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doi: <https://doi.org/10.57709/28891085>

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Pharmacist of the Bench

by

Levi W. Hudson

Under the Direction of Michael Fix, PhD

A Thesis submitted in Partial Fulfillment of the Requirements for the Degree of

Master of Arts

in the College of Arts and Sciences

Georgia State University

2022

## ABSTRACT

The theory of this thesis is that U.S. Court of Appeals case decisions influence rule changes made by the FDA. My hypotheses are (1) Republican appointed judges will favor businesses more often than Democrat appointed judges, (2) when businesses are favored more than consumers the FDA will reduce regulation, and (3) when regulation is reduced there will be an increase in drug approvals. hypothesis 4 states drug approvals decrease when Democrats hold a majority. Hypotheses 1, 2, and 3 were all tested using a  $\chi^2$  analysis for the years 2010, 2011, 2015, and 2016. A descriptive analysis of FDA policy changes is also complete for hypothesis 2. Hypothesis 4 is tested using a time series analysis. Hypotheses 1 and 3 found support. However, the findings of hypothesis 2 suggest political make-up matters more than case decisions. Table 5 supports hypothesis 4, but table 6 does not.

INDEX WORDS: Principle-agent theory, Drug regulation, Food and Drug Administration, Judicial ideology, Judicial decision making, Inter-branch relations

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2022

Pharmacist of the Bench

by

Levi Wayne Hudson

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College of Arts and Sciences

Georgia State University

May 2022

## DEDICATION

This dedication is to my family and friends who have supported my academic success and given me a familiar outlet. I am a first-generation college student from rural South Georgia. My parents are Christy M. Lovett and W. Wayne Hudson. My brother who has autism, Walker Hudson, has always been my partner in challenging the world. We both want to prosper beyond our upbringings and not be bound by any limitations. My family does not understand my work or my academic progress. Despite that, this is my way of moving forward, and they offer their best wishes and respect my decisions. My knowledge of politics, law, and government functions was first noticed by my stepfather, Dan Lovett. He proposed that I study law to show my skills in legal research and knowledge of the government. This May, I will be graduating with a focus in Public Law.

Going to college was a fantasy for me, and it is a dream I would have never attempted if not for the motivation given by my close friend Garrett Bennett. I wanted to perform just as well as he and my other peers. I wanted to be more ambitious, and I saw academic success as being ambitious at the time. I would have never gotten this far in my academic career if not for the spark that Garrett ignited and the flame he guided. Another close friend, Landon Molnar, is the only close friend who truly understands the significance of my academic achievements. Without him, I am not sure I would have been able to continue my education. I felt as if nobody understood my success and struggle, even if they appreciated my progress in school. He made me feel accepted and gave me an outlet as an academic peer. I have enjoyed our many endless conversations. Lastly, Daisy Ortiz and Gavin Wise supported me immensely during the final year of my master's by helping socially and at home. I would not have been able to focus on my work without them.

## ACKNOWLEDGEMENTS

After getting into college, I was alone and didn't have a clear pathway. A man by the name of Michael Evans took me under his wing. Many inner demons and personal challenges made it hard for me to digest information. Dr. Evans gave me an outlet to challenge myself and sort through my issues. His help and guidance are why I've succeeded in academia. This world would never be in poor hands if all educators and leaders were like him. I am thankful that I could be mentored by such an amazing man.

My pathway during my undergraduate degree was pre-law and then law school. I thought law school was the only option for someone with my interest. That may sound foreign to you, but I grew up on a farm in rural South Georgia. Nobody there talks about research, government work, policy, or even college. I knew nothing of the academic world or various pathways until my first year of college. Dr. Robert Howard had completed both a JD and Ph.D. Being one of the only law degree holders in the department, I was greatly interested in what led him here. I became slightly interested in pursuing a Ph.D. after working with Dr. Howard and having multiple conversations with him. At the very least, I decided to earn my master's degree and write this thesis.

My first judicial politics course was taught by Dr. Stephanie D. Kerce. She is a great educator who listens to her students and challenges them to succeed. Dr. Amy Steigerwalt was the first to teach me judicial politics at the graduate level. Dr. Steigerwalt is a fantastic researcher and teacher who furthered my interest in pursuing a Ph.D. Dr. Michael Fix made the groundwork and accomplishments of everyone else seem obtainable. He is the only faculty I've encountered who is also a first-generation college student from a poor rural background. His existence and guidance gave me the hope I desperately needed to succeed.

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## 1 INTRODUCTION

Does the health and general welfare of our nation depend on the identity of non-elected leaders? I believe there is a chance of the United States Food and Drug Administration (FDA) being influenced by the United States Courts of Appeals. To evaluate this assumption, we will need to establish the research of my predecessors who greatly influenced my belief. There are four literature review sections in this thesis. Primarily, we are focusing on principal-agent theory. Principal-agent theory attempts to predict the influence of principles on the actions of agents; in this case, the Court of Appeals' influence on the FDA. We know that judges influence the Internal Revenue Service (IRS) (Howard and Nixon 2003). Howard and Nixon did a study to test if the IRS was influenced by the judiciary's majority ideology. What they found was under a conservative Appeals court majority, the IRS would audit individuals more often than businesses (Howard and Nixon 2003). Of course, the oversight of the judiciary on administrative agencies is not limited to the U.S. Appeals Courts' authority over the IRS.

This research thesis hopes to add onto the current conversation within literature and research regarding known FDA influencers, ideological decisions of judges, and principle-agent theory. It has come to my concern that the health and general welfare of our nation may depend on the identity of non-elected leaders. It is the primary concern of this thesis to discover if the FDA's drug regulation policy decisions and annual drug approvals are influenced by the courts. To establish more known FDA influences I am analyzing if the FDA makes different rule changes or consistent variations in drug approvals when the courts change how they rule on cases. I also believe that courts change how they rule on cases primarily when the majority ideology changes. If my theory is correct, this will establish the judiciary as an influencer of the FDA. Therefore, supporting principle-agent theory and adding another example to the existing

literature. The information we currently have on ideological decision making and the prediction of choices made by judges based on their political appointment is not extensive. There is currently no known literature regarding how Appeals Court judges, Republican or Democrat, rule on pharmaceutical liability cases. There will be literature answering that question by the time this thesis is done. If Republican and Democrat appointed judges consistently make difference decisions than each other, it would support positive theory. Because it would show that the decisions of judges can be predicted by the judge's political affiliation.

This thesis is very important for two major reasons. Firstly, this thesis will determine if scientist decisions that impact public health are influenced by non-elected political leaders. Secondly, it answers an important question of what the difference between decisions made by Republican and Democrat appointed judges could be. Answering this question brings us a step closer to "what is liberal and what is conservative" (Howard and Steigerwalt 2012). Many Political Scientist who study the courts hope to predict votes and measure ideology. Future research focusing on pharmaceutical product liability could use this thesis as a guide to what is likely a conservative or liberal decision. Our results show that over U.S. Court of Appeals Republican appointed judges rule in favor pharmaceutical drug manufacturers 48% more often than their Democrat appointed peers. If we consider most Republicans to be conservative, then it is likely that conservatives are more likely to rule in favor of pharmaceutical manufactures than liberals. This statement is also consistent with Supreme Court decisions. With that said, I find the first reason much more meaningful. Many Americans rely on safe and effective medication. For the regulation of these drugs to be contingent on the party affiliation or ideology of judges is worrying to say the least. If it is the case that the U.S. Court of Appeals influences drug

regulation done by the FDA, then a cost benefit analysis would be required by future research. Those who rely on medication deserve to know how to vote in their best interests.

This thesis seeks to establish known FDA influences, how our legal system works, the process of New Drug Application (NDA), how the judiciary influences agency decisions, that judges have political policy preferences, court decisions often favor the ideology of the judge, and that the ideology of judges influences FDA drug regulation policy. The theory of this thesis is that (a) the decisions of the U.S. Court of Appeals influence rule changes made by the FDA, (b) that political affiliation influences judges to make different decisions on cases concerning pharmaceutical liability, (c) when the ideological majority of the Court of Appeals shifts we expect to see a change in the types of decisions made, and (d) the FDA's rule changes will be influenced by the court's decisions. The reason I believe the U.S. Court of Appeals attempts to influence the FDA is because the judges in those courts have policy preferences they wish to see come into fruition, and the FDA fears having its scientific authority and autonomy challenged by the courts. Judges have a chance at their preferences becoming policy when they create precedent that favors their wants, and the FDA does not want that precedent to negatively affect them. The research completed in this thesis will add to the conversation of principle-agent theory and effect of ideological bias in the courts. Public debate regarding general welfare, the legitimacy of our courts, drug safety, and trust toward health agencies like the FDA is growing in modern political conversation (Annenberg Public Policy Center 2021; Braman and Easter 2014; Olsen and Whalen 2009; The Robert Wood Johnson Foundation 2021). Not only will finding the answers to my questions contribute to the scholarly research regarding principle-agent theory and legal ethics, but it may also contribute to current political debate.

My hypotheses are (1) in the U.S. Court of Appeals Republican appointed judges will favor businesses more often than Democrat appointed judges, (2) when the U.S. Court of Appeals favors business more often than consumers the FDA will reduce regulation requirements for drug manufacturers, and (3) when the FDA reduces regulation there will be an increase in the overall number of annual drug approvals. Lastly, hypothesis 4 states that the FDA reduces drug approvals when Democrats hold a majority in the U.S. Court of Appeals. Therefore, (4) drug approvals will increase the year following a Republican appointed majority in the U.S. Court of Appeals. Hypotheses 1, 2, and 3 were all tested using a  $\chi^2$  analysis for the years 2010, 2011, 2015, and 2016. Results for hypothesis 2 were mixed. To test hypothesis 4, I used a time series analysis testing all years from 1940 to 1990. The time series analysis found mixed results. Without a lagged dependent variable, there was a strong correlation between party affiliation of the U.S. Court of Appeals and annual drug approvals. However, there was no significance found after the lagged dependent variable was included in the analysis. The first test had a Republican appointed majority, and most case decisions were ruled in favor of businesses. For both 2010 and 2011, which are the majority Republican years, the FDA decreased regulation requirements for businesses. However, in 2015 and 2016 majority of the decisions still favored businesses. While the gap between businesses and consumers decreased, there was still a disparity in decisions. Despite this fact, the FDA decreased regulatory requirements following 2015 and 2016. The major difference between 2015 and 2016 is that Democrat appointed judges now held a majority in the U.S. Court of Appeals. It is indeed true that Democrat appointed judges favored consumers more often than their Republican peers. Therefore, hypothesis 1 is true and there were no mixed results in either analysis regarding this. Lastly, hypothesis 3 also found support. When the FDA reduced regulation in 2010 and 2011 there was an increase in drug approvals the following year.

In 2015 and 2016 when the FDA increased regulation there was a decrease in drug approvals the following year.

## 2 LITERATURE REVIEW

### 2.1 Law and Drug Regulation

Before exploring the literature and research of principle agent theory and the other theoretical beliefs this thesis hopes to thoroughly explain, we must first discuss how our legal system works. Our legal system operates on the idea that an individual must first file a complaint to start court activity. To gain standing in the courts, specific requirements must be met, particularly if one is to build a case against large pharmaceutical manufactures or bureaucratic institutions like the Food and Drug Administration (FDA). This article is focused on the FDA; because of this, we will only be discussing health care/pharmaceutical personal injury and product liability cases.

For a drug to be marketed legally to the public, it must first become FDA approved. New drugs must go through the NDA. In the United States, "every new drug has been the subject of an approved NDA before U.S. commercialization" (U.S. Food and Drug Administration 2019). During this process, the "FDA reviews the drug's professional labeling and assures appropriate information is communicated to health care professionals and consumers" (U.S. Food and Drug Administration 2019). After this process is complete, it is marketed to the public and sold to drug consumers and healthcare providers.

If an issue occurs regarding an FDA-approved drug, either with the state or an individual consumer, then litigation may ensue. Pharmaceutical products liability is the main legal battle drug consumers are likely to engage in. The leading players in these cases are usually drug manufacturers and drug consumers. The courts are the only option of relief for drug consumers (Cooper 1986). The FDA cannot offer relief; all they can do is either increase or decrease the regulation of drug manufacturers (Cooper 1986). The regulation of pharmaceutical manufactures

is complex and controversial. Despite the controversy, drug litigation plays a significant role in public health, public law, and private law (McCuskey 2018). It has become a recent trend to decrease the regulation of generic drugs to decrease their prices, but the increase in economic gains comes at the cost of public health and lower quality drugs (Lindenfeld and Tran 2015; McCuskey 2018). However, these efforts to decrease prices have not worked, there is research that shows decreasing regulations and giving immunities to drug manufacturers have "done nothing to combat the price of drugs" and that it has only decreased "thorough premarket testing and studies, putting consumers of generic drugs at an increased risk of injury" (Lindenfeld and Tran 2015). If Lindenfeld and Tran are correct, then not only does decreasing regulations not reduce the price of drugs, but it allows the market to be filled with drugs that have an "increased risk of injury" (Lindenfeld and Tran 2015).

The Supreme Court has added to the debate by stating that the "proper role of federal regulation and state tort laws in promoting product safety" (Davis 2007). The courts used to focus on protecting consumers and giving injured consumers relief, but in recent times, the courts' view additional state drug regulation and consumer protections as a threat to manufacturers and the legitimacy of the FDA (Davis 2007). Some courts have questioned if state laws make it impossible for manufacturers to "comply with both state and federal law" (Sharkey 2008). This may be a change in the legal interpretation of administrative law; however, it may also be because of a change in the political beliefs of the majority of seated judges. Later in this thesis, we will discuss judicial ideology and the political actions of the courts.

## **2.2 Known FDA Influences**

All administrative agencies are at risk of being challenged and being checked by the judiciary. Because of this, our nation's health agencies are also able to be challenged and

checked by the judicial branch of government. I believe it is likely that health agencies, such as those under the HHS, are also influenced by the judiciary. It is the primary concern of this thesis to discover if the FDA's drug regulation policy decisions are influenced by the courts. There is already research showing that the courts played an important role in the FDA's changes to tobacco regulation (Lax and McCubbins 2006). Lax and McCubbins found that judiciary does "wield decisive power over tobacco regulation and their decisions had a major impact on the probability that tobacco would ultimately be regulated by the FDA" (Lax and McCubbins 2006). While this does not show that the judiciary plays a powerful role in drug regulation, it does show that the judiciary has the potential ability to influence the FDA when it comes to regulation. However, there is no literature surrounding how the judiciary influences drug regulation. We do not know if any part of the judicial branch influences drug approvals, pharmaceutical policy, medication labeling requirements, or any other FDA drug related decisions. This research thesis hopes to add onto the current conversation within literature and research regarding principle-agent theory by showing that even in areas that require high scientific and health related expertise, such as pharmaceutical regulation and drug approval, the U.S. Court of Appeals can still influence the decisions made by administrative agencies and the experts within them.

The FDA is the federally agency that controls what drugs get approved and the drug regulations manufactures must follow in order to sell their product. Something that must be followed is the FDA's guidelines on labeling. Failure to follow labeling guidelines could result in recall of the drug and even a lawsuit against the manufacture. Are the actions of the FDA influenced by anything? It is believed that the FDA may be influenced by many different things and institutions. Agencies may make "policy decisions within given regimes and may be constrained by the preferences of different political actors at different times" (Shipan 2000).

During 1972-92 the FDA was under pressure to increase product approvals, and to get this done the FDA reduced monitoring and substituted less resource-intensive enforcement (M. K. Olson 1995). This basically means that there was less regulation and the FDA checked products less often. During this time, the median ideology of the Supreme Court was conservative. Which would lead one to believe that conservative justices favor less regulation. With less regulation, the FDA would be able to increase annual drug approvals with ease.

Does the funding of the FDA influence their drug approvals? The source of the FDA's funding does not likely play a major role in the variation of New Drug Application (NDA) approval (Carpenter et al. 2003). However, the "amount of resources devoted to the FDA" does explain variation in NDA approvals (Carpenter et al. 2003). If the Center for Drug Evaluation and Research (CDER) receives more funding, they can increase their staff. Increasing the number of CDER staff members has a significant impact on shortening the duration of NDA reviews (Carpenter et al. 2003). Which would increase the amount of drug approvals. With that being said, there is a study that suggest increased funding and resources alone are not enough to explain the increase in drug approvals and decrease in drug-review times (M. K. Olson 2004).

Do the other branches of government influence the FDA? There are studies that support the idea that the president influences many federal agencies; however, the extent of this influence is not precise and is not focused on the FDA specifically (Clinton, Lewis, and Selin 2014; Howell and Lewis 2002). The president is the one who appoints people to the FDA (Furlong 1998). The presidents can appoint people to the FDA, or practically any executive federal agency, that agree and will listen to them. The President may also use their powers to make budget changes and use the Office of Management and Budget review actions to influence federal agencies like the FDA (Furlong 1998). President Clinton liked to go public and have

media attention for his announcements against tobacco companies (Cook 2001). Signaling to Congress, the judiciary, the public, and the FDA what his preferences were regarding tobacco.

A study found that “the FDA is responsive to the preferences of committees and floors in Congress, but under other conditions the agency can act autonomously” (Shipan 2004). However, this same study also found that elected politicians do not influence the FDA in any linear fashion. It appears that under some conditions Congress can influence the FDA, but under many conditions Congress does not influence the FDA (Shipan 2004). With that being said, if the FDA deviates from congressional preference, then Congress may cut FDA funding from the budget (Hermes 2001). If Congress were to cut funding, that would decrease FDA drug approvals (Carpenter et al. 2003). While it may be difficult to show that any particular agency is subject to either capture or congressional control, it is very likely that the FDA can be influenced by Congress (M. K. Olson 1995). However, it is believed that modern Congress delegates power to administrative agencies in convenience (Lawson 1994). This allows agencies like the FDA to work without contently requesting for jurisdiction or permission. The reason Congress did this may indicate that they wanted the FDA to operate with little political influence.

There is also a study that supports the idea that the judiciary plays a major role in influencing the FDA, this study shows that the courts have influenced the FDA through tobacco litigation (Lax and McCubbins 2006). There used to be much controversy regarding the harmful effects of tobacco on public health. These debates did not stop at social discourse; they were taken to the courts. Lax and McCubbins concluded that the court do “wield decisive power over tobacco regulation and their decisions had a major impact on the probability that tobacco would ultimately be regulated by the FDA” (Lax and McCubbins 2006). The legal and financial pressure that the courts can put on the FDA and businesses is believed to be a strong influencer.

The FDA might want to act in the best interest of judges to avoid court. Especially when “the decision of a single district court judge” can cost one reputational and financial harm (Lax and McCubbins 2006).

In regard to drug regulation and labeling, the FDA has filed multiple "amicus briefs expressing the view that the FDA approval should preempt failure-to-warn claims in prescription drug cases" (Masters 2014). The courts have not fully adopted the wants of the FDA, but conservative decisions like *Mutual Pharmaceutical Co. v. Bartlett*<sup>1</sup> do lean in that direction (Masters 2014; Wolfman and King 2013). This would suggest that rather than the courts influencing the FDA, the FDA is the principle that influences the judiciary agents. We will discuss *Mutual Pharmaceutical Co. v. Bartlett* later in this article; alongside another Supreme Court decision that had a liberal majority called *Wyeth v. Levine*<sup>2</sup>.

### **2.3 Judicial Oversight and Agency Relationships**

This section will discuss the relationship the court has with bureaucracies and specifically the FDA. The courts are able to review almost any of the FDA’s actions. The courts are able to do this through judicial review. Most legal issues regarding drugs and the FDA are going to be related to regulations and procedures that the manufacturers are supposed to follow. The courts are able to preside over these issues because of the Administrative Procedure Act (APA). Judicial review is supposed to prevent agencies from overstepping their bounds and deter them from acting when their action is not appropriate (Seidenfeld 2009). Agencies are made with a statutory authority, and it is important to make sure that agencies stay focused on their purpose. Meaning that the FDA should make policies regarding drug approvals, regulations on the

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<sup>1</sup> *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 570 U.S. 472, 186 L. Ed. 2d 607 (2013).

<sup>2</sup> *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009).

manufacture, and drug labeling requirements. The FDA should not be regulating the carbon emissions of factories. The courts review these actions, and the manufacture may be sued when they do not follow the regulations legally put in place by the FDA.

This idea that the judiciary influences agency actions, besides making direct changes via case decisions, is central to principal-agent theory. Principal-agent theory is one of the essential theories and primary principles that this thesis is discussing. The foundation of principle agent theory regarding the courts is this belief that "judicial review of agency regulation" will influence administrative agencies, such as the FDA, to make changes to policy (Seidenfeld 2009). There is also the belief that support the idea that Supreme Court opinions influence agency policy changes (Spriggs 1996). Judicial review's purpose is to stop agencies from attempting to gain power over areas outside of their purpose and prevent them from creating actions or regulations that are not appropriate to their designation (Seidenfeld 2009). Because of this, the courts are given the power to use judicial review to check and correct the changes in policy made by federal agencies, such as the FDA (Crowley 1987; Humphries and Songer 1999; Seidenfeld 2009).

Since we all now know the FDA drug approval process and the role courts have in legal drug disputes, the question is if the courts can influence agencies. It has already been established that the judiciary's majority ideology influences the decisions of the IRS (Howard and Nixon 2003). Howard and Nixon's study on the IRS and judicial influence found that the IRS conducted more audits on businesses during a liberal majority in the federal court of appeals, and more audits on individuals when the federal court of appeals was majority conservative (Howard and Nixon 2003). This is similar to what one may expect from the relationship between the courts and the FDA. It may be the case that when the U.S. Courts of Appeals has a liberal

majority that the FDA increases regulation on drug manufactures to protect the health of individual drug consumers. It appears that the liberal courts prefer to put less pressure on the individuals and that conservative courts prefer to free businesses from the burden of too much oversight.

Some scholars suggest that the Courts are concerned about the direction of policy (Crowley 1987; Shapiro 1964). Depending on the Court's ideology, they may seek different agency decisions and regulation outcomes. If agencies are aware that different court ideologies want different outcomes, then they might act in favor of the court majority. Agencies do pay attention to court decisions, and that the "bureaucracies are more likely to implement larger policy changes when resources favor the Court" (Spriggs 1996). Meaning that federal agencies like the FDA are more likely to implement changes in favor of the courts' wants. With this in mind, it is believed "that the courts of appeals are staffed with judges who are policy oriented and attempt to bring agency policy into line with their own policy preferences, but feel constrained to pursue their preferences within limits set by the law" (Humphries and Songer 1999). These principle-agent theory findings support my belief that the courts influence the FDA, and that this influence is based on the courts' political policy preferences. It appears that the Supreme Court also shifts the Court of Appeals. When the Supreme Court precedent shifts in a conservative direction, the lower court decisions from both liberal and conservative judges will also shift in a conservative direction (Humphries and Songer 1999).

The FDA has very little ability to offer redress for private injuries, product liability cases are reviewed and evaluated by judges and juries (Cooper 1986). To protect citizens from bad or illegal usage of drugs, the courts are needed. Drug manufacture regulation is complex and controversial, and drug litigation plays a big role on public health, public law, and private law

(McCuskey 2018). Different courts want different outcomes, the “Circuit Court of Appeals cannot even agree on preemption analyses under the applicable Supreme Court precedent” (McCuskey 2018). How are agencies to act when their courts have different intentions? It is probably in the FDA’s best interest to act according to the preferences of the U.S. Court of Appeals. Decreasing regulation and cost of generic drugs has been a recent trend, but economic drugs come at the cost of safety (McCuskey 2018). The courts can tell the FDA and drug manufacturers what to do because of judicial review. The courts can prevent agencies from overstepping their bounds and acting in inappropriate ways according to their original purpose by using the powers granted to them in the Administrative Procedure Act (APA) and *Marbury v. Madison*<sup>3</sup> (1803) (Seidenfeld 2009).

#### **2.4 Judicial Ideology and Case Decisions**

The judiciary is the third branch of our government, and they are indeed a political institution. The courts are stacked with judges who have political preferences and policy goals (Humphries and Songer 1999). Some justices want agencies to be deregulated and the red tape removed, and these judges would be considered conservative leaning (Garland 1985; Mikva 1986). In contrast, the more liberal judges want more regulation and wish to protect the public (Ausness 2010; Garland 1985; McCuskey 2018; Mikva 1986). The difference in the wants and wishes of judges is rooted in their political beliefs and personal biases. Legal academic theorist are increasingly in favor of the evidence that suggests political affiliation is a motivating factory, if not the primary, that explains the decisions made by the judiciary (Friedman 2005). The attitudinal model says that personal political ideology influences and motivates judges to decide cases as they do. If this is the case, the question is how we expect judges to act, what preferences

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<sup>3</sup> *Marbury v. Madison*, 5 U.S. 137, 2 L. Ed. 60, 2 L. Ed. 2d 60 (1803).

do judges have, and how will their political ideology influence the formation of the decisions they make. However, I do not plan to calculate or explain how much political ideology influences the decisions of judges. What I wish to explain is how judges of different political affiliations are likely to decide cases if ideology was the primary motivation for case decisions.

Federal Court of Appeals judges have political preferences, and they will "attempt to bring agency policy into line with their own policy preferences but feel constrained to pursue their preferences within limits set by the law" (Humphries and Songer 1999). Individual judges are also concerned with the direction of policies, and they intend to make decisions that help produce good law (Crowley 1987; Hausegger and Baum 1999; Shapiro 1964). Good law does not mean objectively exceptional law; political concerns and policy preferences make this idea of good law subjective.

This thesis theorizes that the judiciary has an influence over the FDA's actions, and those judges have a preference regarding drug law and regulation outcomes based on their ideology (Crowley 1987; Hausegger and Baum 1999; Shapiro 1964). The decisions of judges become even more subjective and more closely reflect their ideological preferences as one moves up the federal judicial hierarchy (Zorn and Bowie 2010). Different ideologies favor different outcomes for law and policy (Klein and Stern 2004; McCuskey 2018). It is expected that conservative judges will act on their preferences to decrease regulation and support businesses when making decisions on drug product liability cases, because Republicans tend to favor economic policy and less business regulation (Klein and Stern 2004; Pew Research Center 2017). Meaning that conservative judges are more likely to favor businesses than consumers, and they do not wish for the FDA to create more regulations, even if there are health concerns. Liberal judges are predicted to be more likely in favor of increasing regulation, promote consumer protections, and

influencing the FDA to change regulatory policies that would decrease the chances of bad drugs making it into the market. This thesis hope to add onto the discussion of ideological decisions made by judges. No research currently explicitly states the types of decisions judges make based on their political affiliation. Do Democrat or Republican appointed judges make decisions in favor of drug consumers more often in pharmaceutical product liability cases? This thesis will attempt to uncover the answer to that question.

It is reasonable to believe that conservative judges are more likely to support a decrease in regulation than their liberal counterparts (Pew Research Center 2017). Democrats are more likely to support an increase in regulation or red tape, especially if it increases pharmaceutical safety and general welfare (Klein and Stern 2004). An excellent example of a liberal decision is *Wyeth v. Levine*. *Wyeth v. Levine* is a case that was ruled in favor of protecting consumers and increasing the requirements that pharmaceutical manufacturers must meet when marketing their drugs to the public. The Supreme Court ruled in this case that federal law and FDA policies do not restrict or preempt the state laws or requirements (Ausness 2010). Meaning that this Supreme Court ruling allows states to pass laws or create additional regulations and requirements that are more restrictive than the current federal FDA regulations and requirements. This was a liberal decision made to protect consumers and allow increased regulation. The Supreme Court also said that the FDA “had limited resources to monitor the 11,000 drugs currently on the market” at that time (Ausness 2010). Seems like the Court was worried that the FDA had too many drugs and not enough resources.

Another and later Supreme Court decision came from *Mutual Pharmaceutical Co. v. Bartlett*, and the decision in this case was ruled by a conservative majority. In this case, the Supreme Court ruled that additional state regulations and requirements for defect claims

regarding generic drug warnings and labels put unnecessary pressure on the manufacture and preempt federal FDA laws and policies (Wolfman and King 2013). The drug that did not meet state warning label requirements was called Sulindac, and it caused Karen Bartlett to have a severe drug reaction called Steven-Johnson syndrome, this caused the skin condition toxic epidermal necrolysis (Wolfman and King 2013). The condition caused permanent and serious injuries to Karen Bartlett. Yet, the Supreme Court ruled that “generic drug manufactures will not face liability” if they meet FDA requirements (T. W. Olson 2015). This means that if the FDA approves of a warning label, then that label is legitimate under federal and state law. This means that “injured generic drug consumers will remain without any legal remedies” when they are harmed by these drugs that are approved by the FDA (T. W. Olson 2015).

The FDA may be aware of the court’s inconsistent attitudes regarding drug labeling regulations, because of the different rulings made by the courts on drug labeling preemption cases such as *Wyeth v. Levine* and *Mutual Pharmaceutical Co. v. Bartlett* (Ausness 2010; T. W. Olson 2015; Wolfman and King 2013). These rulings show individual accounts of how the liberal and conservative majorities may not be the same. These cases assist in creating an assumption that conservative majorities prefer fewer regulations on drug manufacturers and disapprove of stricter state drug labeling requirements. While liberal majorities prefer more regulation on drug manufacturers and approve of stricter state drug labeling requirements. When the courts are conservative there will be less pressure on the FDA to be strict on regulation. Because of this, one can expect more drug approvals and when the FDA is not pressured to be strict on regulation by the conservative courts. When the courts are liberal, one can expect more monitoring, regulation, and fewer drug approvals.

Conventional wisdom suggests that the political party which appointed the judge indicates the ideology of said judge, and it is believed that the judge's preferences are not drastically different from the other branches who share the same identity (Pinello 1999). Which is why it's believed that *Mutual Pharmaceutical Co. v. Bartlett* is a good example for how one may expect a conservative court or justice to rule. The Supreme Court ruled that additional state regulations and requirements for defect claims regarding generic drug warnings and labels put unnecessary pressure on manufacturers and preempt federal FDA laws and policies (Wolfman and King 2013). This is the opposite of the liberal decision made in *Wyeth v. Levine*. *Mutual Pharmaceutical Co. v. Bartlett* was a 5 to 4 decision where the five justices who ruled in favor of fewer consumer protections and regulations were all conservative. This conservative majority decision in *Mutual Pharmaceutical Co. v. Bartlett* is consistent with what one would expect after learning the opinions of conservatives in the public (Pew Research Center 2017).

The courts are a political independent institutional that uses their powers to exercise party political preferences. The "most striking evidence of judicial independence is a court's exercise of the power of judicial review" (Segal and Spaeth 2002). Reviewing agency actions with judicial review is possible because of the APA. The independent judiciary must hold the FDA accountable. However, the court views the scientific experience of the FDA as giving the organization enough merit to be given deference (O'Reilly 2007). The deference given to the FDA was mainly for the purpose of drug approvals. Of course, the courts do not have the expertise or time to check if drugs meet the requirements set by the FDA. However, the courts can do have the resources and expertise to review the legalities of drug labeling issues and product liability cases. It is when judges make decisions on these topics that they are often viewed as policymakers (Humphries and Songer 1999). The decisions of these judges often

result in either more or less pressure on drug manufacturers. As we put less regulatory pressure on those in the drug industry, we may suffer extreme health loss with increasingly risky drugs (McCuskey 2018).

### 3 RESEARCH DESCRIPTION

#### 3.1 Theory

This thesis theorizes that the decisions of the U.S. Court of Appeals influence drug regulatory rule changes made by the FDA. Despite the fact that the FDA is given lots of deference due to its scientific expertise (O'Reilly 2007). I believe this deference is likely part of the reason the FDA will follow the courts initiatives. The FDA does not want to lose any of the autonomy it has gained. Product liability cases typically challenge the drug manufactures, but they can also challenge regulatory issues like in *Wyeth v. Levine* and *Mutual Pharmaceutical Co. v. Bartlett*. Some cases may rule against FDA drug regulation and challenge its scientific authority.

We already know that the U.S. Court of Appeals and Supreme Court both play an impactful role in influencing tobacco policy and the status quo regarding tobacco regulation (Lax and McCubbins 2006). The courts can influence drug regulation in a similar manner. Their authority and power of judicial review allows them to influence policy through common law. I see no reason to believe the FDA's drug regulation is any different from tobacco. I also believe that the U.S. Court of Appeals' influence on the IRS is a good indicator that the courts likely influence other agencies like the FDA. All the prior research discussed in the literature review sections influenced my theoretical beliefs. However, my assumptions must still be tested.

It may even be possible to predict how judges of different political affiliations may rule on cases regarding pharmaceutical product liability. Research suggest that when the median federal court of appeals judge in any given circuit is conservative, the IRS is more likely to conduct audits on individual in that region than businesses (Howard and Nixon 2003). Meanwhile, the opposite is true for when the circuit has a median liberal judge. However, this

does not directly translate to judicial attitudes toward federal health agencies, like the FDA or pharmaceutical product liability cases. There is no other literature on this specific research area. Therefore, I believe we should look at the Supreme Court cases of *Wyeth v. Levine* and *Mutual Pharmaceutical Co. v. Bartlett* along with public attitudes toward regulation and the FDA. Recent polls suggest that only 26% of Republicans and 47% of Democrats trust the FDA (The Robert Wood Johnson Foundation 2021). Other polls suggest that 66% of Democrats believe that the government should regulate businesses, while only 31% of Republicans believe the same thing (Pew Research Center 2017). I want to be explicit; I do not think public polling determines case decisions or FDA policy changes. I simply believe this is an indicator of how different ideologies feel about regulation, especially regulation done by the FDA.

It is a combination of prior research, *Mutual Pharmaceutical Co. v. Bartlett*, *Wyeth v. Levine*, and current public discourse that motivated me to believe Republican appointed judges are more likely to rule against additional regulation by health agencies than Democrats. I hope to discover the answer to judicial influence on the FDA. In doing so, I will understand the different types of decisions made by judges of different political affiliations regarding pharmaceutical product liability. I believe that judges of different political affiliations have opposing policy preferences, and they attempt to make decisions on cases concerning pharmaceutical liability that move policy toward their preferences.

While I believe that the judiciary plays a very important role in the decision-making process of FDA drug regulation, others may argue that Congress plays an even more important role in said process. Congress has oversight over federal agencies. Congress makes and determines the rules that the FDA follow. Certain Congressional committees have occasionally had significant influence on the FDA (Shipan 2004). Congress can also use funding as a means

to persuade the FDA to respond positively to Congress's preferences (Carpenter et al. 2003; Hermes 2001). However, Congress typically gives bureaucratic agencies autonomy out of convenience (Lawson 1994). Under most circumstances the FDA is allowed to act autonomously without any influence or restrictions from Congress (Shipan 2004). In fact, the FDA is not influenced by elected politicians directly or linearly in any compacity (Shipan 2004). On the other hand, the FDA will always have to deal with the Courts and its influence. Research has already shown that the courts influenced the FDA on tobacco related issues (Lax and McCubbins 2006). I simply want to add drug regulation to existing literature showing how the courts influence the FDA. I believe the Courts have a greater impact on the FDA than Congress because of what existing literature suggests. In conjunction with existing literature, I believe the constant threat of losing autonomy because of court challenges will pose a greater influence on the FDA than the allowed autonomy by Congress.

The next theoretical question is why I expect the types of decisions to change depending on ideological majority in the U.S. Court of Appeals. The answer is that I believe judges will make different decisions based on ideology. The previous paragraph mentioned two Supreme Court decisions and public polling. The court decisions and polling results suggest the same thing. Republicans are less likely to favor increased regulation regarding public health. The CDC has been increasing regulation to fight COVID-19, and those increased regulations have substantially negatively impacted the percentage of Republicans who trust them. The *Mutual Pharmaceutical Co. v. Bartlett* was ruled primarily by Republican appointed judges, and it decreased regulation of pharmaceutical drug manufacturers. Lastly, Republicans in general typically favor increasing regulation less often than Democrats (Pew Research Center 2017). With that said, I am not arguing that ideology is the only factor determining the decisions of

judges. There is an enormous amount of literature debating what influences judicial decision making. While there is lots of debate regarding multiple influences and how much each influence matters, no literature states that ideology matters none. Some literature has attempted to say ideology is the only determining factor (Segal and Spaeth 2002). However, that is not the purpose of this thesis. Nor is this thesis attempting to add much substance to that area of literature. I simply argue that ideology plays a factor in judicial decision making; thus, we can expect the majority of decisions to change when the ideological makeup of the courts changes.

Why would anyone hold this belief that the courts can influence the FDA? Many people don't believe the courts have much influence on the FDA because of the deference given to them (O'Reilly 2007). This thesis sets out to demonstrate how the FDA is influenced by the judiciary, and how different ideological majorities in the courts influence the FDA in different ways. As far as this thesis is concerned, there is no research showing that the judiciary affects FDA drug approvals. Despite that, I believe that the U.S. Court of Appeals attempts to influence the FDA because the judges have policy preferences and setting precedent through pharmaceutical liability and drug regulation precedent is one avenue to reach their goals. The FDA knows that the courts precedent carries the same weight as policy. The FDA's scientific authority and autonomy in drug regulation are not something the administrative agency would want to be challenged in court. Because if it is, the judges have a chance at their goals being realized through creating precedent that favors their wants. It is in the FDA's best interest to make sure that precedent does not negatively affect them. The FDA can avoid this by shaping their current policies and goals to match those of the U.S. Court of Appeals.

While there are not any studies like mine, there are many academic articles regarding drug policy, regulation, laws, and court cases (Ausness 2010; Cooper 1986; McCuskey 2018; T.

W. Olson 2015; Wolfman and King 2013). There are also many studies that show the judiciary has influence over federal agencies (Howard and Nixon 2003; Humphries and Songer 1999; Spriggs 1996). Howard and Nixon did a study to test if the IRS was influenced by the judiciary's majority ideology. Howard and Nixon found that the IRS conducted more audits on businesses during a liberal majority in the federal court of appeals, and more audits on individuals when the federal court of appeals was majority conservative (Howard and Nixon 2003). If the IRS is influenced by the judiciary, why would we expect the FDA to be immune of judicial influence? This supports the belief that the conservative courts will influence bureaucracies in a way that support businesses. Lax and McCubbins found that the judiciary does "wield decisive power over tobacco regulation and their decisions had a major impact on the probability that tobacco would ultimately be regulated by the FDA" (Lax and McCubbins 2006). While this does not show that the judiciary plays a powerful role in drug regulation, it does show that the judiciary has the potential ability to influence the FDA when it comes to regulation.

If it is true that the courts influence the FDA, what type of influence would they have? A conservative judge's decision is expected to influence the FDA to either decrease or not change the regulation requirements for drug manufacturers. We can expect higher product output and economic gains during times of low regulation or consistent regulation without significant change (Davies 2014; Dufour, Lanoie, and Patry 1998; Loayza 2010). When the courts are liberal it is expected that the FDA will make regulations concerning drug approvals stricter, businesses to decrease their drug production output, and for there to be less pressure on the FDA to approve drugs. Anytime there is an increase in economic gains because of less scrutiny by the FDA, there is a decrease in consumer safety. Less regulated drugs are more likely to have

adverse effects on the public who consume drugs made by the pharmaceutical manufacturers (McCuskey 2018). This may be very important for future research.

The courts have more freedom to operate on their preferences as one moves up the judicial hierarchy (Zorn and Bowie 2010). While one may not expect much variation in the district courts, ideology may be a contributing factor to judicial decisions at the appeals level. The district courts are at the bottom of the judicial hierarchy, and they are supposed to follow the law without any interpretation. Research on the U.S. District Courts suggest ideology does not influence decisions at the district court level (Gunderson 2021). The ideology of judges in the U.S. Courts of Appeals can predict “not only individual judges’ votes but also the votes of their colleagues” (Harris and Sen 2019). However, literature on the distinction of decisions made by judges of different ideologies is not exhaustive. This thesis will be adding to the conversation by stating how liberal and conservative judges typically make decisions regarding pharmaceutical product liability cases. It will also be adding onto principal-agent theory literature, because this thesis is discussing if judicial decisions influence the FDA to make policy changes.

This thesis theorizes that drug approvals and regulations are somewhat contingent on the court’s ideology. Different ideological majorities pressure the FDA in different ways. Liberals have different preferences than conservatives when it comes to the regulation of businesses and drugs (Klein and Stern 2004; Pew Research Center 2017). There is no current reason for one to believe that judges are drastically different from legislatures when it comes to ideological preferences. The reason the courts make different decisions and have different outcomes is because of the judge’s ideological differences (McCuskey 2018). Ideological differences are present in cases favored by the liberals such as *Wyeth v. Levine* and cases favored by the conservatives like *Mutual Pharmaceutical Co. v. Bartlett* (Ausness 2010; T. W. Olson 2015;

Spriggs 1996; Wolfman and King 2013). It is likely that the majority Supreme Court and U.S. Courts of Appeals ideology will influence FDA drug approvals because of these trends in court influence, ideological differences, and changes in case rulings.

### **3.2 Hypothesis Section 1**

For hypothesis 1 I theorize that Republican appointed judges in the U.S. Court of Appeals will make decisions that favor businesses more often than Democrat appointed judges. Meaning that most of the decisions made in favor of drug consumers are by Democrat appointed judges. The fact that different ideologies favor different policies, laws, and case outcomes has already been stated. However, it has yet to be discussed that their ideological differences have different implications. Logically and based on prior research, conservatives favor economic policy and are less likely to support an increase in regulation (Klein and Stern 2004; Pew Research Center 2017). Democrats are measured to support increasing regulation for the purpose of having better pharmaceutical safety control than Republicans (Klein and Stern 2004). Hypothesis 2 is that when most U.S. Court of Appeals decisions favor businesses more than consumers in pharmaceutical drug liability cases within any given year, the FDA will follow the courts' decisions by reducing regulatory requirements. Hypothesis 2 is also true if the FDA makes decisions that increase regulation when the U.S. Court of Appeals makes decisions primarily in favor of drug consumers. With that being said, less drug approvals due to higher regulation promotes general welfare and individual safety (McCuskey 2018). The quantity and regulation of drugs is likely to influence many things that impact the public, such as price and ease of access. I believe finding the answers these hypotheses would not only contribute to current principal-agent theory literature, but also contribute to public discourse.

What does less regulation do exactly? An increase in regulation can lower product output and economic gains (Davies 2014; Dufour, Lanoie, and Patry 1998; Loayza 2010). Hypothesis 3 is that when the FDA reduces regulation, there will be an increase in the overall number of annual drug approvals. Thus, when the FDA increases regulation there will be a reduction in the overall number of annual drug approvals. When the courts want to decrease regulatory pressures, we expect FDA policy changes to make regulations concerning drug approvals less strict. This decrease in scrutiny toward businesses will increase drug production output. Because of this, the FDA will increase the number of approved drugs completed annually.

There is no research or literature that shows how conservative or liberal judges usually rule on cases of product liability. While *Mutual Pharmaceutical Co. v. Bartlett* and conservative attitudes toward regulation support the assumptions made in this thesis, they are not definitive. It could be the case that conservative and liberal judges feel very similar regarding pharmaceutical product liability. A case decided in 2019 called *Merck Sharp & Dohme Corp. v. Albrecht*<sup>4</sup> is viewed as a “positive step for consumer safety; provides a clear, administrable bright line for lower courts; and is not unreasonably broad” (Lindenfeld 2020). This case was a unanimous decision in judgment, and a six to three decision in reasoning. The three justices who did not agree were all Republican appointed judges. It may very well be that judges of different ideologies want the same outcome, but they have different beliefs on how to get there. We do not know the answer to this question, nor do we know the answer regarding influence on the FDA.

### 3.3 Hypothesis Section 2

My hypothesis 4 is that when the U.S. Court of Appeals is primarily Democrat there will be a decrease in drug approvals for the following year. Hypothesis 4 still stands if drug approvals

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<sup>4</sup> *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 587 U.S., 203 L. Ed. 2d 822 (2019).

increase when there is not a Democratic majority party affiliation in the U.S. Court of Appeals. Drug approval will be acting as a proxy for changes in regulation. An increase in regulatory requirements typically increase the cost of producing and inspecting drugs, and this increases the average time taken to develop and approve drugs (Ward 1992). This means that the dependent variable will be annual FDA drug approvals (U.S. Food and Drug Administration n.d.). Funding is a known influence of FDA efficiency and must be a controlled variable (Bureau of the Budget and Office of Management and Budget n.d.; Carpenter et al. 2003). Because all funding is allocated by Congress, we must control for Congress's majority political affiliation.

It is likely that the FDA will react to court decisions. Research has shown instances of how judicial decisions influence federal agencies like the IRS (Howard and Nixon 2003). Judicial ideology and decisions made by judges are often complimented by IRS policy changes (Chow et al. 2020). Corporations are aware of how the ideology of judges can influence decisions, so many of them “engage in forum shopping in tax litigations to avoid liberal judges” (Chow et al. 2020). There is lots of literature regarding how ideology influences the decisions of judges in tax litigation, and how the judiciary influences the IRS. However, there is not similar research regarding pharmaceutical products liability and the FDA. This thesis will light the torches for similar research and discussion with a focus on the FDA.

### **3.4 Methods Section 1**

The first analysis is a simple  $\chi^2$  test. This test's purpose is to analyze policy changes more closely. We are analyzing the years 2010, 2011, 2015, and 2016. These are all years under the Obama presidency. President Obama did not appoint enough justices to the U.S. Court of Appeals to shift it from Republican dominated to Democrat until 2014. I believe analyzing the courts under a single presidency strengthens any conclusions that can be drawn about the U.S.

Court of Appeals. The dependent variable in this analysis is case decisions regarding pharmaceutical product liability. Case decisions will fall into one of two categories. Category one is case decisions that favor drug manufacturers, and this category is labeled as business. The second category is labeled as consumer, because it is populated with case decisions that favor the plaintiff and drug consumers. Pharmaceutical product liability cases are analyzed using WestLaw (Thomson Reuters n.d.).

The independent variable is the majority party affiliation of the panel of judges. The political affiliation of judges will need to be determined using CourtListener (Free Law Project n.d.). When two of the three judges on a panel are affiliated with the same party on any given decision, that decision is coded as the majority party. This  $\chi^2$  test will tell us which party affiliation is more likely to make decisions that favor consumers and businesses. Therefore, the  $\chi^2$  test will test hypotheses 1.

Determining if changes in regulation are influenced by the U.S. Court of Appeals is the entire purpose of this research. To determine the answer for hypothesis 2, we must know if the FDA increases regulation when the U.S. Court of Appeals signals that we should support drug consumers more. The opposite is also at question, does the FDA decrease regulation when the U.S. Court of Appeals believes that we are imposing too much regulatory requirements on manufactures? Answering this principle-agent question is the primary goal of this thesis. However, learning what types of decisions judges make based on party affiliation regarding pharmaceutical product liability cases is something that we can answer without impeding on the time and resources required to produce this thesis.

I will compare the party affiliation of judges to the types of decisions made each year. If in 2010 majority of decisions favored businesses, then I would expect a majority of policy

decisions to also favor business. Rules or policies that favor businesses would decrease regulatory requirements, allow the use of chemicals that were previously deemed unsafe, or something of that nature. All FDA policy changes are tracked using the Federal Register (U.S. Federal Register n.d.). Using the Federal Register one can note if the FDA made policy changes in favor of businesses or for public health and safety. After, we will know if most rule change proposals were in favor of or against the majority of decisions made by the U.S. Court of Appeals each year. There are typically not many regulatory changes made from year to year regarding drug regulation. There are approximately 5 to 10 relevant rule changes or proposals made a year. We will then analyze the drug approval changes of the following year to see if the regulatory changes influence approvals. This test will answer hypothesis 3, and this is important because the second analysis assumes that drug approvals are influenced by changes in regulation. I will discuss the logic and relevancy of these rule changes in accordance with the decisions made by the U.S. Court of Appeals and change in rate of drug approvals. Analyzing these policy changes logically will either compliment or critique the findings of the second analysis.

### **3.5 Methods Section 2**

For the second analysis we will use a time series analysis from the year 1940 until the year 1990. This second analysis will be testing hypothesis 4. The time series analysis will cover all presidents from Franklin D. Roosevelt to George H. W. Bush. Reading all FDA policy changes from the year 1940 to 1990 would take longer than the timeframe I've been allotted; thus, meaning that I do not have the resources to create a comprehensive dataset of FDA policy changes. However, I can use drug approvals to access the impact of drug regulation changes. Studies show that regulation increases can cause the average time taken to develop and approve drugs to be delayed (Ward 1992). Because of this research, it can be expected as regulation goes

up there will be less drug approvals. Also meaning that as regulation goes down, we can expect an increase in drug approvals. Thus, NDA approvals can be treated as a proxy for regulatory change. Overall annual drug approvals are the dependent variable. Monthly drug approvals are made public on the FDA's website (U.S. Food and Drug Administration n.d.). All independent and controlled variables are lagged because we believe the FDA is influenced by the previous year's pharmaceutical liability case decisions. After the previous year's decisions are made, the FDA will purpose a rule regulatory change that will impact overall drug approvals.

This brings us to the main independent variable. The independent variable is the U.S. Appeals majority party affiliation annually. The U.S. Appeals party affiliation majority was calculated similarly as traditionally done for Congress or the U.S. Supreme Court. Instead of using people, we used the common space scores of each circuit to determine when each individual circuit is primarily liberal or conservative. The common space scores come from the data provided in Lee Epstein's Judicial Common Space (Epstein et al. 2007). These scores are then replaced with party affiliation. Conservative scores are replaced with Republican, and liberal is replaced with Democrat. Each year, prior to 1981, when 6 or more circuits are Republican that year is coded as Republican. The same is true for Democrat. After the 11<sup>th</sup> circuit was created in 1981 the number needed to make a majority changed from 6 to 7. Party affiliation is coded as 1 being a Democrat majority and 0 being a non-Democrat majority. In all instances of 0 except for 1985, this means that the majority party affiliation of the U.S. Court of Appeals was Republican. The year 1985 was split perfectly in half between Republicans and Democrats.

There are multiple controlling variables. There is reason to believe that funding may also influence the FDA's drug approval rate (Carpenter et al. 2003). Because of funding's potential

influence in FDA drug approvals, funding is a controlled variable. All data regarding funding comes from Fraser and the federal annual budget (Bureau of the Budget and Office of Management and Budget n.d.). Because the federal budget is being used, congressional party affiliation must also be a controlled variable. Congress was separated by chamber. Rather than have a single congress variable, there is a House and Senate variable. There is research showing that the President has the ability to influence multiple administrative agencies (Clinton, Lewis, and Selin 2014; Howell and Lewis 2002). The president has influence over the federal budget and appoints officials to the FDA (Furlong 1998). Because of this, we must also control for Presidential influence in the same manner we are controlling for congress. Lastly, I am controlling for the Supreme Court as it is the highest court and has more authority than the U.S. Court of Appeals.

A time series analysis would allow us to record and track each year's party majority, drug approvals, and FDA funding. If FDA drug approvals rise under a Republican majority and fall under a Democrat majority, then there may be a link between the two. What could harm this possible link is if FDA funding and drug approvals increase and decrease at the same or similar times. A time series analysis makes tracking this easy because the annual data could easily be tested, viewed, and put onto a table. We could track to see if the changes are consistent or random. Hypothesis 4 would fail if party affiliation were random and not consistent with changes in drug approval rates. Because hypothesis 4 is only concerned with how party affiliation influences FDA drug approvals. Variable data points that do not fluctuate at the same rate as the dependent variable do not likely have a large impact on the dependent variable. The dependent variable data points are based on the overall annual NDA approvals completed by the FDA.

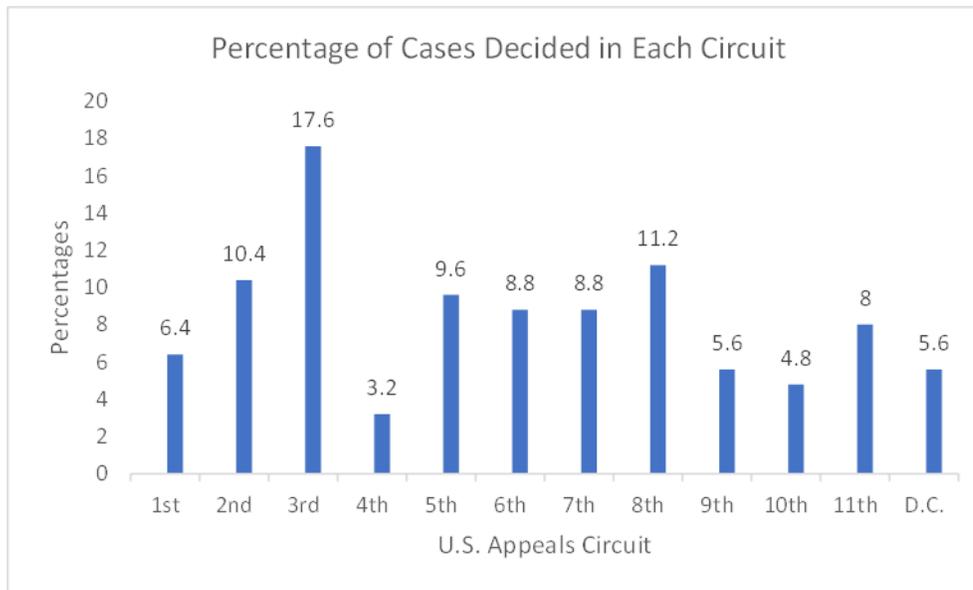
*Table 1: Variable Descriptions*

Dependent Variable (DV)	Overall annual drug approvals
Democrat Appeals Court (Lagged Independent Variable)	Annual Majority of Circuits are run by Democrat Appointed Judges 1 = Democrat
FDA Appropriations (Lagged Independent Variable)	Annual Federal Budget appropriations for FDA
Democrat Senate (Lagged Independent Variable)	Annual Democrat Majority runs Senate 1 = Democrat
Democrat House (Lagged Independent Variable)	Annual Democrat Majority runs House of Representatives 1 = Democrat
Democrat President (Lagged Independent Variable)	Annual Democrat acting as President 1 = Democrat
Democrat Supreme Court (Lagged Independent Variable)	Annual Majority of Supreme Court Judges are Democrat Appointed 1 = Democrat
Lagged Dependent Variable (DV)	Overall annual drug approval delayed by a year and treated as an independent variable

## 4 FINDINGS

### 4.1 Test and Results Section 1

As predicted, most judges in 2010 and 2011 were Republican appointed, and in 2015 and 2016 a majority were Democrat appointed. Table 2 shows that over 70% of decisions were in favor of businesses for both 2010 and 2011. Approximately 87% of Republican appointed judges favored pharmaceutical manufacturers than consumers during that two-year period. Meanwhile, approximately 44% of Democrat appointed judges favored the business during 2010 and 2011. There may be an argument that Democrats are neutral, but it would not be safe to assume that is the case. I also gathered circuit data to create figure 1 showing what percentage of decisions were made in each circuit regarding the total number of pharmaceutical liability cases. I found that no single circuit saw more than a quarter of the total pharmaceutical liability cases gathered. The goal of testing hypothesis 1 is not to determine a measurement for when ideology or party affiliation matters. The goal was to determine what party affiliation primarily rules in favor of pharmaceutical manufactures or consumers. The goal of hypothesis 2 is to analyze if the FDA responds to either majority by influencing the agencies to change their rules to favor the perspective and decisions made by the courts. Since majority of decisions were made in favor of the business, we should expect the FDA to decrease regulation.



*Figure 1: Percentage of Cases Decided in Each Circuit*

Table 3 shows that the FDA proposed rule changes that made their regulations easier to follow, extended application dates, and increased the approval of drugs (U.S. Federal Register n.d.). There were six proposed rule changes in 2010 by the FDA that would affect pharmaceutical manufactures. The FDA made a rule change that allows the use of chemicals not previously allowed without essential-use designations (U.S. Food and Drug Administration 2010d). Benzoyl peroxide was also recognized as safe and effective by the FDA in 2010 (U.S. Food and Drug Administration 2010a). The FDA also increased the number of over-the-counter drugs available for human use (U.S. Food and Drug Administration 2010a). There was a change made to decrease the “ambiguity in the current reporting scheme” that has “caused confusion among sponsors” (U.S. Food and Drug Administration 2010b). Three changes were made to increase clarity in the FDA’s drug regulations and requirements (U.S. Federal Register n.d.). Those three changes made it easier for businesses to accurately follow regulations. The changes did not significantly increase any procedural requirements. Pharmaceutical manufacturers did not

have to adapt to any changes or put in more effort to ensure the safety of their drugs. One rule change was made to reduce biologics regulations because the regulations were “too prescriptive and unnecessarily restrictive” (U.S. Food and Drug Administration 2010c). In 2010 the FDA decreased regulation, increased use of chemicals in the production of drugs, and increased regulation clarity. These changes have allowed more flexibility and eased production. In 2011 there was a 20% increase in drug approvals from the previous year (U.S. Food and Drug Administration n.d.). As scrutiny toward drug manufacturers decreased, NDA approvals increased. This answer is the goal of hypothesis 3; however, we must analyze the non-Republican majority years before any hypotheses can find support.

Table 2: 2010 and 2011  $\chi^2$  Analysis

	2010 & 2011 Decision Favored		Total
	Business	Consumer	
Democrat Appointed Judge	11	14	25
Republican Appointed Judge	47	7	54
Total	58	21	79
Pearson $\chi^2 = 16.22$		Probability = 0.00	

We saw slightly different results in 2011. There were twelve rule changes either proposed or finalized in 2011 that were relevant to pharmaceutical manufacturers. However, most of these rule changes were about committees, change in address for certain FDA facilities, and announcement of name changes for certain offices. There was also a mix of changes favoring consumers and businesses. As shown in table 3, there was exactly one more rule change in favor of easing requirements for pharmaceutical manufacturers than increasing them. Because of this, we should only expect a small increase in annual drug approvals. In 2012 we got exactly that, there was only an increase in drug approvals by 4%. The findings for both 2010 and 2011 support the idea that *Wyeth v. Levine* and *Mutual Pharmaceutical Co. v. Bartlett* are indeed good

examples of how judges rule based on ideology. However, hypotheses two and three cannot find support until we analyze the assumed Democrat majority years 2015 and 2016.

*Table 3: FDA Rule changes and Effects on Businesses*

Rule Year and Citation	Scrutiny Toward Businesses
2010a - 75 FR 9767	↓ Decreased
2010b - 75 FR 7412	- Neutral
2010c - 75 FR 15639	↓ Decreased
2010d - 75 FR 19213	↓ Decreased
2011 - 76 FR 7743	↑ Increased
2011 - 76 FR 44475	↑ Increased
2011 - 76 FR 13880	↓ Decreased
2011 - 76 FR 12916	↓ Decreased
2011 - 76 FR 12847	↓ Decreased
2015a - 80 FR 55237	↑ Increased
2015b - 80 FR 57756	↑ Increased
2015c - 80 FR 50762	↓ Decreased
2015 - 80 FR 38915	↑ Increased
2015 - 80 FR 25165	- Neutral
2016 - 81 FR 69668	↑ Increased
2016 - 81 FR 61106	↑ Increased
2016 - 81 FR 74298	↑ Increased
2016 - 81 FR 92603	↑ Increased
2016 - 81 FR 81685	↑ Increased
2016 - 81 FR 85854	- Neutral
2016 - 81 FR 40512	↓ Decreased

The years 2010, 2011, 2015, and 2016 support hypotheses 1. A panel is more likely to rule in favor of the consumer when majority are appointed by Democrats. Seventy-nine percent of all decisions made in favor of the consumer were made by a majority Democrat panel of judges. Fifty-nine percent of all cases where there were a Democrat majority went in favor of the consumer as well. Meaning that anytime there is a pharmaceutical products liability case you are more likely to be favored as a plaintiff if the majority party affiliation of the U.S. Appeals panel is Democrat. This knowledge may allow pharmaceutical manufacturers to forum shop to avoid more Democratic or liberal courts. Corporations already forum shop to avoid liberal judges in tax litigation cases (Chow et al. 2020).

Table 4: 2015 and 2016  $\chi^2$  Analysis

	2015 & 2016 Decision Favored		Total
	Business	Consumer	
Democrat Appointed Judge	10	16	26
Republican Appointed Judge	19	1	20
Total	29	17	46
Pearson $\chi^2 = 15.51$		Probability = 0.00	

The most interesting outcome of the Democrat majority years of 2015 and 2016 is that the FDA primarily increased regulation even though most decisions were made in favor of businesses. Meaning that hypothesis 2 does not find support. Instead of the FDA decreasing regulation when most decisions favor businesses, they reduced regulation when most decisions were made by a Democrat-appointed panel of judges. Hypothesis 2 tested if case decisions influenced regulation, but the results suggest that the political make-up of the courts matter more than case decisions.

In table 4 approximately sixty-three percent of cases favored pharmaceutical manufacturers. Yet, in 2015 there were nine relevant proposed or final rule changes that could have an influence on pharmaceutical drug manufactures. One of these changes were clarifications to previous rule changes, one was a change in office names, and one was the termination of an advisory committee. Of the remaining six changes, only one was in favor of drug manufacturers. That one rule change was regarding color additives in coating formulations applied to dietary supplements and drug tablets and capsules being allowed (U.S. Food and Drug Administration 2015c). The remaining five promoted public health and the safety of drug consumers. Meaning that the FDA increased regulatory requirements even though majority of case decisions did not favor the plaintiff or drug consumer. There are three notable rule changes.

One of them is the destruction of drugs no longer deemed safe or refused admission into the United States to increase the “integrity of the drug supply chain” and “allow FDA to better protect the public health” (U.S. Food and Drug Administration 2015a). Secondly, there was a rule change that over-the-counter antiseptics with antimicrobial properties are subject to additional research and clinical simulation studies before it is deemed safe and effective. Lastly, is the inclusion of all products made or derived from tobacco “intended for human consumption will be subject to regulation as a drug, device, or a combination product under the Federal Food, Drug, and Cosmetic Act” (U.S. Food and Drug Administration 2015b). This rule change amended the definition of tobacco product to expand the FDA’s control over tobacco-based products. This allows the FDA to take action in regards to “products made or derived from tobacco that were marketed with claims of therapeutic benefit but that did not have approved new drug applications” (U.S. Food and Drug Administration 2015b). Theoretically, we should expect this to increase the number of annual NDA approvals. However, that does not seem to be the immediate effect. Following the increased regulatory requirements of 2015, we have a fourteen percent decrease in drug approvals in 2016.

The year 2016 was very similar to 2015. There were roughly 10 relevant policy changes. There were the usual annual clarifications and changes to committees. Then there were three decisions that recused regulatory requirements. The remaining 6 were all increasing regulatory requirements for pharmaceutical manufacturers and expanding FDA oversight. In 2017 there was a twenty-two percent decrease in overall drug approvals. Therefore, hypothesis 3 finds support from both  $\chi^2$  test. However, hypothesis 2 does not find support. In our analysis, the FDA increases regulatory requirements when there is a Democrat appointed majority in the courts. Despite this, I believe the results we found are important to the discussion at hand. Despite if a

majority of decisions favor pharmaceutical manufacturers, the FDA is more likely to increase regulations under a Democratic majority. The FDA is also more likely to reduce regulatory requirements when there is a Republican majority in the U.S. Court of Appeals. According to the results we found, the political make-up of the courts matters more than the case decisions.

However, more testing would need to be done before we can confidently make that claim. As seen in table 2, the case decisions made in 2010 and 2011 were primarily made by Republicans and they primarily favored businesses. Despite 2015 and 2016 being Democratic majority years, table 4 shows that case decisions primarily favored businesses. We need to test years where most cases favor the plaintiff but have different political affiliation majorities.

#### **4.2 Testing and Results Section 2**

Hypothesis 4 has mixed results. Hypothesis 4 states that when the U.S. Court of Appeals is primarily Democrat there is a decrease in drug approvals for the following year. This is to test my assumption that Democrat appointed judges favor consumers in product liability cases more often than businesses. Favoring consumers more often would imply to the FDA that the courts want to promote public safety and therefore increase regulation to uphold public health. Thus, passing rules that would increase regulation and decrease annual NDA approvals. Annual drug approval is the dependent variable being analyzed in this analysis. Annual drug approvals as a proxy for FDA regulatory change is assumed because we already know from the previous analysis and research that an increase in regulatory requirements decreases production and increases the average time taken to process a drug approval (Ward 1992). The results for hypothesis 2 suggest that hypothesis 4 will find support. The first time series analysis supports hypothesis 4.

*Table 5: Time Series Analysis with Lagged Independent Variables*

	Coefficient	Standard Error	P Value
Democrat Appeals Court	-624.65	336.14	0.07
FDA Appropriations	501.13	109.53	0
Democrat Senate	-1767.51	422.91	0
Democrat House	1321.22	636.85	0.04
Democrat President	312.27	302.63	0.31
Democrat SC	-311.22	440.35	0.48
Constant	-6976.81	2016.88	0.001
N = 50	R <sup>2</sup> = 0.76	Adjusted R <sup>2</sup> = 0.72	F = 0

The results show that when the U.S. Court of Appeals is primarily filled with Democrat appointed judges there is a decrease in drug approvals in the following year. This test supports hypothesis 4. However, this model does not account for possible autocorrelation due to the lack of a lagged dependent variable. A lagged variable for annual drug approvals is added to the analysis and shown in table 6. The table utilizes a time series analysis test using Huber-White robust standard errors with a lagged dependent variable for autocorrelation. This test appears to show a weak and not significant correlation between drug approvals and the majority political affiliation of the U.S. Courts of Appeals. The first table only represented 75% of the variation in the overall sample, but the second test represents nearly 95% of the sample. While hypothesis 4 may no longer be able to find significant support, these results may still support my theoretical argument. Because table 5 and the findings of hypothesis 2 both found similar results that support hypothesis 4.

*Table 6: Duplicate Time Series Analysis with Lagged Dependent Variable*

	Coefficient	Standard Error	P Value
Democrat Appeals Court	260.89	175.74	0.15
FDA Appropriations	56.71	63.65	0.38
Democrat Senate	-227.48	237.76	0.34
Democrat House	180.4	317.22	0.57
Democrat President	84.7	145.21	0.56
Democrat SC	-296.22	209.54	0.17
Lagged DV	.88	.07	0.00
Constant	-882.98	1082.64	0.42
N = 50	R <sup>2</sup> = 0.95	Adjusted R <sup>2</sup> = 0.94	F = 0

This thesis is unable to claim that the FDA’s drug regulatory changes are influenced by the majority political affiliation of the courts. However, it is also unable to claim that the political affiliation of the courts does not matter to the FDA when they are making regulatory changes. The findings of hypotheses 2 and 4 conflict with each other. The analyses ran in this thesis need to be rethought and reran in a different manner. The sample size likely needs to be increased from 50, because the lagged dependent variable has too much impact on all variables. Even variables founded in prior research, such as the funding variable. Ultimately, the findings of hypotheses 2 and 4 have opened more questions than answers. Further research on this topic will need to be complete before a conclusion can be drawn regarding the U.S. Court of Appeals influence on FDA drug regulation.

### 4.3 Conclusion and Discussion

Ultimately, we cannot confidently say that the U.S. Court of Appeals influences FDA drug rules or NDA approvals. We can claim that Republican appointed judges rule in favor of pharmaceutical manufactures more often than Democrat appointed judges. The Republican-appointed judges create precedent that increase business protections and leave drug consumer “without any legal remedies” when they are harmed by pharmaceutical manufactures (T. W. Olson 2015). The same would be true regarding the fact that Democrat appointed judges rule in

favor of drug consumers more often than Republican appointed judges. It also seems that drug approvals increase when the FDA is being less stringent. When the FDA makes rule changes that increase regulation regarding drugs there are fewer NDA approvals the following year. However, the cause of these rule changes is not apparent. Table 6 failed to show that political affiliation influenced drug approvals. However, table 5 and the findings of hypothesis 2 suggest that political affiliation of the U.S. Court of Appeals does influence drug approvals and regulation. Despite this, my thesis fails to show that either U.S. Court of Appeal pharmaceutical liability cases or political affiliation influenced rule changes made by the FDA. Because of this, we cannot answer why the FDA proposed these rule changes when they did. Future research should attempt to answer this question. We can only conclude that hypotheses 1 and 3 are likely true.

The courts are divided by ideology on their opinions regarding pharmaceutical product liability and drug regulation. That was the finding of hypothesis 1. The judicial branch of government is an independent political institution, and the judges seated in the upper hierarchy of this institution often use their personal ideology when making case decisions (Friedman 2005; Segal and Spaeth 2002; Zorn and Bowie 2010). The courts are stacked with judges who have political preferences and policy goals (Humphries and Songer 1999). Judges often disagree and make different decisions, this division is due to their ideological differences (Humphries and Songer 1999; Pinello 1999). Despite the ideology of judges, both conservative and liberal judges influence federal agencies. Howard and Nixon demonstrated how different ideologies in the courts influence the IRS to make different decisions regarding audits (Howard and Nixon 2003). The research demonstrated in this thesis has attempted to come to a similar conclusion regarding the FDA.

Decreasing the cost of drugs and reforming how pharmaceutical institutions price drugs is currently a huge debate (Igoe 2020; Sachs 2020; Waxman 2019). Drug safety has been a long-standing concern of the public (Olsen and Whalen 2009). American society seems to be becoming increasingly divided on topics of healthcare, drugs, and health related bureaucracies. Healthcare, Covid-19, and drug safety are all topics of importance in recent (Gallup n.d.; Mithani et al. 2022; Olsen and Whalen 2009). According to the finding of hypothesis three, drug approval decreases as the FDA increases regulation. The results of hypothesis 2 suggest that regulation increases when majority of pharmaceutical liability cases are decided by Democrats. However, maybe the public has nothing to worry about regarding the FDA. I was unable to establish a statistically causal link. There are also opposing theories that believe health related agencies are becoming increasingly autonomous (Cuéllar 2014). It seems that this opinion is in the minority, but it is worth considering. Some legal scholars agree with the *Mutual Pharmaceutical Co. v. Bartlett* ruling and state that it is not the purpose of courts to make health regulation decisions for agencies. They instead believe that Congress should improve the funding of the FDA and give them the resources they need to remedy issues (Schuck 2008). Schuck argues that society is more interested in getting good drugs approved than preventing bad drugs from entering the market. It is not apparent that Shuck's arguments are true today, especially given the current vaccine hesitation for COVID-19 (Sallam 2021).

This thesis and its research hoped to contribute to the literature of principle-agent theory and how ideology influences judicial decision making. Future research should expand on the FDA and judicial relationship presented in this thesis. Especially given the fact that this thesis has serious limitations and mixed results. The sample size of my time series analysis should be increased from 50 to 70 years. The ideology of the FDA itself is also of concern and should be

further evaluated. Agencies do have their own interest (Yolles 2019). Knowing how the ideology of the FDA changes annually would allow future research to track changes more easily in regulation policy, track ideological influences of the FDA on itself, and many other avenues of research. If the ideology of the FDA was used in this research, this thesis would have tested the FDA's ideology as another independent variable. I would assume the FDA and U.S. Court of Appeals have similar wants when their political affiliation is the same.

I wanted to know if FDA rule changes are influenced by the ideology of judges. Ultimately, answering that question was one of the original goals I had when developing this thesis. Unfortunately, it has been neither answered nor disproven. First, the test gave mixed results. Secondly, the analysis did not directly test ideological influence on regulation. Doing another time series analysis is required. Instead of the dependent variable being annual drug approvals it should be annual policy changes. The policy changes should then be coded to either primarily favor businesses or consumers. Possibly, a score or measurement could even be made to replace dummy type variables. In addition to this, more recent years should be tested. My time series analysis included years where Southern Democrats still had some influence in politics and government. Meaning that my party affiliation test may be flawed. If unable to complete a test using more recent years, then it would be best to replace party affiliation with ideological scores or measurements instead.

Federal agencies like the FDA can be influenced by funding and governmental institutions (Carpenter et al. 2003; Clinton, Lewis, and Selin 2014; Howell and Lewis 2002; Shipan 2004). The courts are likely concerned about policy outcomes, and they have the ability to review agency actions (Crowley 1987; Humphries and Songer 1999; Shapiro 1964). Agencies like the FDA will likely implement changes when the resources or purpose favor the Courts

(Spriggs 1996). Meaning that the FDA will change policies when they know the courts are not likely to disagree. The findings of hypothesis two suggest the courts increased regulation when there was a Democrat majority in the U.S. Court of Appeals. Table 5 of hypothesis 4 showed that NDA approvals decreased under a Democrat majority as well. The findings of hypothesis 3 support research that suggest regulation influences drug approvals. The FDA has to rely on the courts to give redress for those who are negatively impacted by drug manufacturers (Cooper 1986). The outcome of these cases may depend on the ideology of the courts. The results of hypothesis 1 suggest that Democrats rule in favor of the plaintiff more often than Republicans in pharmaceutical product liability cases. This is consistent with the fact different courts cannot even agree on the way preemption should be analyzed (McCuskey 2018). In *Wyeth v. Levine*, the liberal majority ruled that states are allowed to add their own safety regulations in addition to federal FDA regulations (Ausness 2010). While *Mutual Pharmaceutical Co. v. Bartlett*, with a conservative majority, ruled that the federal FDA regulations are sufficient enough and can give liability protections to drug manufactures (T. W. Olson 2015; Wolfman and King 2013). These assumptions found partial support from the research produced in this study. However, the ultimate goal of this thesis was not met. Table 5 of hypothesis 4 and the findings of hypothesis 2 found similar results, yet table 6 of hypothesis 4 contradicts those results. Further examination is required before we can truly know if the U.S. Court of Appeals plays a role in FDA drug regulation.

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