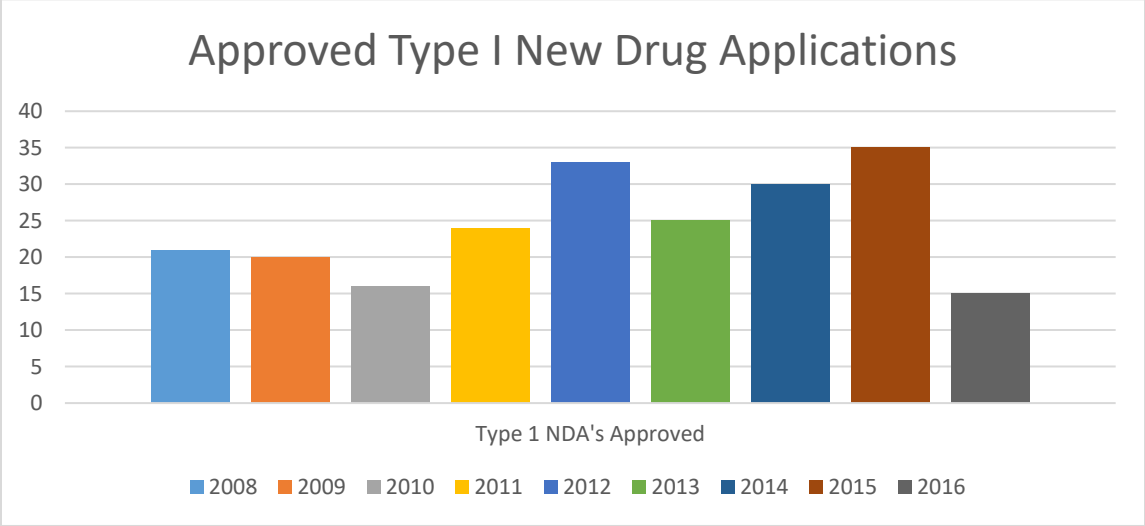


Figure 3 shows the number of Type 1 NDAs approved for each pharmaceutical organization who submitted their application for review to FDA. Total 78 drug firms got Type 1 NDA approvals between years 2008-2016. Novartis received highest number of approvals (11) followed by AstraZeneca (8), Janssen (7), Pfizer and Gilead Sciences (6) respectively.

In order to accurately assess the impact of lobbying money on NDA approvals, I calculated deviations from the mean for the top three companies that received maximum

[17] Manual of policies and procedures, Center for drug evaluation and research, NDA Classification codes, pg 2

number of NDAs approved over the time period considered. Novartis received 11 Type 1 approvals (maximum over 2008-2016). It is almost 1 (0.61) standard deviation away from the mean. AstraZeneca received 8 approvals over the same time period. It is also almost 1 (0.55) standard deviation away from the mean. Janssen (which received 7 NDAs approvals), is very close to the mean (-0.29). Hence it can be implied that companies that contribute more in lobbying, receive higher number of NDAs approved.

Table 1 shows the working of public interest or capture theory based on the characteristics of the firm that submitted the application.

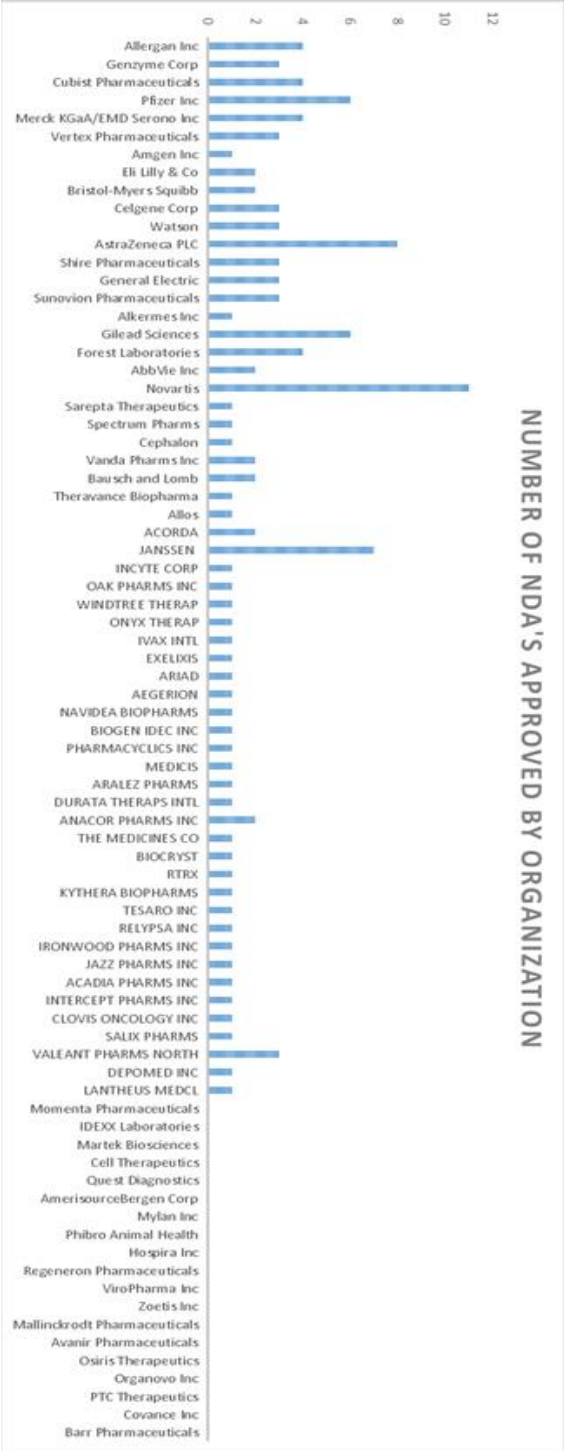
Table 1.

Firm Characteristic and their Relation to Theories

Firm Characteristic	Theory
Big firms receiving higher approval of drug applications	Capture
Firms receiving higher approvals for lifesaving drugs	Public Interest/Capture
Big firms receiving higher priority reviews	Capture
Small firms receiving more approvals	Public Interest

Figure 3.

Number of Type 1 Approvals for each pharmaceutical organization (2008 – 2016)



NDAs approved based on Review Types

When an NDA is submitted for approval with the FDA, it can be reviewed either under standard designation or under priority designation. "Priority review designation is assigned to applications for drugs that treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions compared to available therapies. A priority review designation is intended to direct overall attention and resources to the evaluation of applications for drugs that, if approved, provide significant improvements to public health as noted above. Standard review designation is assigned to applications for drugs that do not meet the priority review designation criteria. A priority review designation will set a goal date for taking action on an application within 6 months of receipt. A standard review designation will set a

goal date for taking action on an application within 10 months of receipt"[18].

Figure 4 shows the distribution of the standard and priority reviews for the companies in the dataset. Novartis (11) received maximum number of approvals followed by AstraZeneca (8) and Janssen (7). Novartis not only received maximum NDA approvals, it also received maximum priority reviews (7). AstraZeneca with second highest approvals in the dataset, also received maximum standard reviews (6). Janssen with third highest approvals, also received second most priority (4) reviews. In other words, companies that received the most number of NDA approvals over the years 2008-2016 also received the most number of priority or standard reviews. This implies that review type is an important consideration in the drug approval process.

The decision to provide priority or standard designation is also dependent on the type of ailment the drug is supposed to treat. I created categories for different types of drug[19]. Figure 5 shows the number of drugs approved by FDA for each drug category based on the review type. Category 1 (cancer medication) and category 7 (HIV medication) received maximum number of priority reviews.

Figure 6 shows the number of cancer drugs approved by FDA for each company. Novartis received maximum number of cancer drugs approved.

[18] Manual of policies and procedures, Center for Drug Evaluation and Research. Review Designation Policy.
[19] The list of different drug categories is included in the Appendix

Figure 4.

Type of NDAs approved for each organization (2008-2016)

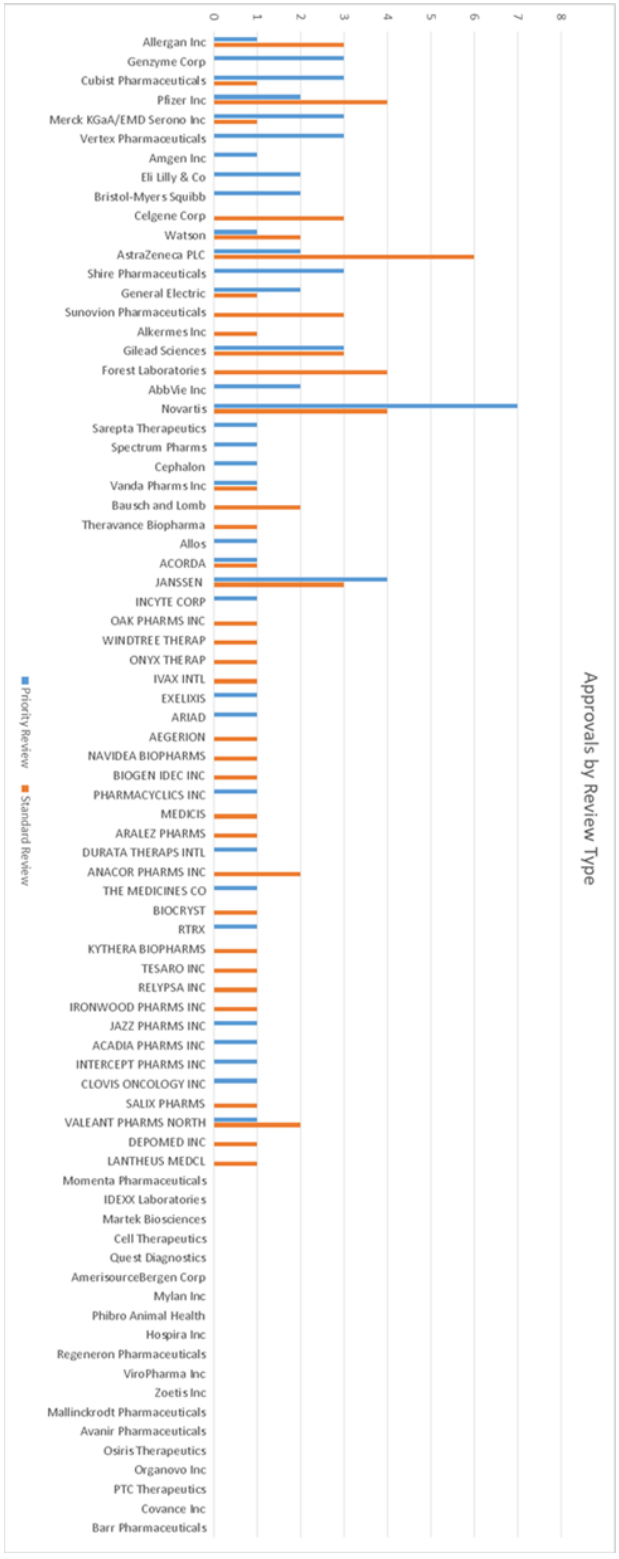
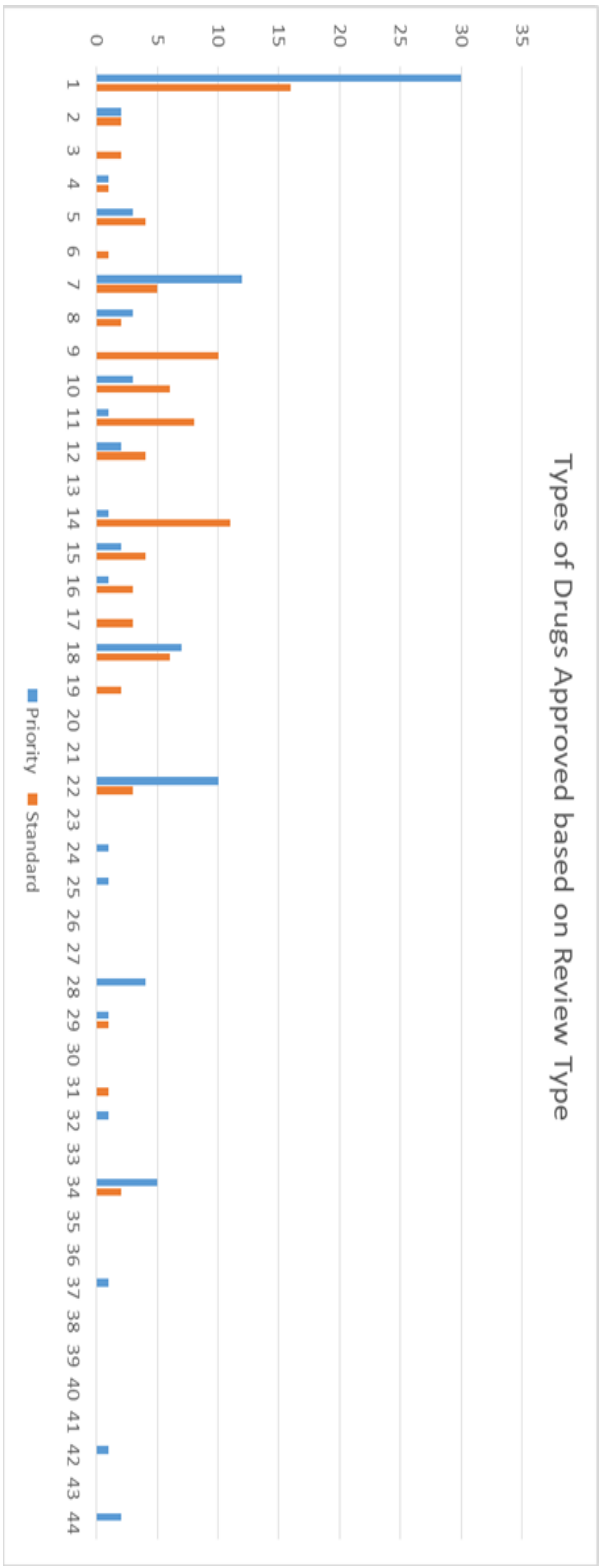


Figure 5.

Number of NDAs approved for each drug category



Size of the firms (Total assets)

Scholars have noted the importance of the size of a firm in the drug approval process. Carpenter et al. (2004) show that the larger pharmaceutical firms receive faster drug approvals mainly because of two factors: 1). Greater familiarity of the regulator with the large firms because of their histories of drug application submissions; and 2). Companies that enter the disease market early receive favorable response from the regulator, which is usually because of pressure from consumers for approval.

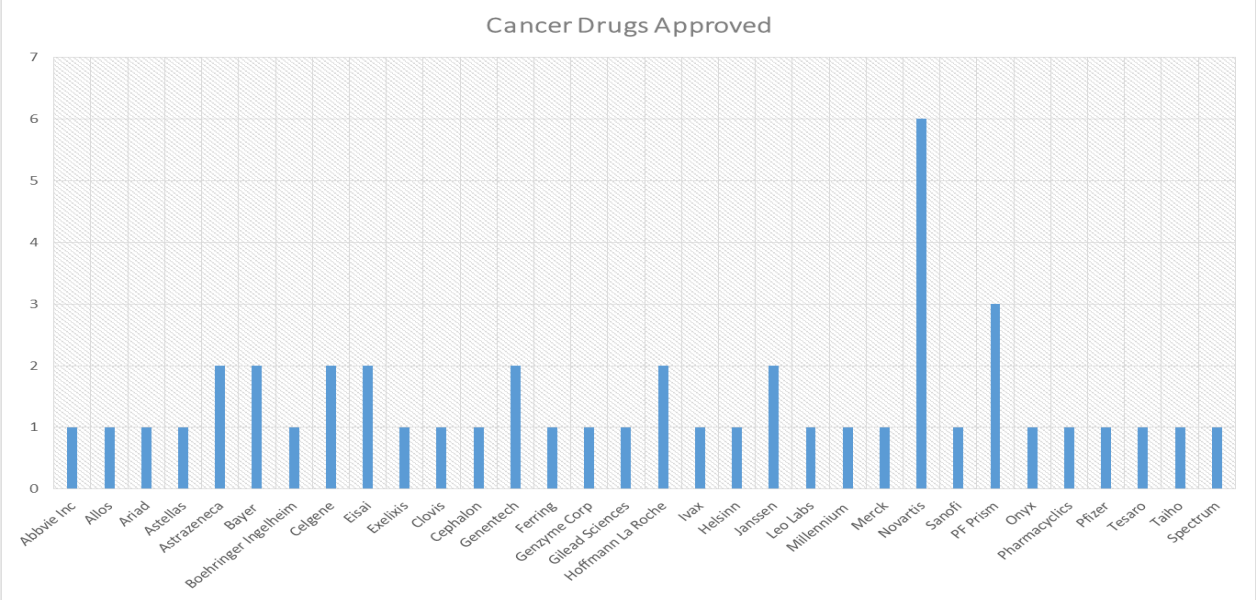
The size of a company is important in terms of financial stability and the amount of money it can spend on R&D or lobbying. Nord (2011, 1) notes that "as firms spend more on research and development they are increasing the likelihood of innovation, which will cause growth in the company". In other words, size of the firm has an impact on the number of drug applications submitted to the FDA. Therefore, when measuring the impact of lobbying contribution on NDAs approved, it is important to control for the size of the companies. A company's asset tends to be more or less stable over the time. It does not change abruptly unless there is a merger. Another measure for size of firm could be the amount of revenue generated. The problem with this measure is that sometimes companies (particularly companies in their nascent stage) can run into losses. As such, there will be negative revenues. For this paper, size of the firm is measured based on the total amount assets owned by the companies. The mean of the asset is $196,653.7 million and the standard deviation is $708, 396.5 million. The median of this variable is $6,008 million.

Most companies have to file an annual report (Form 10-K) with the U.S. Securities and Exchange Commission (SEC). This document provides a comprehensive summary of a company's financial performance. For this paper, the data of total assets owned by a firm is

collected by analyzing this form for each company in the dataset on the SEC website for the years under consideration (2008-2016). Some companies may be exempt from the SEC registration requirements and are not required to file reports with the SEC. This can happen for multiple reasons – number of shareholders fall below a particular threshold; intrastate offerings; Regulation A and D offerings; sales of securities through employee benefit plans[20]. In my dataset, there are 31 companies that did not report their financial statements to the SEC. As such, these observations were dropped from the total number of observations (109). Data on total assets is collected for the remaining 78 companies.

Figure 6.

Number of Cancer drugs approved by FDA



III. Analysis

In order to assess the model to be utilized for this dataset, I calculated the mean and the variance. The variance of the dependent variable is 4.41 which is more than twice the mean

[20] U.S. Securities and Exchange Commission, Information about some companies not available from the SEC

(1.65). As the data is over dispersed, Negative Binomial Regression is utilized. The main independent and dependent variables are the amount of money spent on lobbying the FDA by the pharmaceutical organizations; and the number of NDAs approved by the FDA. The time period under consideration is 2008-2016. The main controls in the model are size of the firm (assets); the type of review the drug application receives (priority or standard)[21] and type of drug application (i.e., if it is a lifesaver drug - cancer or HIV medication)[22].

Table 2.

Relation between political money and drug applications approved by the FDA

Approvals	**Model 1** **IRR (s.e.)**	**Model 2** **IRR (s.e.)**	**Model 3** **IRR (s.e.)**	**Model 4** **IRR (s.e.)**	**Model 5** **IRR (s.e.)**
Variables	Lobby 1.01 (0.005)**	Lobby 1.00 (0.007)	Lobby 1.01 (0.004)**	Assets 1.00 (1.29e-07)**	Lobby_size 1.29 (0.12)**
		Assets 1.00 (2.38e-07)	Review 0.66 (0.15)*	Review 0.61 (0.14)**	Review 0.63 (0.14)**
		Review 0.61 (0.14)**	Lifesavers 2.87 (0.66)**	Lifesavers 2.85 (0.64)**	Lifesavers 2.85 (0.64)**
		Lifesavers 2.85 (0.64)**			

**p≤0.05; *p≤0.10 in one-tailed tests

Table 2 reports the five different statistical models that display the relation between lobbying contributions on drug applications approved by the Food and Drug Administration. I utilized Incidence Rate Ratios (IRR) to explain my models, as they will help provide better understanding of the "magnitude of predicted effects" of lobbying contributions (Yackee and Yackee 2009, 134).

Model 1 shows the positive relationship between the main independent and the dependent variables. If a pharmaceutical company were to increase their lobbying contribution

[21] Coding scheme for the review type is as follows: 1 if the number of priority reviews is greater than or equal to the number of standard review a company receives; 0 if the number of priority reviews is less than the number of standard review a company receives

[22] Coding scheme for the lifesaver drug is as follows: 1 if it is a cancer/HIV medication; 0 otherwise)

by 1 million, there is almost 100% increase in the number of drug applications approved. This relationship is statistically significant.

In Model 2, I included size of the company, review type of the application and if the drug is a lifesaver drug (i.e., all the variables in the dataset). In this model, although lobbying money has a positive influence on the number of NDA approved, it loses its statistical significance. Similarly, if the drug application is submitted for priority review or is a lifesaver drug, then there is a 61% and almost 200% increase in the number of NDAs approved.

In Model 3, I test the main hypothesis while controlling for the review type and if the drug is a lifesaver. If a pharmaceutical company were to increase their lobbying contribution by 1 million, their rate for getting NDA approval would be expected to increase by almost 100% (similar to model 1), while holding all other variables in the model constant. The same statistically significant relation holds if the drug type is a lifesaver and received a priority review.

As discussed previously, the size of the firm might have an impact on the number of drug applications that receive approval. Therefore, Model 4 looks at the impact of the size of the firm on the number of approved drug applications, while controlling for the type of review of the application and the lifesaver criteria. The results indicate that size of the firm has a positive and significant effect on the number of NDA approvals. Review type and lifesavers also have significant relation to the dependent variable.

In both Model 3 and Model 4, it is observable that the variables lobby and assets have a statistically significant relation to the number of NDAs approved. It is likely that the companies which have more assets are also more likely to have greater financial resources. As

a result, they are able to spend more money on lobbying. Therefore, it is important to look at the correlation between the lobby and the assets variable in order to correctly establish the relationship between the main independent and dependent variables. As expected, the correlation between the lobby and the asset variable is very high (0.8). In order to solve this correlation problem, factor-analysis is utilized. Factor-analysis creates a set of uncorrelated variables (index) from the set of correlated variables (i.e., lobbying contributions and assets owned). This new variable is included in Model 5 (Lobby_size). The results show that an increase in lobbying contributions by 1 million is expected to significantly increase the chances for getting NDA approval. As in Model 4, if the NDA receives priority review or includes a lifesaving drugs, it has higher chances of being approved.

These results lend support to the main hypothesis in the paper (i.e., companies that contribute more towards lobbying the FDA tend to get more NDAs approved), showing the working of capture effect.

IV. Conclusion and Discussion

In United States, the pharmaceutical industry is a major player. There are various channels of donation (i.e., through candidates, political parties, and political action committees). “They can also fund outside spending organizations or spends money separate from the candidate or the political party” (Jorgensen 2013).

Based on the evidence presented in this paper, it can be concluded that lobbying the federal agencies help the regulated parties achieve favorable policy outputs. Lobbying contributions made to FDA leads to greater chance of NDA approvals. The size of the lobbying

organization also has a positive and significant impact on the regulatory agency (i.e., FDA). This paper supports the working of the capture theory.

Previous studies that have denied the presence of capture effect have reached their conclusion by analyzing the impact of campaign contributions on roll-call votes of the members of Congress (Bronars and Lott 1997; Stratmann 2001; Chappell 1981; Kau et al. 1982; Fleisher 1993; Luke and Krauss 2004; Frendreis and Waterman 1985; Silberman and Durden 1976; and Kau and Rubin 1981). The unique contribution of this paper to the literature of political money is the direct impact of lobbying on the governmental agency (i.e., FDA). Future extension of this research might include collecting data on more than one administration. Doing so will help understand the changes in policy priorities of different administrations that have an effect on the federal agencies. It will also increase the number of observations which will help in producing generalizable results.

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APPENDIX

Category	Drug Category
1	Cancer medication/precancerous growths/tumor
2	Anti-parasite/anti-worm
3	Anti-inflammation/rheumatoid arthritis/gout
4	sedative (insomnia)/sleep disorder
5	Skin/anti-wrinkle/psoriasis/acne/double chin/varicose veins
6	Gastrointestinal/heartburn/stomach intestinal ulcers/stomach
7	Anti-viral/hepatitis B/HIV/Aids
8	Antibiotic
9	Diabetes
10	Mental/Neurological disorder/Parkinson's disease
11	Anti-convulsant
12	Eye medication/infection
13	Smoking
14	**Blood**/sodium/uric acid/iron/cholesterol/protein/urea/potassium/calcium
15	**Hypertension**/High blood pressure/arterial hypertension/low blood pressure
16	Bladder/Urinary tract
17	**Allergy**/Pain/Fever/Ibuprofen/Cold Sore/Nasal decongestant
18	**Heart**/Blood Clot/Reverse blood clot
19	**Pregnancy/**Contraceptive/prevent pregnancy/morning sickness/premature birth
20	Headache/migraine
21	Kidney
22	Rare/Genetic Disorder
23	Anesthesia
24	Anti-fungal
25	Immunosuppressant
26	**Bone/**Osteoporosis/Bone imaging
27	**Reproductive Organs/** Prostate/ Erectile dysfunction/testosterone treatment/low sex in female
28	Lungs/Asthma/Bronchitis/tuberculosis/lung disease
29	Bowel/Laxative
30	Anti-addiction
31	Anti-depressant
32	Enzyme replacement
33	Poisoning
34	Contrast Agent/Diagnostic Agent
35	Weightloss
36	Thyroid
37	Immune System Disorder
38	replace body fluids/salts/lipid emulsion
39	Menopause/hot flashes
40	opioid overdose

41	high level of fat
42	Liver
43	Laughing Gas
44	**Other**
	Dupuytren's Contracture
	Restless legs syndrome
	Drooling
	Muscle Relaxer
	Thyroid
	Supplement
	Hormone Replacement Therapy
	Post-Surgery
	Stem Cell Transplant
	Sun Exposure

SIMULTANEOUS LOBBYING THROUGH MULTIPLE CHANNELS: EFFECT ON THE FOOD AND DRUG ADMINISTRATION

Abstract: There has been a lot of research about lobbying activities that take place during the rulemaking process. This sort of lobbying involves commenting on the Notice of Proposed Rulemaking. Another set of research looks at lobbying that takes place at the Executive level – through in person meetings, oral communication and written letters with the OIRA officials when the rule is under review. However, there has not been any systematic study which looks at the combined effect of both these activities on the Final Rule which gets published in the Federal Register. This paper addresses this loophole in the literature and shows the working of Capture effect in the Food and Drug Administration. This paper sheds a new light on the influence enjoyed by the regulated entities over the regulator when they utilize more than one channel of lobbying.

I. Introduction

The Constitution delegates the lawmaking authority to the Congress and the president (through executive orders). The interaction and conflict between these two branches determine the final laws. Krehbiel (1998) provided a significant theoretical foundation regarding the mechanism of interaction between the legislative and executive branches, and the choice of policies by the lawmakers. He isolated the role of parties in gridlock and argued that the decision of the lawmakers to pick a particular policy was a function of the status quo, ideal point of the policymaker and pivot point legislators.

Besides the legislative and the executive branches, laws are also passed by the federal agencies through rules. In fact, federal agencies participate more actively in the rulemaking process than the Congress or the executive. "In 1999, Congress and the president passed 170 laws, while the president issued 35 executive orders. At the same time, national-level agencies issued 1,636 final rules, and considered thousands more" (Potter and Shipan). As such, Krehbiel's (1998) idea of gridlock and policy preferences extends to federal agencies as well. However, there is one major difference between the laws passed by the institutions (i.e. the Congress and the president) and the federal agencies: the rules issued by the agencies have to take into consideration the interaction between institutions and their political oversight on the bureaucrats' incentives. Potter and Shipan show that the bureaucrats adjust the volume of rules depending on the political oversight of the institutions.

Similar to policy preference of the lawmakers in the institutions, bureaucrats in the federal agencies have rulemaking preferences. Their decision to issue a rule is dependent on the costs (imposed by the political oversight) and benefits (career advancement of the bureaucrats) associated with it. "Externally imposed costs are more important. Agencies that

propose rules that run counter to the wishes of elected politicians can quickly find themselves the target of unwanted scrutiny and pressure." (Potter and Shipan, 6). If the agency pushes for a rule that is contrary to presidential priorities, Office of Information and Regulatory Affairs (OIRA) can compel the agency to take action during review of the rule. Similarly, if agencies push for a rule that is contrary to congressional intent, it can issue laws overturning the rule or create unfavorable conditions for the agencies.

Boushey and McGrath (2015) extend the idea of bureaucrats being pivot players who work the disagreement between the institutions to their favor and pursue preferred policy objectives. As it is easier for the institutions to exercise political oversight when the government is unified, bureaucrats use their expertise to influence policy outcomes when the government is divided. Therefore there is an increase in the volume and content of rulemaking when the executive and the legislative branches are controlled by different parties. In contrast to Boushey and McGrath (2015), Yackee and Yackee (2009) contend that divided government reduces the rulemaking activity by the federal agencies. This happens because divided government leads to stronger oversight by the president and the Congress.

As political oversight by the Congress and the president has significant influence on the rulemaking process, interest groups try to sway policy outputs to their preferred position by lobbying both the institutions. Originally, public participation during the notice and comment period was meant to safeguard the democratic aspect of the rule making process" (Golden 1998, 246). However, there have been studies (Naughton et al. 2009; Yackee 2005) which have shown that the concept of public participation to promote democratic accountability has failed, and has led to greater influence of the interest groups.

The influence of the regulated industry has also been noted at the Executive level (through OMB review of the regulations). Studies (GAO Report 2003; Haeder and Yackee 2015; Croley 2003; and Balla et al 2011) indicate that interest group lobbying during the OMB review leads to a change in the regulations (especially if the lobbying is done by the business interest groups) as well as the duration of review (Balla et al. 2011).

Existing scholarly research on both the mechanisms of influence during the rule making and OMB review of regulations have been kept independent. It is surprising to see that there has not been a single study which looks at the impact on the final rules when a regulated entity tries to influence the policy output through more than one channel. In order to truly solve the debate between capture theory and public interest, it is important to take into consideration the coordinated impact of lobbying at both levels. This paper focusses on the influence of the regulated industries on the Food and Drug Administration. This paper has two objectives. First, to build on existing research and analyze the influence of comments during the rulemaking period. Second, to measure the influence of regulated parties on the final rules when they lobby during the rulemaking period as well as during OMB review. The analysis focusses on only those rules which moved through the complete rulemaking cycle – from proposed rule to final rule during the Obama administration.

The second section forms the theoretical argument of the paper. This section draws on the literature of the APA; interest group's influence on the rulemaking and the executive to show the working of capture theory in the Food and Drug Administration. The third section outlines the research design and analysis of this paper. The fourth section provides the conclusion and avenues of future research for this paper.

II. Theoretical Foundation

Interest Group Influence over Rulemaking

Before delving into the rule making process, it is important to define 'rule'. According to the Administrative Procedure Act of 1946, "rule means the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy" (Kerwin 1994, 3). As the implementation and management of laws are done through these rules, the federal agencies enjoys a lot of discretion in their authority. The mandates governing these federal agencies are vague, they are open to influence by the external interest groups making the regulator susceptible to capture. Although these federal agencies are created out of people sentiments, "public support for its mission declines over time, discretion is used more and more in the service of the regulated groups which the agency was created to control. This is because such interests come to constitute the only viable source of political support for the agency before Congress and elsewhere" (West 1985, 27). For example, the Food and Drug Administration was created as a "federal consumer protection agency with the passage of 1906 Pure Food and Drugs Act. This law was the culmination of about hundred bills over a quarter-century that aimed to rein in long-standing, serious abuses in the consumer product marketplace"[23]. However, overtime FDA has lost the significance of its creation and is often cited as a protector of regulated pharmaceutical companies instead of public. Another drawback of vague mandates is the usage of symbols. Edleman (1960) notes symbols are "generally stated intentions to do something, they placate

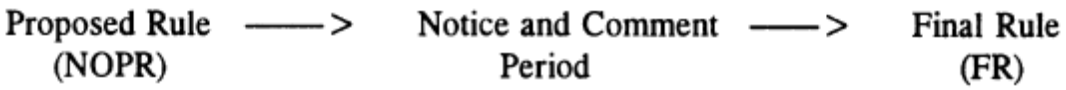
[23] U.S. Food and Drug Administration: https://www.fda.gov/aboutfda/transparency/basics/ucm214403.htm (Last visited: August 11, 2018)

the public, yet at the same time they provide latitude for administrators to do nothing and thus serve dominant economic interests".

The Administrative Procedure Act (APA) of 1946 mandates the federal agencies to publish their proposed regulations in the Federal Register. Once these Notice for Proposed Rulemakings are published, they are opened to public and interested parties to provide comments and voice their concerns. This period is referred to as the notice and comment period. Once the comment period closes, the agencies reviews the comments and adopts the final regulations. Figure 1 provides a visual representation of the process.

Figure 1.

Rulemaking Process



Source. Marissa Martino Golden (1998, 250)

Based on this process, there are three core elements of rulemaking: Information, Participation and Accountability (Kerwin 1994). In the following paragraphs, I will discuss how capture is engrained in the entire rulemaking process.

Information: There are two types of information. 1). Federal agencies provide to public to get their viewpoints through notice of proposed rule; 2). The information the agencies depend on to formulate the rules. For both these types of information, "the agencies enjoy considerable discretion when deciding how much information to disclose" (Kerwin 1994, 53). In order to solicit comments from the public and the interested parties, agencies need to provide the public with the information about what it is proposing to do through the notice. For the second type

of information, the basis and the purpose of the rule shows the information the agency has considered for developing the rule. As APA is not clear about this type of information, the agencies only need to provide a general description of the rule and provide some discussion about the basis of the rule.

Sometimes through the rulemaking process, the agencies try to collect information to provide a basis for their rule. For example, in the case of the Food and Drug Administration, the agency may be required by law "to base their rules on rigorous assessments of risk to human health and safety. The fact that some of the information needed to conduct such studies is in the possession of the regulated community, might increase their ability to participate" (Kerwin 1994, 205). The dependence on regulated companies in order to formulate the rule might increase the decisional bias of the FDA, leading to a favorable rule towards the regulated companies. As Thaw (2014, 337) points out "engaging private expertise carry substantial risk of regulatory capture as the agency is free to formulate rules upon the basis of materials in its files and the knowledge and experience of the agency, in addition to the materials adduced in public rulemaking proceedings. Many agencies have adopted this viewpoint, determining that they are free to ignore comments submitted during informal rulemaking proceedings and promulgate regulations based on their own expertise."

Participation: An important dimension of information is the cost of obtaining information. In order to successfully participate in the rulemaking process, public needs to be sufficiently informed about the rule under consideration. However, it is often overlooked that there is a cost involved in order to obtain information. The cost may be in the form of money, time or resources. Such costs increase in case of technical rules.

Although the federal agency solicit comments during the rulemaking process in order to promote democratic accountability, there is no explicit linkage in APA between the participation provision of the act and the requirement that agencies base their decisions on the commenter recommendations. The main purpose for soliciting comments is to educate the agency and to ensure that the agencies are exposed to relevant views (Kerwin 1994; West 1985).

Even before a formal notice of proposed rule is published in the Federal Register, the agencies are in contact with the affected parties. They collect information, consult with the affected parties and formulate the policy even before the notice is published. If the agency is satisfied with all the information conveyed to them during these informal proceedings they do not need to consider the comments which they receive during the comment period.

Based on a survey result on interest group influence (Kerwin 1994), "more than 80 percent of the respondents considered themselves able to influence the particular agency 50 to 75 percent of the times they got involved in the rulemaking".

Accountability: The APA provides judicial review as a way to hold the federal agencies accountable for the rulemaking process. Based on this, if someone is dissatisfied with a rule, they can challenge it in court. However the standard against which the rule will be judged are not very strict. "The substance of rules could not constitute an arbitrary or capricious abuse of discretion" (Kerwin 1994, 55). It is very difficult to establish a rule random and unpredictable as most of the rules have a basis and purpose. Therefore although judicial review exists in order to hold federal agencies accountable for their actions, it is very difficult to utilize it making it susceptible to capture.

Scholars have been divided on the theories of rulemaking. There are studies that show little evidence of capture (Furlong 1997; Golden 1998) while others contribute the influence of interest groups to alternative explanations (Yackee 2005; Hrebenar 1997; Pika 1983; Naughton et al. 2009; McCubbins and Schwartz 1984). Furlong (1997) uses survey data to collect information on the relationship between interest groups and bureaucratic relations. The result reveal that eighty percent of the respondents participate in the rulemaking process. Among different ways of participation, "seventy one percent believed informal contacts with agency before the notice was issued was most effective, followed by forming coalitions and providing written comments to the Federal Register". Golden (1998) analyzes written comments on the rules issued by 11 agencies, followed by telephone survey about the notice for proposed regulation. Furlong (1998, 54) tested the "theory of political influence from the perspective of agency officials. Survey results showed that agency officials perceived providing written comments to proposed rule makings as the most used technique, followed by participating in public meetings, communicating with Congress and communicating informally with agency personnel". McKay and Yackee (2007, 349) provide evidence that "federal bureaucrats listen to interest groups and tend to favor the more dominant side" (i.e., if the comments from interest groups provide a united message, they are more likely to make changes to the final regulation. Thaw (2014, 337) believed that "to fully engage private expertise, agencies must either be subject to capture through the placement of sympathetic individuals in key positions within the agency, or the regulatory process must be structured in a way that incentivizes (or even compels) the agency to engage private expertise."

On the other hand, alternative set of research contributing to interest group influence during notice and comment period involve information collection or the fear of accountability

(in case a rule's docket is reviewed in court) (Yackee 2005; Hrebenar 1997; Pika 1983; Naughton et al. 2009; McGarity 1992; Schmidt 2002; and Shapiro 1988). The fear of accountability and judicialization might compel the agency to pay attention to the interest groups appeals. Another alternative explanation highlighted in the literature includes the fear of negative reputation (McCubbins and Schwartz 1984; Carpenter 2002; and Wilson 1989). McCubbins and Schwartz (1984) show that "bureaucrats may be forced to cooperate with interest groups because of the fear of negative attention that they might bring to the agency".

The APA Act has made it easier for the interests group to participate and influence the rulemaking done by the federal agencies. The APA "allows for influence over rulemaking because it requires agencies to provide notice of proposed policies and invite comments, which may be used to enfranchise important constituents in agency-decision making processes, thereby assuring that agencies are responsive to their interests" (Naughton et al. 2009, 260). Balla et al. (2001, 810) implies that "all active interests in legislative debates should be represented in the bureaucratic proceedings that develop and implement congressional directives". Similar conclusion has been reached by Furlong (1998, 4) where he states that "providing comments to proposed rule makings, participating in regulatory negotiations, and having informal contact with agency personnel can help an interest group influence agency policy".

Based on the above discussion, it can be said that federal agencies (in this case the FDA) are captured by the regulated entities. The first hypothesis of this paper can be stated as:

Hypothesis 1: Given the influence enjoyed, regulated companies are more likely to participate in the rulemaking process during the notice and comment period. The final rule should follow the recommendations provided by these companies during the comment period.

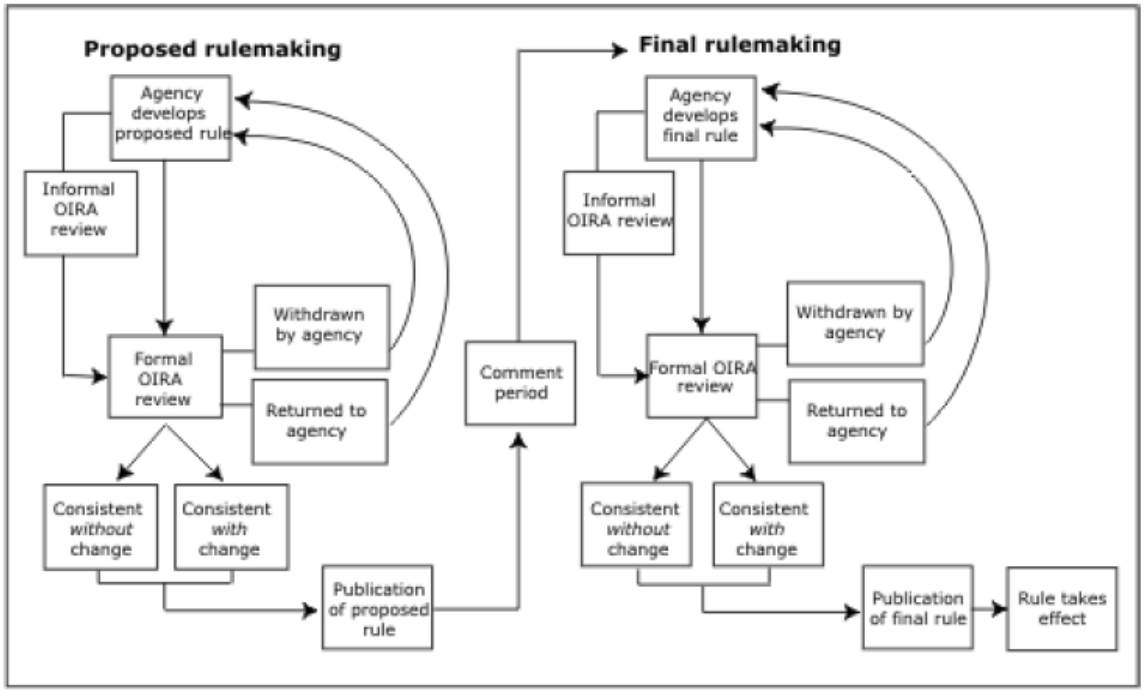
Interest Group Influence on the Executive

The executive branch controls the rulemaking process through the Office of Information and Regulatory Affairs (OIRA). OIRA is a part of the Office of Management and Budget (OMB) and was created by the Paperwork Reduction Act of 1980. "President Reagan in 1981 issued the Executive Order 12291, which gave OIRA the responsibility to review the substance of agencies' regulatory actions before publication in the Federal Register" (Copeland 2009). Three main aspects of the Executive Order included: refraining from taking regulatory action unless the benefits to society for the regulation outweighed the costs; preparing regulatory impact analysis for major rules; sending a copy of each draft proposed and final rule to OMB before publication in the Federal Register for review (Copeland 2009). This made OMB "a major presidential institutional resource for controlling contemporary federal administration" (Newbold and Rosenbloom 2007, 1052). "Major rules must be submitted to OIRA sixty days before the publication of notice in the Federal Register, and again thirty days before their publication as final regulations. Non major rules must be submitted ten days prior to notice and to final publication. However, these deadlines could be changed by the OMB unilaterally unless Congress has legislated a deadline or the courts have imposed one. Although the agencies could choose to defy OMB by submitting rules for publication before OMB review has been completed, their legal right to do so is less clear" (Cooper and West 1988, 876). Moreover, it is a standard practice to comply with the OMB suggested changes (Rosenbloom 2003). By allowing the OMB to review the rules even before the notice was published, it allowed the OMB to stop a rule before the rulemaking process gained momentum. Through this process, the Executive greatly expanded its control over the rulemaking process as OMB had the power to "stay the publication of the notice of proposed rulemaking or the

promulgation of final regulation by requiring that agencies respond to its criticisms, and ultimately it may recommend the withdrawal of regulations which cannot be reformulated to meet its objections" (Cooper and West 1988, 870). Figure 2 shows the process of OIRA reviews of the proposed/final regulations.

Figure 2.

OIRA Review Process of Draft Proposed and Final Rules



Source. Copeland 2009

Although scholars have studied the influence of the executive over the rulemaking process through OMB reviews, they have ignored the fact that the Executive Orders allows the public or interest groups to provide direct feedback to OMB when a rule is under review (Steinzor et al. 2011). A major aspect of the Executive Order 12291 was to identify troublesome regulations through information provided by the regulated parties. Such forms of information collection were not open to public and the communication was done in the form of "letters or calls from regulated interests, informal contacts with agencies, and monitoring of

trade publications as well as internal memoranda alerting OIRA staff to sensitive regulatory issues" (Cooper and West 1988, 877). Through these communications, the outside parties practiced significant influence over the OMB during the rulemaking process. The lack of transparency regarding these communications with the outside parties and the unseen influence of the regulated parties made OIRA's role in the rulemaking process debated. In order to address the issue of lack of transparency of the regulatory reviews, President Clinton issued the Executive Order 12866 "to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public" (Copeland 2009, 9). Specifically OIRA is required to make its written and oral communications with the outside parties available to the agencies as well to the public (Croley 2003; West 2005). "Timelines for review of the regulations were also established through this Executive Order – (1) within ten working days of submission for any preliminary actions prior to a notice of proposed rulemaking; or (2) within ninety calendar days of submission for all other regulatory actions (or forty five days if OIRA had previously reviewed the material)" (Copeland 2009, 14).

The goal of OMB review is to analyze if the important regulatory proposals are in line with presidential priorities (Header and Yackee 2015). The strength of interest group lobbying acts as a source of information for the OMB. It helps to gauge strength of support/opposition regarding the rule under consideration and the potential support/backlash against the president; as well as information on the technical data on the rule (Haeder and Yackee 2015). Studies have shown that contact with regulated entities have impact on the OIRA reviews (GAO Report 2003; Haeder and Yackee 2015; Croley 2003; and Balla et al 2011). These contact are done usually before or during the review process. These contacts are done through meetings with the OIRA officials or by sending letters. A study done by GAO (2003) showed evidence

that the actions that OIRA took (i.e., to suggest significant changes to rules or to return them to the agencies for reconsideration) were traceable to suggestions offered by regulated entities or other parties outside of the federal government. The regulated entities contacted the OIRA regarding 11 of the 25 rules. In 7 of those 11 cases, the outcome of the OIRA review were similar to the suggestions made by the regulated parties. Haeder and Yackee (2015) analyzed 1500 regulations and found that interest group lobbying during OMB review led to a change in the regulations. Balla et al (2011) contends out of the 25 rules that were affected by OIRA reviews, eleven rules (44%) were contacted by outside parties.

According to Baumgartner and Leech (1998), "as interest groups largely exist to move public policy towards the preferences of their clients and members, they try communicate and engage with the policymakers as much as possible". Although previous studies have analyzed the influence of the regulated parties on OIRA reviews, they have not addressed the influence exerted through multiple channels by the interest groups to affect the policy outputs. Sometimes the issues raised during the meetings with outside parties are similar to the comments provided during the notice and comment period. Therefore, I theorize that in order to understand the presence of capture theory, it is important to take into consideration multiple channels of lobbying/influence utilized by the regulated parties in order to pressurize the policymakers. In this paper, I test this theory by analyzing the rules that gets lobbied both during the rulemaking process as well as the OMB review. Following is the second hypothesis in this paper:

Hypothesis 2: When same interest groups/regulated parties participate in both the rulemaking process (during the notice and comment period) and OIRA review, it is possible to see their combined effect on the final rules that gets published in the Federal Register.

III. Research Design

The analysis in this paper is divided into two parts. The first part focusses on the notice and comment period. In order to test the first hypothesis and show the presence of capture in the Food and Drug Administration, I examine the influence of comments on the final rules that gets published in the Federal Register.

The second part shows the impact of lobbying on the rulemaking process when interest groups try to influence the final rules through multiple channels. The two channels of lobbying considered for this paper are: comments provided by the regulated entities during the notice and comment period; and meeting between the OIRA officials (when the rule in under review) and the regulated parties.

Commenter Influence on the Final Rules

Rule Selection and Variables

The main focus of this paper is to show that the Food and Drug Administration is captured by the regulated industries. A total of 19 rules passed the complete rulemaking process (i.e., rules that moved from proposed rule stage to the final rule stage).

Rules were drawn from a single presidential administration, as it was necessary to control for the party in the White House. According Golden's study (1998, 251), if rules were covered for more than one presidential administration, then "changes between notice for proposed regulation and the final rule might otherwise reflect the change in presidential administration rather than the comments received during the notice and comment period." For this paper, the rules were based on the Obama administration covering the years 2009 – 2016. I collected data on the rules that moved from proposed rule stage to final rule stage from the

'Historical Unified Agenda and Regulatory Plan' under the Reginfo website from Spring 2009 – Fall 2016 for the Food and Drug Administration. Each individual rule "appearing in the Unified Agenda or Regulatory Plan is assigned a Regulation Identifier Number (RIN), in accordance with the requirements for the Unified Agenda set forth in section 4 of Executive Order 12866. RINs help the public to identify and follow the progress of each regulatory action or rulemaking proceeding in the Unified Agenda, the Federal Register, and on the Reginfo.gov website. Each regulatory action retains the same RIN throughout the entire rulemaking process"[24].

Previous studies have focused on high-profile rulemaking (Golden 1998; Kerwin 1994). The drawback of such a strategy is that it provides an incomplete picture of commenter influence during the notice and comment period. As a result, rules with greater than fifteen and less than two comments were excluded from the analysis. Rules with high number of comments were removed to focus on "the normal reactions of agency officials to interest group involvement in rulemaking" (McKay and Yackee 2007, 342). This criteria of rule selection provides a "more complete picture of the kinds of low salience rules typically written by executive department agencies, as opposed to providing insights concerning rules with very high levels of commenter participation" (Yackee 2005, 110). Another major advantage of this criteria for rule selection is that the focus can be on low salience rulemaking activity which the previous literature has ignored (Kerwin 2003; Golden 1998). The drawback of this strategy is that it will not allow me to provide generalizable results. In total, I analyzed twelve rules[25].

[24] Reginfo.gov: https://reginfo.gov/public/jsp/eAgenda/StaticContent/UA_HowTo.jsp#rin
(Last visited: August 10, 2018)
[25] Appendix 1 provides the details of the 12 rules
Two rules were eliminated because of less than two comments. Additionally, there were five rules that were eliminated:

The data on public comments for the rules were collected from regulations.gov website. The RIN's for each rule were searched on this website to collect data on the comments submitted. In order to see if the FDA changes its final rule based on the recommendations made by the commenters, I went through each comment for the rules and catalogued the recommendations made. Following the coding strategy of Yackee (2005) and Naughton et al. (2009), I identified the three most commonly referenced recommendations made by the commenters for each rule[26].

After the recommendations were coded for the each of the twelve rules, I collected data on final rules from the Federal Register. For each final rule, I evaluated if there was a change in the final rule based on the recommendations made by the commenters. If the final rule followed more than one recommendation suggested during the comment period, it was coded as 1; 0 otherwise.

The importance of salience and complexity has been cited in the literature during the rulemaking phase (Yackee 2005; Naughton et al. 2009; Gormley 1986; Ringquist et al. 2003; and Worsham et al. 1997). The salience of the rules is reflected in the 'Priority' section of the rule in the Unified Agenda. If the priority is set as 'Economically Significant[27]' or 'Other Significant[28]', then the rule is salient and is coded as 1. If the priority is 'Routine and Frequent'

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i). Two rules were eliminated that did not have a final rule citation in the Federal Register
ii). Two rules that did not have any common recommendations.
iii). One rule was dropped because the regulated entities communicating outside the comment period.

[26] Some comments had less than three recommendations, in such cases only one or two recommendations were coded

Based on Executive Order 12866:

[27] 'Economically Significant' refers to those rules that have an anticipated economic impact in excess of $100 million per year.

[6] 'Other Significant' refers to those rules that raise novel or controversial policy issues or meet one of several other criteria. It also refers to those rules which are considered significant by the agency but is not considered economically significant by the Unified Agenda.

or ‘Substantive, Nonsignificant’, then it can be concluded that the rule in consideration is not salient and is coded as 0. Ringquist et al. (2003, 145) defines “complexity as the technical complexity of the policy area (i.e., the degree to which specialized technical knowledge is necessary to craft effective policy solutions or understand the policy area)”. Every rule has an abstract which provides an overview of the rule. Following the coding strategy of Naughton et al. (2009), complexity in this paper is calculated by measuring the length of the rule’s abstract in characters. This is done based on the expectation that complex rules will tend to have longer abstracts because more content needs to be explained. The mean of this variable is 95. The complexity variable is coded as 1 for rules that have an abstract length greater than 95; 0 for those whose length is less than 95.

Agencies receive comments from diverse constituencies. There has been extensive debate in the literature about which constituency has greater influence (Balla 2000; Golden 1998; Yackee and Yackee 2006; and Croley 1998). Since the main question analyzed in this paper tests the influence of the regulated parties on the regulator, I will not delve into the identity of the party that has participated in lobbying the FDA (through the rulemaking process) or the executive (by contacting the OIRA officials).

Findings

Table 1 shows the information on the twelve rules analyzed in this paper. It shows the impact of recommendations received through comments during the notice and comment period on the final rules (taking into consideration the salience and the complexity). Following paragraphs sums up the findings of this table.

Table 1.

Influence of Comments, Salience and Complexity of rules on the Final Rules

RIN	Total Number of Comments	Salience	Complexity	Final rule
0910-AF36	2	0	1	0
0910-AF82	15	1	1	1
0910-AF86	7	1	0	1
0910-AF88	3	1	1	0
0910-AF96	6	1	1	1
0910-AF97	12	1	0	1
0910-AG29	7	1	1	1
0910-AG39	5	1	1	0
0910-AG48	11	1	0	1
0910-AG74	12	1	0	1
0910-AH08	6	1	0	0
0910-AH12	6	0	0	1

- Rules that received high number of comments (i.e., more than 8 comments), their final rules adopted the recommendations provided by the commenters. This finding lends support to the previous literature on the influence of group comments on final rules. The unique contribution of this study is that these rules completed the whole rulemaking cycle (i.e., move from proposed rule to final rule) in a single presidential administration.
- More than 50% of the rules that are high on salience as well as complexity (RIN numbers: 0910-AF82, 0910-AF96, 0910-AG29) follow the commenter recommendation (irrespective of the number of comments) in the final rule. Two rules

that are exception to this trend and do not follow the recommendations (RIN numbers: 0910-AG39 and 0910-AF88).

- For most rules that are high on salience and low on complexity (RIN numbers: 0910-AF86, 0910-AF97, 0910-AG48, 0910-AG74), the final rules tended to follow the commenter recommendations. There is one rule (RIN: 0910-AH08) that does not follow this trend.
- There is only 1 rule that is low on all three variables (comments, salience and complexity- RIN: 0910-AH12). However, the final rule followed the commenter recommendations. This abnormality can be explained by the fact that the recommendations mainly included clarifications on the proposed rule[29].

From Table 1, it is noticeable that regulated companies exercise their influence through comments during the notice and comment period. In order to determine if the FDA is captured by the regulated industries, I did an additional analysis to determine the direction of the final rules based on content of the comments. Table 2 shows the movement of final rules towards public interest and capture effect either separately or together, and in some cases neither[30]. The comments for each of these rules were coded as capture effect or public interest depending on the details mentioned in the comment. I read through each comment and final rule in order to make the assessment.

[29] Top 3 recommendations provided by the commenter on this rule (RIN: 0910-AH12) include:
a). Clarify regarding storage and destruction of consignment
b). Clarify as to when FDA will opt to destroy a refused product and when it will opt to export a refused product
c). Clarify how agency's policies regarding personal importation impact new destruction authority
[30] RIN 0910-AH12 was removed from this analysis as most comments were regarding clarification about the rule

- In three rules (RIN: 0910-AF36, 0910-AF82 and 0910-AF96), the final rule moved towards either capture or public interest following the comments.
- For four rules (RIN: 0910-AF86, 0910-AF88, 0910-AF97 and 0910-AG39), the final rules incorporated both components of public interest as well as capture effect. In all these four cases, the number of comments signifying capture were higher.
- For four rules (RIN: 0910-AG29, 0910-AG48, 0910-AG74 and 0910-AH08), the final rules did not incorporate either component of public interest or capture effect.

Table 2.

Movement of Final Rule towards Public Interest or Capture Effect together or separately

RIN	Number of Comments (Public Interest)	Number of Comments (Capture Effect)	Neither	Final Rules
0910-AF36	2	0	0	Public Interest
0910-AF82	0	7	8	Capture
0910-AF86	1	6	0	Both
0910-AF88	0	3	0	Both
0910-AF96	0	5	1	Capture
0910-AF97	0	6	6	Both
0910-AG29	3	0	4	Neither
0910-AG39	0	4	1	Both
0910-AG48	3	3	5	Neither
0910-AG74	0	0	12	Neither
0910-AH08	4	0	2	Neither

Lobbying by Regulated Parties through Multiple Channels

Data Description

In order to show the presence of capture when the regulated parties engage in more than one channel of influence (second hypothesis), I have matched the rules issued by the FDA which have completed the whole rulemaking stage (i.e., moved from proposed rule to final rule), with the meetings regarding the same rules with the OIRA officials, when they are under

review. Similar to previous analysis, I focused on one presidential administration (Obama) as different presidents have different priorities and policy preferences that might have an impact the OMB review process.

As in the first analysis, I collected data on the rules that moved from proposed rule to final rule from the 'Historical Unified Agenda and Regulatory Plan' under the Reginfo website from Spring 2009 – Fall 2016 for the Food and Drug Administration. There was a total of twelve rules that passed the whole rulemaking cycle during this period[31].

OIRA officials engage in various forms of communication with outside parties. These communications take the form of in person meetings, oral communications and letters/comments. "Historically OIRA's outside communications were either not disclosed or have been accessible solely via files maintained at the White House" (Balla et al. 2011). In 2001, these records were made available on the Internet, making it easily accessible to the public. "It is now possible to readily ascertain whether OIRA officials had any contact with outside parties during the review of particular agency submissions, as well as the identities and organizational affiliations of the individuals whom OIRA communicated" (Balla et al. 2011, 151). These communication logs are a part of the Executive Order 12866 which reflects an attempt to overcome the White House criticism during the Reagan administration that "White House review provided an opportunity for powerful interest groups to enlist the White House to change rules outside of public scrutiny" (Croley 2003, 844).

Balla (2011) notes that although the OIRA catalogues the nature of the contact as well as the identity of the participants and their organizational affiliations, it is not very informative.

[31] Same numbers of rules were excluded as in the first analysis

For the Food and Drug Administration, the meeting records for OIRA were much clearer to understand after April 2014 than before. The data for the meetings with the OIRA/OMB officials after the April 2014 was obtained from the Office of Information and Regulatory Affairs/ Office of Management and Budget[32]. I checked each rule from my dataset on this website. There was only one meeting record in this time period for RIN: 0910-AG81[33]. On the other hand, the data for the meetings with the OIRA/OMB officials before the April 2014 was obtained from a separate webpage of the Office of Management and Budget[34]. The meeting records were extremely unclear[35]. Also the records seemed "cryptic" (Croley 2003) as they did not even provide the details of the rules for which the meeting was held. The only way the rules could be associated with the meeting record was by looking at the topic, which was vague. The problem of the meeting records being unclear has been cited in the previous studies as well (GAO Report 2003; Balla 2011; and Croley 2003). There were no match with meeting records for any of the rules in my dataset from this time period.

The main motive for this analysis is to show the working of capture effect when the regulated parties lobby the policymakers through more than one channel. For this paper, the two channels of influence are: 1). through comments provided during the notice and comment period; and 2). meeting with the OIRA officials when the rule is under review. Therefore after matching the rules for which there were comments as well as meeting, I analyzed the data for

[32] Office of Information and Regulatory Affairs/ Office of Management and Budget website: reginfo.com (Last visited: August 9, 2018).
[33] Link for the rule: https://www.reginfo.gov/public/do/eom12866SearchResults?pubId=201310&rin=0910-AG81&viewRule=true
(Last visited: August 9, 2018).
Meeting Record: https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0910-AG81&meetingId=174&acronym=0910-HHS/FDA
(Last visited: August 9, 2018).
[34] Office of Management and Budget website: https://obamawhitehouse.archives.gov/omb/oira_0910_meetings/
[35] Appendix 2 shows the screenshot of the meeting records before April 2014

common regulated entities that engaged in both these activities. For only one rule (RIN: 0910-AG81), this condition was met. The influence of the regulated parties is measured in terms of the common recommendations that they provided to the FDA during the comment period, as regulated parties often raise similar concerns when they lobby the regulator as well as the executive. As GAO (2003, 91) reports shows "during its review of an EPA final rule on identification and listing of hazardous waste, industry representatives from steel manufacturers and a chemical company sent letters and met with OIRA opposing the listing of manganese as a hazardous waste constituent due to concerns about the costs that the rule would impose on certain facilities. Industry representatives had raised similar points in the public comments submitted during the proposed rule stage of this rulemaking".

The next section provides an in depth case study analysis of RIN: 0910-AG81 rule where the interest groups participated in the rulemaking process as well as met the OIRA officials when the rule was under review in the executive branch. The influence of these activities was measured in terms of the recommendations that the final rule followed when it was published in the federal register.

Case Study

Rule Title: Requirements for the submission of data needed to calculate user fees for manufacturers and importers of tobacco products (RIN: 0910-AG81) [36]

[36] Link to the Final rule: https://www.gpo.gov/fdsys/pkg/FR-2014-07-10/pdf/2014-16153.pdf (Last visited: Aug 10, 2018)
Link to the Proposed rule: https://www.gpo.gov/fdsys/pkg/FR-2013-05-31/pdf/2013-12927.pdf#page=1 (Last visited: Aug 10, 2018)

The Federal Food, Drug, and Cosmetic Act (FD&C) was passed in 2009 providing FDA with the authority to regulate tobacco products. Through this rule, the Food and Drug Administration intended to collect information from the domestic tobacco product manufacturers and importers in order to calculate the amount of user fees assessed under the FD&C Act. The total amount of user fees was a proportionate amount each quarter of the fiscal year. The assessment was allocated among the classes of tobacco products (i.e., cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco). Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its share of the market for that tobacco product class. Before this rule was passed, this information was collected by the United States Department of Agriculture (USDA) and it provided the FDA with the data to calculate the amount of user fees. With the passage of this rule, the USDA would cease to collect this information and the information would be collected by the FDA directly. This rule provided for a two-step process to calculate quarterly assessments:

Step A allocated assessments among the six classes of tobacco products based on each class volume of tobacco products removed into commerce.

Step B allocated the assessment for each class of tobacco products among the domestic manufacturers and importers in that class, so that each domestic manufacturer's or importer's assessment is proportional to its percentage share within that class.

During the notice-and-comment period, ten companies provided comments[37]. The entities of these companies include: coalition of tobacco manufacturers, individual tobacco

[37] List of companies that commented is listed in Appendix 3

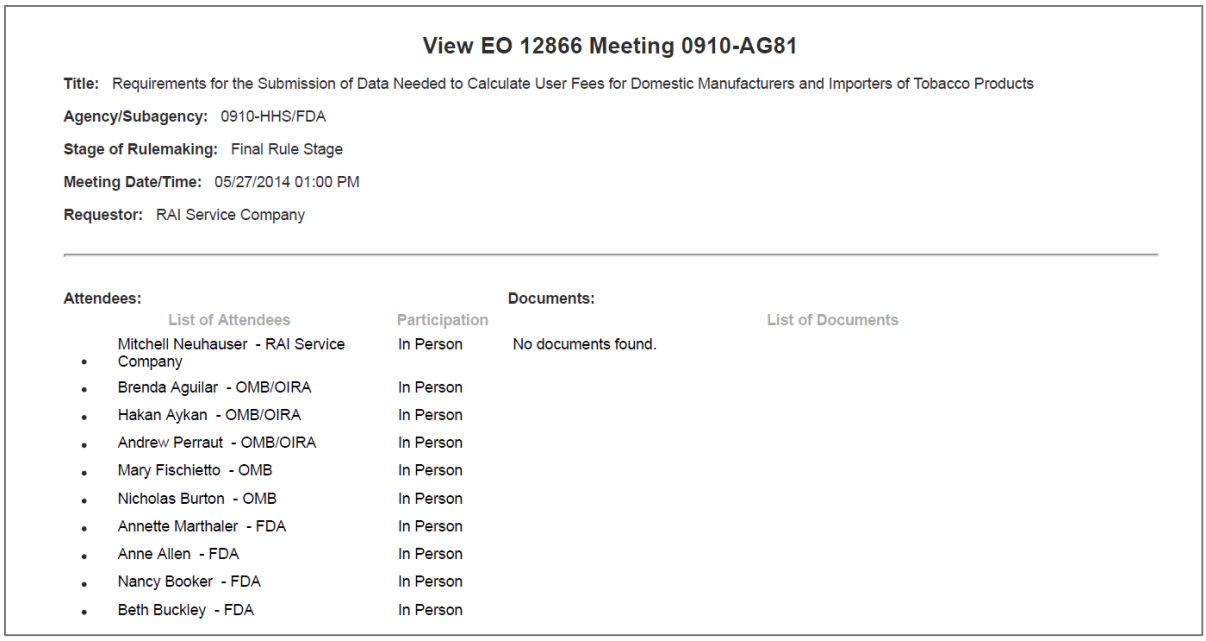
manufacturers, cigar trade organization, council of independent tobacco manufacturers, association of electronic cigarettes, cigar rights advocacy organization, and pipe tobacco trade association. I collected data on all the comments that were submitted for this rule from regulations.gov website. I went through each comment for the rules and identified the three most commonly referenced recommendation made by the commenters for this rule. Top thee recommendations made during the comment phase for this rule include: Assessing user fees for all classes/types of regulated products; creation of appropriate mechanism for calculating user fees; and refunds on erroneous payments should include interest.

In order to check if regulated parties engaged in more than one form of influence, I collected data on meetings with OIRA officials about the rule in consideration. Figure 3 shows the meeting record for the rule[38].

[38] Meeting Record: https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0910-AG81&meetingId=174&acronym=0910-HHS/FDA
Last visited: August 9, 2018

Figure 3.

Meeting Record for the rule (RIN: 0910-AG81)



View EO 12866 Meeting 0910-AG81

Title: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

Agency/Subagency: 0910-HHS/FDA

Stage of Rulemaking: Final Rule Stage

Meeting Date/Time: 05/27/2014 01:00 PM

Requestor: RAI Service Company

Attendees:

List of Attendees	Participation
Mitchell Neuhauser - RAI Service Company	In Person
Brenda Aguilar - OMB/OIRA	In Person
Hakan Aykan - OMB/OIRA	In Person
Andrew Perraut - OMB/OIRA	In Person
Mary Fischietto - OMB	In Person
Nicholas Burton - OMB	In Person
Annette Marthaler - FDA	In Person
Anne Allen - FDA	In Person
Nancy Booker - FDA	In Person
Beth Buckley - FDA	In Person

Documents:

List of Documents
No documents found.

There was only one meeting recorded for this rule. The requestor for this meeting was RAI Service Company which has also commented during the notice and comment period. The meeting included representatives from OMB, OIRA as well as FDA.

Another observation can be made regarding the date of the meeting. The meeting was held in May 2014 and the final action for this rule was taken in June 2014. This meeting was done right before the final action was taken and after the end of the public comment period (August 2013)[39].

After the OIRA review was concluded, it was coded as 'consistent with change'[40] which implies that the rule was changed after it was submitted to OIRA. And OIRA concluded

[39] Timetable for the rule: https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201310&RIN=0910-AG81
Last visited: August 10, 2018

[40] Executive Order review:
https://www.reginfo.gov/public/Forward?SearchTarget=RegReview&textfield=0910-AG81
Last visited: August 10, 2018

that the rule was consistent with the executive order requirements. “The consistent with change category includes all rules that were changed between their formal submission to OIRA for review and their issuance by the agency, regardless of the source or the significant of the changes made” (GAO Report 2003, 72). It is possible to imply here that the changes might have been made when the regulated party met with the OIRA officials.

If the same regulated parties participate in both the rulemaking and OIRA review, I should be able to see their influence on the final rule that gets published in the federal register. The main reasoning behind this argument is that the concerns communicated by the interest group through various contacts with the policymakers are usually similar. Therefore, in this case, the impact of regulated group’s participation in the rulemaking process as well as OIRA review can be seen in the final rule (if the FDA is captured by the regulated parties). I collected information on the final rule from the Federal Register. Out of the three recommendations made during the comment period, the final rule did incorporate one recommendation (i.e., creation of appropriate mechanism for calculating user fees).

IV. Discussion and Future Research

The motive of this paper was to analyze the capture of the Food and Drug Administration by the regulated parties. This paper makes two contributions to vast literature on interest group influence on the regulator: 1). Scholars who accept or deny the interest group influence tend to focus on all the rules that originate during the given number of years. They do not consider the complete rulemaking cycle that the rules need to undergo in order to become laws. Although hundreds of rules originate every year, they do not reach the ultimate final rule stage. This paper looks at only those rules that moved from proposed rule to final rule within a single presidential administration. 2). Most studies on lobbying activity and their

influence base their results on a single activity that the interest groups/regulate entities undertakes. In reality, in order to get their preferred policies implemented, these groups leave no stone unturned. This study attempts to fill this gap and analyzes those groups that comment both during the rulemaking phase and also meet the OIRA officials when the rule is under review in the executive.

The results of this paper reveal the presence of capture effect when regulated companies participate in the rulemaking process. Rules which were high in regards to the number of comments, salience and complexity changed their final rules to incorporate one or more commenter recommendations. Three out of five rules that were high on salience and complexity (irrespective of the number of comments) had recommendations from comments being implemented in the final rule. These results provide support to the first hypothesis of the paper.

The second analysis in the paper attempts to show the presence of capture theory when the regulated parties lobby both the rulemaking process as well as the executive (during OIRA review of the rules). Through the OMB reviews, the executive enjoys significant influence over the rulemaking process. Although the availability of data has improved after the passage of executive order 12866, it is difficult to connect the meeting records with rule under review before April 2014 for the FDA. As there is only one rule where the regulated parties engaged in both channels of influence, I provided a case study analysis of the rule. This case study shows little evidence of capture in the case of the Food and Drug Administration, hence, not lending much support to my second hypothesis.

The main drawback of this study is the small number of observations which makes utilization of any statistical analysis unfeasible. As a result the results are not generalizable.

However the main advantage of this qualitative study is that it helped provide an in-depth understanding of the rulemaking/OMB review process and the techniques utilized by the regulated organizations to influence the regulator. Long term goal of this study includes analyzing rules with more than fifteen comments which will increase the availability of data making statistical inference possible.

APPENDIX 1

Description of rules examined in the rulemaking process

RIN	Title	Abstract
0910-AF36	Over-The-Counter (OTC) Drug Review--Internal Analgesic Products	The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products. The third action addresses combination products containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. The fourth action addresses other miscellaneous issues relating to internal analgesics. The fifth document finalizes the document regarding the required warnings and other labeling. The last document finalizes the Internal Analgesic Products monograph.
0910-AF82	Postmarket Safety Reporting for Combination Products	The proposed rule would clarify the postmarket safety reporting requirements for combination products (combinations of a drug, device, and/or biological product). The proposed rule would provide a framework for the reporting of adverse events for combination products. The proposed rule would clarify that a combination product is subject primarily to the reporting requirements associated with the type of marketing application under which the product is approved or cleared. In addition, the proposed rule identifies unique reporting provisions that must be complied with if applicable. The regulation would ensure the consistency and appropriateness of postmarket safety reporting for combination products while avoiding the need for duplicative reporting requirements.
0910-AF86	Medical Device Reporting; Electronic Submission Requirements	The Food and Drug Administration (FDA) is proposing to amend its postmarket medical device reporting regulations to require that manufacturers, importers, and user facilities submit mandatory reports of medical device adverse events to the Agency in an electronic format that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. The proposed change would help the Agency to more quickly review safety reports and identify emerging public health issues.
0910-AF88	Electronic Registration and Listing for Devices	This rule will convert registration and listing to a paperless process. However, for those companies that do not have access to the Web, FDA will offer an avenue by which they can register, list, and update information with a paper submission. The rule also will amend part 807 to reflect the timeframes for device establishment registration and listing established by sections 222 and 223 of Food and Drug Administration Amendment Act (FDAAA) and to reflect the requirement in section 510(i) of the Act, as amended by section 321 of the Public Health Security and Bioterrorism Preparedness and Response Act (BT Act), that foreign establishments provide FDA with additional pieces of information as part of their registration.
0910-AF96	Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements	The final rule would amend FDA's postmarketing safety reporting regulations for human drug and biological products (21 CFR part 310.305, 314.80, 314.98, 600.80, and 600.81) to require that safety reports submitted to the Agency by persons subject to mandatory reporting requirements be transmitted in an electronic format that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. The rule will allow the Agency to review safety reports more quickly, to identify emerging safety problems, and disseminate safety information more rapidly in support of FDA's public health mission. The amendments would be a key element in harmonizing FDA's postmarketing safety reporting regulations with international and ICH standards for the electronic submission of safety information.
0910-AF97	Abbreviated New Drug Applications and 505(b)(2)	This proposed rule would make changes to certain procedures for Abbreviated New Drug Applications and related applications to patent certifications, notice to patent owners and application holders, the availability of a 30-month stay of approval, amendments and supplements, and the types of bioavailability and bioequivalence data that can be used to support these applications.

0910-AG29	Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure	The regulation would implement section 515A(a) of the Federal Food, Drug, and Cosmetic Act (added by FDAAA) by amending part 814 to require applicants who submit premarket approval applications (PMAs), product development protocols (PDPs), and applications for humanitarian device exemptions (HDEs) to include readily available information regarding the actual and potential pediatric use of their medical device. These applications must include if readily available: A description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and the number of affected pediatric patients. The proposed rule does not require additional clinical research or other costly efforts, and simply requires the applicant to briefly summarize readily available information that will have been reviewed by the applicant during the course of its development of the device and preparation of its application to FDA. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure; the number of approved devices labeled for use in pediatric patients; the number of approved pediatric devices that were exempted from a review fee pursuant to section 738(a)(2)(B)(v) of the act; and the review time for each such device.
0910-AG39	Tobacco Product Substantial Equivalence Exemptions	This rule implements the substantial equivalence exemption provision of the Family Smoking Prevention and Tobacco Control Act. The Secretary may exempt from the requirements relating to demonstration that a tobacco product is substantially equivalent, tobacco products that are modified by adding or deleting a tobacco additive or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines the modification would be a minor modification of a tobacco product that can be sold under the law, a report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health, and an exemption is otherwise appropriate.
0910-AG48	Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices	This rule will amend FDA's regulations on acceptance of data from clinical studies for medical devices to require that clinical studies conducted outside the United States in support of a premarket approval application, humanitarian device exemption application, an investigational device exemption application, or a premarket notification submission be conducted in accordance with good clinical practice.
0910-AG74	Use of Certain Symbols in Labeling	The purpose of this rule is to allow for the inclusion of certain stand-alone symbols contained in a standard that FDA recognizes, provided that such symbols are explained in a symbols glossary that contemporaneously accompanies the medical device.
0910-AH08	Additions and Modifications to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness	This rule would update and amend the list of drug products to add to or modify the list of drug products that may not be compounded because the drug products have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective.
0910-AH12	Administrative Destruction of Certain Drugs Refused Admission to the United States	The rule would provide the owner or consignee of a drug that has been refused admission into the United States and that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) with written notice that FDA intends to destroy the drug and an opportunity to present testimony to the Agency before the drug is destroyed.

APPENDIX 2

Meeting Records

Selected agency: **Food and Drug Administration**

Tue Feb 25 2014. **Topic: Tobacco Products: Subject to the Federal Food, Drug, and Cosmetic Act as, as Amended by the Family Smoking Prevention and Tobacco Control Act.**
Tue Feb 25 2014. **Topic: Tobacco Products: Subject to the Federal Food, Drug, and Cosmetic Act as, as Amended by the Family Smoking Prevention and Tobacco Control Act.**
Tue Feb 4 2014. Topic: **Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products.**
Fri Jan 17 2014. Topic: **Tobacco Deeming.**
Tue Jan 14 2014. Topic: **"Tobacco Products" Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act.**
Mon Jan 13 2014. Topic: **"Tobacco Products" Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act.**
Mon Jan 13 2014. Topic: **Electronic Dist. of Prescribing Information for Human Prescription Drugs Industry Biological Products.**
Wed Jan 8 2014. Topic: **"Tobacco Products" Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act.**
Mon Jan 6 2014. Topic: **Tobacco Deeming.**
Fri Jan 3 2014. Topic: **Tobacco Deeming.**
Thu Jan 2 2014. Topic: **Tobacco Deeming.**
Mon Dec 30 2013. Topic: **Tobacco Deeming.**
Mon Dec 30 2013. Topic: **Tobacco Deeming.**
Mon Dec 23 2013. Topic: **"Tobacco Products" Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act.**
Fri Dec 20 2013. Topic: **Tobacco Deeming.**
Fri Dec 20 2013. Topic: **Tobacco Deeming.**
Thu Dec 19 2013. Topic: **Tobacco Deeming.**
Thu Dec 19 2013. Topic: **Tobacco Deeming.**
Wed Dec 18 2013. Topic: **Tobacco Deeming.**
Wed Dec 18 2013. Topic: **Tobacco Deeming.**
Mon Dec 16 2013. Topic: **Tobacco Deeming.**
Fri Dec 13 2013. Topic: **Tobacco Deeming.**
Thu Dec 12 2013. Topic: **Tobacco Deeming.**
Wed Dec 11 2013. Topic: **Tobacco Deeming.**
Fri Dec 6 2013. Topic: **Tobacco Deeming.**
Fri Dec 6 2013. Topic: **Tobacco Deeming.**
Thu Dec 5 2013. Topic: **Tobacco Deeming.**
Thu Dec 5 2013. Topic: **Tobacco Deeming.**
Wed Dec 4 2013. Topic: **"Tobacco Products" Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act.**
Tue Dec 3 2013. Topic: **Tobacco Deeming**
Tue Dec 3 2013. Topic: **Tobacco Deeming.**
Mon Dec 2 2013. Topic: **Tobacco Deeming.**
Tue Nov 26 2013. Topic: **Tobacco Deeming.**
Mon Nov 25 2013. Topic: **Tobacco Deeming.**
Mon Nov 25 2013. Topic: **Tobacco Deeming.**
Wed Nov 20 2013. Topic: **Tobacco Deeming.**
Wed Nov 20 2013. Topic: **Tobacco Deeming.**
Mon Nov 18 2013. Topic: **Veterinary Food Directive.**

APPENDIX 3

List of companies that commented for rule (RIN: 0910-AG81)

Rule Title	Organizations
Requirements for the Submission of Data Needed to Calculate User Fees for Manufacturers and Importers of Tobacco Products	**Small Manufacturers Association for the Reasonable Treatment of Tobacco (SMARTT)**
	Altria Client Services
	Cigar Association of America
	Council of Independent Tobacco Manufacturers of America (CITMA)
	Electronic Cigarette Industry Group (ECIG)
	Lorillard Inc.
	Cigar Rights of America (CRA)
	Pipe Tobacco Council
	Reynolds American Inc. (RAI Services)
	Tantus Tobacco Sales

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CONCLUSION AND FUTURE RESEARCH

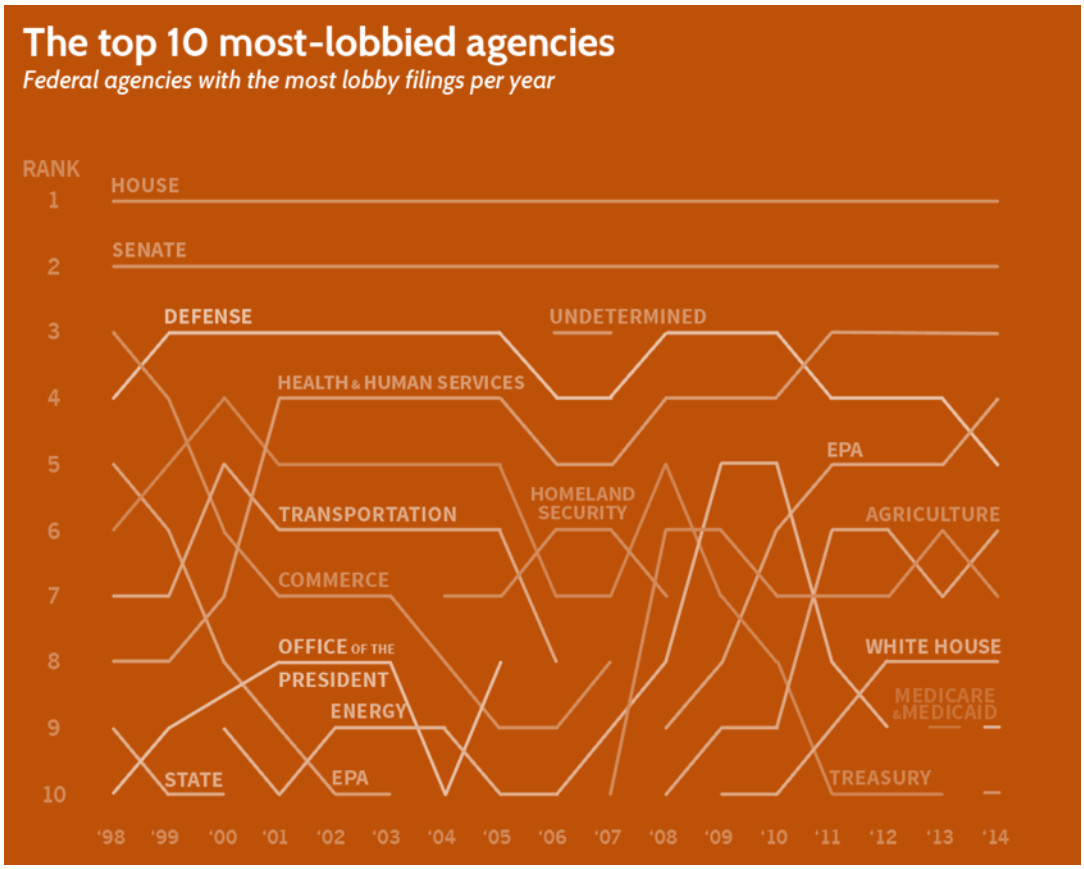
Regulatory agencies are created for fulfilling two major goals: a). To protect the well-being of the people; and b). Creation of new laws through rules and helping Congress in implementation of laws. As these new laws have an impact on the regulated companies, interested parties try to participate in the creation and passage of such laws. Among the myriad ways of involvement, lobbying and campaign contributions constitute one of the ways of influencing regulations. In words of Jorgensen (2013, 564), "if you are paying the people who solve social problems, you may have a say in deciding what gets called a social problem". In other words, when a resource dependent political parties receive campaign contributions or money through lobbying from the pharmaceutical company, the enacted legislation might reflect a bias towards the moneyed interests rather than the general public interest.

This dissertation focusses on one regulatory organization - The Food and Drug Administration (FDA), federal agency of the U.S. Department of Health and Human Services. The FDA is one of the most powerful and most lobbied agency in the U.S. According to Figure 1, the Department of Defense was the most lobbied agency from 1999-2011. The Health and Human Services was the second most lobbied agency from 2001-2011, and became the most lobbied agency since then.

The impetus of this study was to determine the motivation behind the decisions taken by the FDA. The two competing explanations included Public Interest and Capture Effect. The papers in this dissertation show that the organized interest groups/regulated companies achieve their favorable policies at the expense of public interest.

Figure 1.

Most Lobbied Federal Agencies (1998-2014)



Source: PBS (https://www.pbs.org/newshour/politics/agencies-lobbies-target)

Besides showing the presence of capture in the decisions of the FDA, this dissertation explores the channels of influence utilized by the regulated companies. In the first paper, I analyzed the influence of the regulated companies indirectly through the Congress. The result revealed a positive and significant relationship between campaign contributions received by the members of Congress and the bills sponsored by them.

The second paper tests the direct impact of lobbying contributions on the number of new drug applications approved by the FDA. The analysis reveals that with an increase in lobbying contribution, there is also an increase in the number of drug applications approved.

Also, bigger companies are able to spend more money on lobbying, and hence, more approvals. Companies that get more approvals are also the ones that submitted applications for lifesaving medications – e.g. cancer or HIV. It can be implied that FDA takes into consideration the type of ailment while making decisions about approvals.

The third paper incorporates the role of institutions on the bureaucratic decision making. As the bureaucracy's decision to issue rules are based on the political influence utilized by the executive and legislative branches, the regulated companies try to influence FDA's decisions by lobbying through both these institutions. The first half of the paper builds on existing scholarly research and shows that interest groups exercise their influence over FDA through the rulemaking process. The second half of the paper analyzes the impact on final rules when regulated companies lobby during the rulemaking phase as well as rule review phase by the executive. The case study analysis shows some positive effect between simultaneous lobbying and final rules that gets published in the federal register.

Although the papers in this dissertation show positive influence of regulated companies on the regulator, there are some drawbacks that needs to be addressed. Due to lack of more data points, the results of the third paper are not generalizable. Future extension might include collecting data on more than one presidential administration which will increase the number of data points. Doing so will also help us analyze the impact of change in policy priorities on the entire rulemaking process.

The decision to issue rules by the federal agencies is partly dependent on the bureaucrats' incentives (Potter and Shipan). Sometimes the bureaucrats may issue favorable rules, so that they can work with the regulated companies in the future. Therefore, future work must include some control in order to account for the revolving door incentive.

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