Bipartisanship in the 21st Century Cures Act

In a partisan environment, what characteristics of political compromise lead to the passage of legislation?

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Abstract

In the 114th Congress, only 2.7% of introduced bills became laws. During this Congress, the 21st Century Cures Act passed with an overwhelming majority of 392 to 26 in the House and 94 to 5 in the Senate. The purpose of the act was to accelerate the discovery, development, and delivery of treatments and cures, which is normally a partisan topic. Little comprehensive work has been done towards understanding the act. Content analysis allowed the exploration of the two questions: did political compromise occur in the act, and if so, what were the main characteristics of political compromise? Political compromise is a method of achieving bipartisanship. This project defined it as agreement over the wording of a section, lack of specific content, the removing of content, and the inclusion of content. Political compromise was identified in three main areas: the bipartisan committees used to develop the ideas for the act, the use of preexisting bills as provisions, and the resolving of disputes. The two characteristics that most strongly allowed for political compromise in this act are strategic planning and experienced leadership. These characteristics can help in the analysis of other bills to understand why they do or do not pass.

Introduction

The question this project poses is "In a partisan environment, what characteristics of political compromise lead to the passage of legislation?"

The passage of the 21st Century Cures Act inspired this question as it created new regulations for the discovery, development, and delivery of treatment and cures. The act had strong bipartisan support, passing with a majority of 392 to 26 in the House and 94 to 5 in the Senate (Upton). This is unusual because Republicans and Democrats generally do not agree on pharmaceutical drug legislation. The Republicans emphasize decreasing regulation stringency to increase innovation and expedite development and approval speeds (We Believe in America, 34; Republican 2016 Platform, 38). The Democrats emphasize three things. First, they want to keep the public safe through the FDA regulation process and are hesitant to decrease regulation (Pal, 79). Second, they want to remove laws that protect United States pharmaceutical companies by inhibiting the availability of cheaper foreign pharmaceutical drugs in the United States (Moving America Forward). Third, they want to increase spending to fund research to increase innovation in the United States drug industry (2016 Democratic Proposal, 32).

Even though there are plenty of pharmaceutical regulation bills introduced each year, they rarely pass. For example, in the 2015-2016 Congress, 48 bills related to the 21st Century Cures Act were introduced, yet none passed (Congress.gov). Prior to the 21st Century Cures Act, the last pharmaceutical drug regulation bill, the Food and Drug Administration Safety and Innovation Act (FDASIA), was passed four years prior in 2012. According to John McDonough, a health policy adviser to Ted Kennedy, the last major healthcare bill, the Affordable Care Act, avoided pharmaceutical drug regulation due to the polarity of the topic (Norman). This begs the question of what allowed this bill to pass in a partisan, an increasingly polarized, environment.

There has been little comprehensive work done towards understanding the 21st Century Cures Act. This perhaps could be because the act recently passed in December 2016. The lack of research done on the 21st Century Cures Act emphasizes the importance of studying it. This project sought to understand if political compromise contributed to the passage of the 21st Century Cures Act. Political compromise is a method of achieving bipartisanship. This project defined political compromise as agreement over the wording of a section, lack of specific content, the removing of content, and the inclusion of content. If political compromise did occur, the project sought to identify the characteristics of it in the passage of the 21st Century Cures Act.

Literature Review

A. Bipartisanship

1. Bipartisanship and Partisanship in Congress

It is first necessary to understand how often bipartisanship occurs in Congress before discussing bipartisanship in drug innovation, creation, and regulation policy. In the 114th Congress, only 329 laws were passed out of a total of 12,063 pieces of legislation (2.7%) (Statistics and Historical Comparison). These bills were able to pass due to bipartisan support: when both parties agree or compromise in order to support a bill. In order for a bill to pass, there needs to be a majority number of votes at each of the stages that the bill passes through. Having as many legislators in support of the bill as possible allows for the bill to have a greater chance at becoming law. Bipartisanship support of a bill helps to secure a larger number of votes. This probes an important question: how do bills achieve bipartisan support?

According to Trubowitz, bipartisanship is more likely to occur under three conditions. The first condition is when the economy is growing. During times of economic growth, politicians are viewed more positively, and they experience less of a strain on resources for legislation. The second condition is when the parties are competitive nationally. Under this condition, legislation must be more moderate in order to gain support from across the aisle and to eventually pass. The third condition is when control of the federal government is divided between parties because divided governments reduce the influence that politicians have to push legislation that they want. Thus, when the federal government is split between parties, politicians have to work harder to ensure that they will have the majority vote for each of the stages that the bill passes through. These conditions are found together infrequently, so political incentives for members of Congress to pursue bipartisanship are briefly lived (Trubowitz 436-438).

In addition to the infrequent occurrence of these three conditions, Layman argues that bipartisanship is becoming even harder to attain. This is because of polarization within each party. Party polarization means that the Republican Party is moving in a conservative direction on major issues while the Democratic Party is moving further in a liberal direction on major issues. This has led to greater homogeneity within each party and a greater distance between the two parties' political stances (Layman). Therefore, due to party polarization, fewer moderate bills are being introduced. For the legislation that is introduced, the opposite party is less likely to vote for it due to the greater distance between the parties' political stances.

Trubowitz argues that bipartisanship still occurs because it is an electoral strategy that politicians use to expand their appeal to voters outside of their party or to secure the support of moderate and independent voters. Politicians normally choose to follow party lines in order to secure the support of the members of their party and out to of fear that they will receive political retribution if they do not (Trubowitz, 435). Epstein expands further on which type of bills receive bipartisanship support. He states that bipartisanship will be the preferred mode of policy making when partisan differences over a given policy are small or when the uncertainty associated with policy outcomes is large (Epstein, 184).

2. Political Compromise as a Method to Achieve Bipartisanship

One of the methods of achieving bipartisanship is through political compromise. In order to create legislation, politicians must be able to create political compromises both within their party and the opposing party. Gutmann discusses the idea of an uncompromising mindset and a compromising mindset in politicians. She argues that politicians tend to have uncompromising mindsets, or mistrust their opponents. This biases the democratic process towards hindering political compromise. In order for political compromise to occur, a politician must have a

compromising mindset, which is defined as when politicians adapt their principles to respect their opponents' opinions (Gutmann).

If a politician has a compromising mindset, the extent of political compromise needed to garner bipartisan support depends on how partisan the bill is. When legislators introduce their bills, they locate the legislation near the ideal point of their party (Martin). This signals their preferred policy. The farther the ideological position of the bill deviates from the ideological position of the median, the more changes the bill must receive in order to satisfy the opposing party (Martin). The changes that the bill receives to satisfy the opposing party are political compromises.

B. Partisan Opinions on Drug Innovation, Creation, and Regulation

1. Opinion of the Right

The Republicans have held a consistent stance as observed in both their 2012 and 2016 platforms. Their 2012 platform, "We Believe in America," has a section titled "Reforming the FDA." The Food and Drug Administration (FDA) is the regulatory body for pharmaceutical drugs in the United States. This section discusses how other countries are threatening the United States' current lead in life sciences research and development and medical innovation. The Republicans state that the FDA is causing this decline in the U.S. industry and that the FDA must improve its "predictability, consistency, transparency and efficiency"(We Believe in America). They continue that they will reform the FDA so that the new devices and drugs are able to progress through the FDA clinical stages and are ultimately approved faster *(see Appendix 1 for FDA Approval Process).* In this section, as well as an additional section titled "Regulatory Reform: The Key to Economic Growth," the Republicans plan to increase FDA efficiency by decreasing the use of U.S. tax-payer resources on "bureaucratic red tape" (We Believe in

America, 34).

In their 2016 Platform, the Republicans echo similar sentiments, in a section titled "Putting Patients First: Reforming the FDA," the Republicans state that the "burden of governmental regulation and red tape" is hurting the research and development and innovation of devices and drugs. It further states that the FDA has become an agency that puts public health at risk by delaying the development of new drugs and devices through overregulation. The platform states that the FDA must return its focus to approving new medicines rather than overregulation (Republican 2016 Platform, 38). The Republicans' main interest is streamlining FDA requirements for putting new drugs and medical devices on the market while decreasing regulation stringency (Gaffney).

2. Opinion of the Left

The Democrats take a different approach to addressing drug creation and innovation policy as observed in their 2012 and 2016 platforms. Their 2012 platform "Moving America Forward" largely avoided talking about the FDA. In more broad terms, the platform says that "a 21st century regulatory system must promote economic growth, innovation, and job creation while also protecting public health and welfare." However, when discussing specifically prescription drugs, the platform only directly mentions making prescription drugs less expensive. It does not further expand on the idea of promoting economic growth in the pharmaceutical industry. (Moving America Forward).

In the Democrats' 2016 platform, they avoided entirely talking about FDA approval and delivering drugs to the market faster. Instead, they again emphasize that the price of prescription drugs is too high and that pharmaceutical companies are making profits at too high of margins. The Democrats prioritize making drugs more affordable. They proposed doing this through

decreasing the profit margin of drug companies, allowing more generic drugs on the market, importing drugs from other countries, and renegotiating lower prices for Medicare drug manufacturers. They also propose increasing funding to the National Institutes of Health (NIH) in order to increase medical research (2016 Democratic Proposal, 32).

Despite a lack of direct mention of the FDA approval process in their 2012 and 2016 platforms, the Democrats are concerned with drug approval and safety monitoring processes. They want to keep the public safe through the FDA regulation process and are hesitant to decrease regulation (Pal, 79).

The Republicans emphasize decreasing regulation stringency to increase innovation. However, the Democrats stress keeping the public safe with current regulations, removing legislation that inhibit the availability of cheaper drugs in the United States to protect pharmaceutical companies, and increasing spending to fund research to increase innovation in the United States drug industry (Pal, 79; Gaffney).

3. Bipartisanship in Pharmaceutical Drug Policy

The last major health care bill passed was the Affordable Care Act (ACA) in 2010. The vote was extremely divisive between the parties with no Republicans voting in favor of the bill. Despite the wealth of changes that were made with the passage of this act, there were no reforms made for the pharmaceutical industry. After the passage of the ACA, drug prices only became higher (Norman). Moreover, the government not only lacked a way to respond, but the ACA required the government to pay for increased drug coverage (Norman).

The most recent law to increase drug innovation was the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012. The most important accomplishment of this act for drug innovation was that it created the breakthrough therapy designation, an expedited

approval track through the FDA. This act received strong bipartisan support with a 92 to 4 vote in the Senate and an unrecorded voice vote in the House (Gillenwater; Reviewing; Milestones).

The passage of this act, along with the 21st Century Cures Act, may seem to show that bipartisan support for pharmaceutical drug related legislation is extremely common; however, in the same Congress that FDASIA passed, seven related bills failed to pass (Harkin). Likewise, in the 2015-2016 Congress in which the 21st Century Cures Act passed, forty-eight related bills failed to pass (Congress.gov).

C. How Literature Informs This Project

A review of relevant literature provides background information for answering the question of "In a partisan environment, what characteristics of political compromise lead to the passage of legislation?" The literature details why the act focused on in the case study, the 21st Century Cures Act, would normally be a partisan bill. It also discusses why there is the partisan divide on pharmaceutical drug policy. Understanding the difference in opinions on pharmaceutical drug policy provides an understanding of why pharmaceutical drug legislation generally fails. Legislation that proposes changes to current laws often caters to one side of the political divide and fails. However, there are infrequent instances such as FDASIA and the 21st Century Cures Act where bills receive overwhelming bipartisan support. The literature provides a background for understanding what bipartisanship is and why it is used. It explains how political compromise is used as a method for achieving bipartisanship. The research also gives some previously studied characteristics of political compromise, which helps to identify the characteristics in the 21st Century Cures Act.

Methodology

This project is a single in-depth case study. The case is the 21st Century Cures Act. This case is both intrinsic and instrumental. An intrinsic case is one where the study is undertaken because the researcher wants a better understanding of this particular case (Punch, 144). This project is an intrinsic case because the first goal was to create a comprehensive understanding of the events that allowed the act to pass. An instrumental case is one where a particular case is examined to give insight into an issue (Punch, 144). This case is also instrumental, as it developed an understanding of how Congress can overcome the partisan divide in passing legislation. Strong bipartisan support for a hyperpartisan topic occurs infrequently. The intensive study of this unique case created an understanding of general characteristics of political compromise that can be used to pass legislation in a partisan environment.

The method used was content analysis, which is used frequently for understanding politics. Content analysis is a research method developed to investigate the content of communication (Hyde Carlson, 264). Content analysis can be used in its own right, and therefore, this project does not have a hypothesis. Content analysis allowed the exploration of the two main underlying questions: did political compromise occur in the act and if so, what were the main characteristics of compromise? Manual analysis, the researcher reading and analyzing the documents without the aid of processing software, was used. Manual analysis is employed when the rhetoric and context of documents and media articles are important.

First, the project sought to answer four questions in order to better understand the act. How was the act developed? Did this act build on drafts of prior bills? What was the initial intent of the act? How did the act progress through the 2015-2016 Congress?

To understand how the act was developed, Congressional Research Service Reports, House Reports, and media articles were studied. The Congressional Research Service Reports provided background information created about the act and were accessed through Proquest Congressional. Proquest Congressional is a database useful for finding general background information about legislation. The House Reports provided the information the House Committee of Energy and Commerce gave to Congress and were accessed through Congress.gov. The media articles were used to gather statements of what Fred Upton, the sponsor, and other supporters of the 21st Century Cures Act were saying about the act and were retrieved from the Committee of Energy and Commerce's online record of press coverage of the 21st Century Cures Act.

To observe if the act is building on prior efforts, GovTrack and Congress.gov were used to search through the Congressional Records to see which bills the 21st Century Cures Act's sponsor had supported in the past. GovTrack is a website that tracks bills and provides information and statistics about legislators including: party, sponsorship, cosponsorship, and voting records. The site has an interface that is easier to use than Congress.gov. It is a newer resource, so a representative sampling of facts from GovTrack were crosschecked with Congress.gov. All checked facts matched. Prior sponsorships and voting records on related legislation specifically were used to research which bills Upton had supported.

In order to understand the intent of the act, media articles written by sponsors or cosponsors of the act were reviewed. These media articles were accessed through the Committee of Energy and Commerce's record. The media articles provided interpretations of the act's intent.

To develop an understanding of how the act progressed through Congress, the Actions Taken section of Congress.gov for the act was used. This helped to identify which steps of the act were the most important to its passage. These questions provided the context on the act necessary to answer whether political compromise occurred throughout the legislation creation process.

To understand if political conflict and subsequent compromise occurred, this project identified four main stages of the act to study. The first stage was the introduction of H.R. 6 into the House and its passage through committees. The second stage was the passage of H.R. 6 through the House. The third stage was the House amending the text of H.R. 34 by replacing the bill entirely with text similar to H.R. 6. The fourth stage was passage of H.R. 34 in the Senate. The days that discussion occurred on for each of these stages were identified using Congress.gov. This step was important in order to utilize the database HeinOnline, which organizes congressional documents by date. Searching by date ensured that no discussions regarding the act were missed. Specifically, Congressional Record Daily reports were used. Traditionally, the Congressional Record would be used; however, this act was passed too recently and has not yet been published into the Congressional Record.

To identify where political conflict and compromise had occurred, a coding scheme was used. The first node, or a collection of references about a specific theme, was labeled political conflicts. Political conflict was further divided into disagreements over the wording of a section, lack of specific content, the removing of content and the inclusion of content. The second node was labeled political compromises. Political compromise was further divided into agreement over the wording of a section, lack of specific content, the removing of content, and the inclusion of content. Detailed notes were taken for each interaction.

Conducting content analysis allowed the compilation of primary sources like congressional documents and media articles to develop an understanding of the steps it took to pass this bill and the dynamic of partisan relations. Both the background of the act and identifying whether political compromise occurred creates a deep understanding of the act through which characteristics of political compromises in the 21st Century Cures Act can be identified.

Results

I. Foundation of the Bill

A. 21st Century Cures Initiative

The intent of the 21st Century Cures Act is to expedite the discovery, development, and delivery of new treatments and cures. Those that introduced the idea for the 21st Century Cures Act strategically planned how to develop a successful bill. These leaders knew that bipartisanship was necessary for the passage of a pharmaceutical drug regulation bill.

The development of this act began in 2012 with representative Joe Barton (R-TX), an influential representative that spearheaded the reauthorization of the NIH during the 109th Congress. He proposed the idea of a task force to the previous Majority Leader, Eric Cantor, and Chairman on the Energy and Commerce committee chairman Fred Upton. Barton described the task force as

> "a bipartisan task force with equal numbers of Republicans and Democrats from the Energy and Commerce Committee and the Appropriations Committee to work with outside groups and experts to see if there were … some ideas that … could … improve the ability to find and implement cures for all the various diseases that afflict our Nation" (Congressional Record 161, pg H4981).

This initial task force began with 24 members (Congressional Record 161, pg H4981). The development of ideas for the bill began in the spring of 2014 when the House Energy and Commerce Committee formed its own bipartisan group, specifically in the Subcommittee on Health, to investigate how to approve medical treatments and take them to market faster. The group called its cause the 21st Century Cures Initiative (Upton, US News). Having both Republicans and Democrats contributing to the foundation of the bill in these committees was

essential to the success of the 21st Century Cures Act because it allowed political compromises to occur in the bill's development stage.

The ideas for the bill were developed through a series of hearings and roundtables held by the 21st Century Cures Initiative from May 2014 through September 2014. The focus of the initial hearings was to understand the problems restricting innovation. These hearings were entitled " The President's Council of Advisors on Science and Technology Report on Drug Innovation," "Examining the Role of Incentives in Advancing Treatments and Cures for Patients," "Modernizing Clinical Trials," Incorporating the Patient Perspective," and "Technology for 21st Century Cures," "Examining Barriers to Ongoing Evidence Development and Communication," "Examining the Regulation of Laboratory Developed Tests," and "Examining Ways to Combat Antibiotic Resistance and Foster New Drug Development"(House Report 114-119). The Subcommittee received testimony from patients, advocates, doctors, non-profits, executives of pharmaceutical and biotechnology companies, research institutes, academics, and government organizations (House Report 114-119).

After the committee held a number of hearings, and roundtables resulting in a series of four white papers, it began working on a bipartisan bill to improve medical innovation. Then, the 21st Century Cures Initiative held a hearing with a focus on reviewing the text of the bill itself. This hearing was held on April 30th, 2015 and included several doctors and representatives from the NIH and FDA. A yearlong series of hearings and roundtable meetings hosted by the House Energy and Commerce Committee culminated in H.R. 6 21st Century Cures Act (House Report 114-119).

B. Support from the Senate

On February 3, 2015, Senators Lamar Alexander and Patty Murray, chairmen and ranking Member of the Committee on Health, Education, Labor and Pensions, respectively, also announced the start of a bipartisan initiative to "examine the process for getting safe treatments, devices and cures to patients and the roles of the FDA and the NIH in that process" (CRS). The Senate initiative was designed to be the counterpart to the House's efforts (CRS).

The Senate wanted to have a companion set of legislation to emphasize the importance of these issues and to have a chance to pass these bills through the Senate if H.R.6 failed.

The Senate's work culminated in a package of 19 bipartisan bills that were reported out of the Senate Health, Labor, Education, and Pensions Committee in a series of three executive sessions held on February 9, 2016, March 9, 2016, and April 6, 2016 (CRS).

Additionally, Vice President Joe Biden strongly supported the bill after it incorporated his Cancer Moonshot initiative. Biden saw an opportunity to pass the cancer moonshot provision through Upton's 21st Century Cures bill. In March of 2016, Upton, Biden, and the leadership of the House and Senate's health care committees met to incorporate the Cancer Moonshot initiative. This led to the inclusion of a provision that increased funding to the NIH for cancer research (Karlin-Smith). The Senate effort is important because it demonstrates that the entirety of Congress, both Republicans and Democrats and the House and the Senate, recognized the need for legislation that increased medical innovation.

C. Strategic Sponsor

In order to understand the progression of the 21st Century Cures Act, it is first important to understand how the sponsors and cosponsors of H.R. 6 were uniquely situated to ensure its success. The sponsor of this bill, Fred Upton, has served Michigan's 6th Congressional District

since January 5th, 1993 and previously represented Michigan's 4th Congressional District from 1987-1992. He also served as Chairman of the House Energy and Commerce Committee from 2011-2017 (GovTrack).

Upton is a more liberal Republican. He is well known for working with both parties on legislation. In the 114th Congress, of the 102 bills that Upton cosponsored, a Democrat introduced 23% of those bills (GovTrack). These characteristics made Upton an ideal sponsor. First, he held significant influence, as he was the chairman for the committee that the legislation would originate from. Second, he was known for supporting legislation from both parties, which means that he would have the understanding of how to make legislation appeal to both sides as well as the connections to secure enough votes for the bill to pass.

Upton also introduced 10 bills and resolutions in the 114th Congress. He primarily sponsors health related bills (30%). In particular, Upton has a history of sponsoring FDA-related regulation bills (GovTrack). In the 114th Congress, he introduced two health related bills, both of which related to FDA regulation. The first bill was H.R. 6: 21st Century Cures Act and the second bill was H.R. 5414: FDA Cross-Center Collaboration Act of 2016 (Congress.gov). This shows that Upton had a strong background in introducing health related bills, specifically those concerning FDA regulation, which made him an ideal sponsor.

The first health related piece of legislation that Upton introduced into the 114th Congress was H.R. 6: 21st Century Cures Act. The purpose of H.R. 6 was to increase innovation in medical research and drug production. The bipartisan bill would reform the standards and appropriations for biomedical research and provide funding for five years to the NIH and to the FDA. The bill also reduced regulations on access to medical research and expedited the testing processes of new drugs (GovTrack).

The bill is related to 46 other bills many of which were incorporated into H.R. 6. After H.R. 6 passed the House, it was never heard by the Senate. Because of delays by the Senate on H.R. 6, Upton amended H.R. 34 and replaced its text with the text of H.R. 6. H.R. 34 was then renamed the 21st Century Cures Act. Therefore, action took place on H.R. 34 in lieu of action on this bill (GovTrack).

Upton next introduced H.R. 5414, the second health related bill. H.R. 5414 was related to H.R.6 as both of these bills work with increasing the speed of FDA approval of drugs. The purpose of the bill was to amend the Federal Food, Drug, and Cosmetic Act to require the FDA to establish one or more Intercenter Institutes. Each Intercenter Institute would focus on a major disease area and structure activities for that area such as coordinating staff with relevant expertise, streamlining product review, and enhancing interactions with patients, sponsors, and the biomedical community (CRS). This bill died after its introduction in the House. This is because provisions of H.R. 5414 were also placed in H.R. 34 once it became the 21st Century Cures Act. Therefore, action took place on H.R. 34 in lieu of H.R. 5414 (GovTrack). This is one example of how many bills were incorporated into the 21st Century Cures Act.

D. Strategic Cosponsors

Upton asked Chief Deputy Whip Diana DeGette (D-CO) to be the first cosponsor. She helped lead the 21st Century Cures Initiative with Upton. She is a more moderate Democrat, who at times leans conservative (GovTrack). She was instrumental for getting support across the aisle for a bill introduced by a Republican. The act also had three other influential original cosponsors: Frank Pallone (D-NJ), Joseph Pitts (R-PA), and Gene Green (D-TX). Pallone was the Ranking Member of the House Energy and Commerce Committee. Pitts and Green were also very powerful members of the House Energy and Commerce Committee. The bill had an equal

number of original cosponsors on both sides of the aisle that spoke adamantly in favor of it throughout its progression through the House. This bill had 230 cosponsors on both sides of the aisle- 121 were Democrats and 109 were Republicans (Congress.gov).

II. Purpose of H.R 6: 21st Century Cures Act

A. Bipartisan in Nature from the Beginning

The initial intent of the bill can best be explored through statements given by the representatives who worked on the bill through the 21st Century Cures Initiative. One member of the initiative was Representative Cathy McMorris Rodgers (R-WA). McMorris Rodgers is the highest ranked Republican woman in Congress and serves as the Chairman of the House Republican Conference (GovTrack). She emphasized the bipartisan nature of the 21st Century Cures Initiative in an article for Forbes in July of 2014. In the article she states that: "as a Congress, we will ensure, with your ideas big and small, that we can take medical advancement into the 21st century. This goal is not political or partisan. It is personal. Medical innovation affects everyone." Fred Upton, the House Energy and Commerce Committee Chair, similarly stated, "health care innovation and the development of cures and treatments is an urgent and nonpartisan priority" (TIME).

This effort to be bipartisan is apparent from the collaboration between Upton and DeGette in the efforts to learn how to accelerate the pace of innovation, development, and approval of treatments and cures in America. They wrote in an article for the Detroit Free press in April of 2015 that the 21st Century Cures Initiative is "uniquely personal, non-partisan and transparent" and that they have a "common goal: faster and better cures and treatments for patients." The bipartisan nature of the initiative is apparent from some of the statements from some of the most influential members in Congress on both sides of the aisle.

B. Intent Remains the Same Though Content Changes

As the 21st Century Cures Initiative held hearings to understand the problems in medical and drug innovation, the intent of the bill remained the same, although the content changed significantly. The elements of the bill did become more specific and detailed. This is illustrated through articles that the key members of the initiative wrote in the media.

Upton wrote an article for *U.S. News* on March 6th, 2014 to explain to the public the reasoning for creating the 21st Century Cures Initiative. Upton writes that the committee would hold a series of listening sessions and roundtables to gather advice and advance ideas about how to streamline the approval process and how to spur more scientific collaboration. He continues to layout the five overarching priorities for this initiative that are detailed in Table 1.

Table 1: March 6, 2014 Priorities

Principle	Method
1. Target diversity in both individuals and diseases	• Encourage the use of personalized medicine
2. Work to better understand diversity of diseases	• Harness the power of social networks
3. Foster better partnerships	• Modify the FDA regulatory structure to encourage greater collaboration among scientists, doctors, patients, and big data analysts
4. Use new tools to lower the costs of clinical trials	• Use communities of people online along with companies with molecular and genetic databases to help target, contact, and monitor people
5. Modify the FDA's risk culture	• Utilize the growing arsenal of tools to avoid mishaps so that safety can be maintained with more rapid and innovative treatment experimentation

In Upton and DeGette's article on *CNN*, on January 13, 2015, they further again listed five main priorities for the bill in Table 2.

Table 2: January 13, 2015 Priorities

Principle	Method
1. Modernize clinical trials to streamline the approval of drugs and devices	• Use genetic testing • Streamline paperwork associated with conducting scientific investigations
2. Better integrate the patient perspective into the regulatory process	• Build public-private partnerships to move towards faster cures and better-involved patients.
3. Foster more collaboration among researchers	• Promote better access to and sharing of information such as genomic and other clinical data
4. Invest in the future of science	• Expand access to resources for young, emerging scientists
5. Better incentivize new drugs and devices for unmet medical needs	• Streamline the premarket process • Establish mechanisms to better capture real world evidence post-market. • Include changing incentives to produce drugs and devices for diseases with unmet needs

Upton and DeGette's goals listed in this *CNN* article differ slightly from those in Upton's article for *TIME,* although the intent is still the same. In both versions of the goals, the intent is to work toward expediting the process of discovery, development, and delivery of new treatments. Elements of focus likely changed as the 21st Century Cures Initiative held more hearings and learned what experts found to be the pressing needs of health care.

After the bill was introduced to the House of Representatives, Upton wrote an article for *TIME* that was released on June 4, 2015. The Committee on Energy and Commerce considered this article to be extremely important in educating the public about the intent of the bill. The

goals Upton listed in the *TIME* article were the same as the goals given in the CNN article, but more specific. He wrote that the bill would:

Table 3: June 4, 2015 Priorities

Principle	Method
1. Modernize the health-care innovation infrastructure and streamline clinical trials	• Modernize and streamline the FDA approval process • Prioritize resources for basic science and medical research • Support antibiotic development
2. Incorporate a patient perspective into the drug and device approval process	• Remove unnecessary paperwork burdens • Begin to establish a structured framework for the meaningful incorporation of patient experience data, informing scientists, regulators, and researchers on how a treatment is or is not working • Provide a regulatory framework to unleash new mobile medical apps and other technological tools • Offer new pathways for health monitoring treatment, and communication
3. Support advances in personalized medicine and provide more resources to support cutting-edge research and help young scientists	• Deliver $10 billion to the National Institutes of Health • Reauthorize the NIH for three years • Provide additional resources to the Food and Drug Administration with the intent of improving research

By the introduction of the bill, the goals had become fewer but more specific. Overall, the goals still contributed to the intent of the bill to expedite the processing of creating new treatments.

III. Political Conflict and Compromise in the Progression of the Act

There were four major stages in the progression of the 21st Century Cures Act through Congress. The first stage was the introduction of H.R. 6 into the House and its passage through committees. The second stage was the passage of H.R. 6 through the House. The third stage was the House amending the text of H.R. 34 by replacing the bill entirely with text similar to H.R. 6. The fourth stage was the Senate concurring with the House amendment and the subsequent passage of H.R. 34. Each of these four phrases were marked by points of political conflict that could have ended the bipartisan nature of the bill and points of political compromise that continued the bipartisanship nature of the bill.

A. Introduction to the House and Markup By Committee

On May 19th 2015, Fred Upton introduced H.R. 6: 21st Century Cures Act into the House of Representatives. H.R. 6 was then referred to the two committees that had jurisdiction over the bill: the House Committee on Energy and Commerce and the Ways and Means committee. On May 19th- June 7th, the Committee on Energy and Commerce held a mark-up session of the bill (Congress.gov). The bipartisan effort showed through the committee's goal for this legislation that was recorded in House Rept. 114-190 Part 1. The document stated that the goal of this legislation is "To help accelerate the discovery, development, and delivery of promising new treatments and cures for patients and strengthen the innovation ecosystem in the United States" (pg. 90).

The legislation passed out of Energy and Commerce's Subcommittee on Health on May 19th on a voice vote, and it passed the full committee on May 21st, 51-0, the second time in 3 years that the committee has had a 51-0 vote (Congressional Record 161, H4977). On June 7th, the Ways and Means committee also discharged the bill (Congress.gov). Later discussion reveals

that many other bills were incorporated into this bill to gain the approval of the entire committee. This phase of the progression of the bill yielded many political compromises; however, later conflict over these decisions occurred in the discussion and passage of the bill in the House.

B. Discussion and Passage in the House

On June 9th- 10th, the House of Representatives debated H.R. 6 and ultimately passed the bill (Congress.gov). There were points of political conflict and political compromise in the general debate over the bill and in the discussion of amendments.

1. General Debate Over H.R. 6

Political conflict in the general debate was caused by the addition of an amendment in between the committee hearing of the bill and the discussion of it in the House. Political compromise in the general debate resulted from the addition of provisions to H.R. 6 that individual politicians felt very passionate about.

a. Conflict

Louise Slaughter (D-NY) expressed her dissatisfaction for the way an amendment was added on to the bill and for the content of the amendment. She stated:

> "After the [Energy and Commerce] committee had voted out this bill unanimously, major changes were made with no committee input at all…They added some policy riders that literally made no sense. Why in the world would you put an abortion rider on a thing for medical research? As far as I know, the NIH and most medical universities doing this research do not perform abortion procedures. But they [the sponsors and cosponsors of the bill] had to have that in order to get the votes to pass the bill. That is the kind of horse trading and all the things that go on here" (Congressional Record 161, H4979).

Slaughter here acknowledges the negotiation process that has occurred in order to get sufficient

support for this bill. She clearly feels that this add-on has sacrificed the bipartisanship of the bill.

Burgess and Rosa DeLauro (R-CT) echoed similar sentiments. Burgess stated,

> "For all of the bipartisanship and positive aspects of this bill. It is like the majority couldn't help themselves. They couldn't resist an opportunity to add a contentious rider to an otherwise bipartisan package to advance medical research" (Congressional Record 161, H4978).

Similarly DeLauro followed that, "The majority is yet again using this bill as a vehicle for anti-choice … amendment language. Since January, the majority and its counterpart in the other Chamber have sought to restrict access to abortion no fewer than 37 times" (Congressional Record 161, H4982).

Even the original cosponsor, Diana DeGette (D-CO) spoke against the addition of the amendment to the bill. She stated:

> "I do want to mention that I was disappointed when, after the bill passed in the Energy and Commerce Committee 51-0, that in the manager's amendment the annual riders from the Labor-HHS bill were put into the bill. I think it is unnecessary, and I think that it distracts our attention from the important mission this bill brings. I will be voting for the Lee amendment (an amendment to remove the rider), but I would urge all of our colleagues, no matter how you vote on the amendments that are made in order in these rules, to please vote "yes" for the patients of America" (Congressional Record 161, H4983).

DeGette as the original cosponsor, spoke against the addition of the provision, but still stood behind the idea of the bill. She encouraged others to vote their preferences on the amendment that would remove the controversial provision but to still vote yes on the bill either way.

b. Compromise

Michael Burgess (R-TX) gave an example of the political compromise that occurred in committee. Burgess stated,

> "I introduced H.R. 293, with Representative DeFazio of Oregon, to protect continuing medical education, which plays a vital role in our healthcare system. This improves patient outcomes, facilitates medical innovation, and keeps our Nation's medical professionals up-to-date. With the inclusion of this provision in H.R. 6, we will ensure that doctors continue to have access to these vital tools" (Congressional Record 161, H4977).

This example shows how the inclusion of other representatives' bills and ideas allowed this bill to gain support to pass through the Energy and Commerce committee. By including Burgess's provision, he was incentivized to vote and speak in favor of the bill. This is an example of political compromise on behalf of the sponsor, Upton. Additions like this provision were useful for gaining support because the Energy and Commerce committee and the House also agreed with this amendment.

2. Discussion of Amendments to H.R. 6

There were three main categories of amendments seen in the House discussion of amendments. The first two categories, solving disagreements over text or failing controversial amendments, were points of conflict and then compromise. The third category, approving amendments that supported the bipartisan goals of the bill, was a point of compromise.

a. Conflict- Disagreements Over Text

i. Young Amendment

Two amendments could have disrupted bipartisanship due to their wording. Todd Young (R-IN) introduced House Amendment 657, which would create the authority within the NIH to conduct a prize program with intent to incentivize health innovation by offering competitors the chance to win a prize for creating research and technology (Congress.gov).

Frank Pallone (D-NJ) the Ranking Member of the House Energy and Commerce committee spoke against the amendment. He said that the he "would prefer to work with the sponsors on the language to find a more appropriate way to accomplish their goals. Therefore, I would urge my colleagues to vote ''no" (Congressional Record 161, H5072).

Upton spoke in favor of the amendment stating "I would just like to say as chairman of the committee that I look forward to working with the gentleman on the language. I think this is an important amendment. I am going to speak in favor of it … I just want to pledge that we will work with you on language that certainly we can all accept, knowing that the goal is a very good one" (Congressional Record 161, H5072). After Upton assured the House that the language would be improved, the amendment was subsequently passed by voice vote (Congressional Record 161, H5072).

ii. Polis Amendment

Jared Polis, a Democrat from Colorado, introduced House Amendment 662, the second amendment where there was conflict over the language. The amendment directs the Food and Drug Administration to issue a report on the risks and benefits associated with a two-tiered approval process that would permit certain medical devices to provisionally come to market if they have demonstrated safety but not efficacy (Congress.gov).

Gene Green (D-TX) stated that he was "concerned this amendment as drafted would lower the approval standard for medical devices and suggest that patients should be exposed to products that are not proven effective" (Congressional Record 161, H5078). He continued, "the FDA approval is a global gold standard for safety and effectiveness. While I support efforts to modernize and improve the standard, safety cannot be evaluated in a vacuum, and patients should not be offered treatments that have not been studied or proven useful to their care" (Congressional Record 161, H5078).

Upton responded that he "would like to work with the gentleman from Colorado. This is an important issue. I believe it has got merit, but we have got to make sure that it is designed just the right way… It is my understanding the gentleman may withdraw the amendment—I would appreciate that—and allow us some time to really get together and see if there might be another day" (Congressional Record 161, H5078). At the request of Upton, the amendment was withdrawn, and the issue of political conflict was resolved (Congressional Record 161, H5078).

In both the Young and Polis amendments, Upton was able to move the amendments in a direction that would garner the most support for the bill.

b. Conflict- Amendment Addressing a Controversial Part of the Bill

i. Lee Amendment

Barbara Lee, a Democrat from California, introduced House Amendment 658 with Jan Schakowsky (D-IL) and Yvette Clarke (D-NY). This amendment addressed the point of conflict from the general debate on H.R. 6. It would strike a provision in this bill that applies to any policy riders included in the annual Labor, Health and Human Services and Agricultural appropriations bills to the new NIH funds and the FDA funds included in H.R. 6: 21st Century

Cures Act (Congress.gov). This amendment could have derailed the bill by turning the debate into a partisan one over whether the bill supports abortion.

Lee stated, "This provision reiterates the current law restrictions on appropriations bills… which is restrictive and discriminatory against low-income women to make their own reproductive healthcare decisions. Now this would apply to this new fund created for the NIH in this bill. Let's be clear what this is really about. It is yet another attempt to insert abortion restrictions and other inappropriate riders into an unrelated bill. This is a bill to increase biomedical innovative research. The 21st Century Cures Act should have been a non-controversial, bipartisan effort" (Congressional Record 161, H5072).

This amendment created a political divide in discussion with Democrats speaking in favor of it and Republicans speaking against it. DeGette (D-CO), spoke in favor of this bill as well stating that the Lee amendment, "removes completely unnecessary and intrusive policy riders attached to the funding provisions of the underlying bill after its unanimous passage from our committee" (Congressional Record 161, H5073).

Joseph Pitts (R-PA) said that, " the underlying bill simply applies current federal health policies that have been approved by both Republican and Democrat majorities for decades to new funds appropriated in the Cures bill. It is nothing more than the status quo applied to new funding." Similarly, Marsha Blackburn (R-TN) stated that, "The American people have spoken out on this issue. Sixty-eight percent of all Americans oppose taxpayer dollars being used for abortions. Seventy-one percent of all millennials oppose this. What the Lee amendment would do is strip away bipartisan agreements that we use in appropriations bills. This is not something that is new. It is not language that is new" (Congressional Record 161, H5073).

Finally, Upton stated that "the amendment would strip dozens of important limitations and restrictions that routinely apply to funding appropriated by Congress with bipartisan support and through the normal appropriation process. For example, this amendment would strike limitations that, as has been noted, would prevent taxpayer dollars from being used to destroy life. And, frankly, they have been in place since the seventies... the Lee amendment would also strike other commonsense protections that normally apply to appropriated funds" (Congressional Record 161, H5073).

Thus, the Democrats argued that the bill was including unnecessary policy riders that included abortion restrictions. The Republicans argued that this amendment would remove bipartisan agreements that are standard across bills. The amendment passed by voice vote but then later failed by recorded vote 176-245 (Congress.gov). Upton ultimately was able to convince the majority of the House to vote against the controversial amendment to appease Republicans that were in favor of this clause in order to secure more support for the bill.

c. Compromise

i. Castro Amendment

Several amendments proposed demonstrated many representatives' efforts to introduce bipartisan amendments. Two examples are the Castro and Slaughter Amendments that were both approved. One example is House Amendment 659 introduced by Joaquín Castro, a Democrat from Texas. This amendment ensures that underrepresented individuals, such as women and minorities, are included in the Supporting Young Emerging Scientists Report (Congress.gov).

Upton immediately spoke in favor of the bill stating that, "We support this amendment. I think that it is important. It would include underrepresented individuals in the sciences in the NIH report on efforts to attract, retain, and develop emerging scientists. It is important to ensure

that the NIH is indeed focused on including all qualified individuals dedicated to finding cures." The amendment was overwhelmingly supported and was subsequently agreed to by voice vote (Congressional Record 161, H5074).

ii. Slaughter Amendment

Louise Slaughter, a Democrat from New York, proposed House Amendment 660 that directs the CDC to conduct a study to determine whether incentivizing the use of new antibiotics will lead to antibiotic resistance and cause these lifesaving drugs to be less effective (Congress.gov).

Upton stated that, "We strongly support this amendment, and I congratulate the gentlewoman for offering it. I fear that paying hospitals more to use a new generation of antibiotics will just repeat the cycle of overuse and develop more drug-resistant superbugs. Quite simply, the taxpayers should not foot the bill for practices that are making antibiotics less effective. This amendment directs the CDC to study the effect the bill would have on drugs that are part of the foundation of modern medicine. I urge my colleagues, many of whom have expressed their alarm at the rise of antibiotic resistance, to support the amendment" (Congressional Record 161, H5074). After the strong support of Upton, the bill was then agreed to by voice vote.

The sponsor of this bill, Upton, demonstrated his leadership skills that allowed him to continue the bipartisanship work of the bill. He allowed popularly supported amendments to be added to the bill in committee. He also was crucial to fielding the amendments in the House discussion to either pass or fail through his speeches in a way that would lead to continuing the bipartisan nature of the bill and gaining support for the bill. Additionally, DeGette, the main

cosponsor, led the general debate over the bill to result in a positive outcome with the majority of representatives voting in favor.

One June 10th, 2015, H.R. 6 passed in the House of Representatives by recorded vote 344-77. On June 12th, the bill was then received in the Senate, read twice, and referred to the committee on Health, Education, Labor, and Pensions. No further action took place on this bill (Congress.gov). This could have been due to disagreements in the committee on provisions in the bill at the time.

C. H.R 34 is Replaced with Text Similar to H.R. 6

Because the Senate did not take action on H.R. 6, Upton needed to find another way to continue the progression of the ideas of H.R. 6 through Congress. This opportunity took place through H.R. 34. On January 6th, 2015, H.R. 34 Tsunami Warning, Education, and Research Act of 2015 was introduced in the House of Representatives by Susan Bonamici (D-OR). The intent of the bill was to authorize and strengthen the tsunami detection, forecast, warning, research, and mitigation program of the National Oceanic and Atmospheric Administration, and for other purposes (Congress.gov). On January 7th, 2015, the act passed in the House by a voice vote. On January 8th, the bill was referred to the Senate Committee of Commerce, Science, and Transportation. On September 6th, 2015, the committee amended the bill by nature of a substitution of bill written on the same general topic. On October 6th, the Senate unanimously approved the amendment, and the bill was subsequently passed by unanimous consent. On October 7th, the bill was then sent back to the House. On November 30th, 2016, the House heard H.R. 34. Fred Upton proposed an amendment to H.R. 34 by nature of substitution to replace the content of the bill with content similar to H.R. 6 (Congress.gov).

1. Conflict

During the debate over this amendment there were only two speakers who strongly opposed the amendment. The first speaker was Bonamici who stated her disappointment that the intent of her bill, the Tsunami Warning, Education, and Research Act, had been removed. However, no other speaker supported her statement, and Bonamici eventually ended up voting in favor of H.R. 34 even though it had become the 21st Century Cures Act (Congressional Record 162, H6889). Jim McDermott (D-WA) was the second speaker strongly opposed to the amendment. He said that

> "The pharmaceutical industry has no control on it whatsoever…You either pay now or you are going to pay later, because if you do not screen those drugs carefully and make sure that they are really doing something, and let the pharmaceutical companies add a Chlorine ion or a Boron or whatever, they are simply putting drugs out on the table that cost too much for the Americans to buy…I urge a ''no'' vote."

McDermott argued that this bill would make the drug approval process less precise and therefore more costly to the American people (Congressional Record 162, H7004).

Although McDermott opposed the bill, other speakers, with significant influence, only spoke in favor of the increased drug innovation that would result from the bill. Joe Barton (R-TX) stated that the bill is,

> "the best pathway forward to get new drugs and new therapies to our citizenship more quickly and efficiently… This bill makes it possible for Cures to actually be put into practice without all the red tape and regulatory overkill" (Congressional Record 162, H6994).

Burgess similarly countered McDermott's argument by speaking about increased efficiency that

would result at the FDA as a result of the 21st Century Cures Act.

> "The 21st Century Cures Act establishes a review pathway at the Food and Drug Administration for biomarkers and other drug development tools that can be used to help shorten drug development time while, at the same time, maintaining the safety standard that the public demands and that we have all come to expect from the agency. The very confused regulation of combination products by the very different centers at the Food and Drug Administration will be improved to cut down on inefficiencies and to reduce the cost of development" (Congressional Record 162, H6888).

2. Compromise

H.R. 34 showed the results of significant political compromise because it included segments that were important to individual representatives.

Earl Blumenauer (D-OR) gave one example of provisions in the bill that affect particular representatives constituents. Blumenauer stated that this bill

> "means that hospitals like Oregon Health & Science University, who made significant investments in building off site departments under one set of Medicare rules, suddenly faced a new set of rules that were changed by Congress midstream. I am pleased that this will prevent pulling the rug out from underneath them" (Congressional Record 162, H6890).

Similarly, Tim Murphy (R-PA) spoke about why he was supporting the bill and emphasized the importance of one particular provision. He stated that,

> "This bill includes in it elements of H.R. 2646, the Helping Families in Mental Health Crisis Act, which is the most revolutionary change to mental health since the Community Mental Health Act of 1963" (Congressional Record 162, H6889).

Ultimately, McDermott was found to be in the minority of opinions as the bill received 392 Ayes with 218 votes from the Republicans and 174 votes from the Democrats and 26 Noes with 20 votes from the Republicans and 6 votes from the Democrats. On December 1, 2016, H.R. 34 was sent back to the Senate (Congress.gov).

D. Senate Concurs With the House Amendment

The Senate debate of whether to concur with the House's amendment to the Senate amendment revealed both political conflict and political compromise. Elizabeth Warren (D-MA) and Jeff Merkley (D-OR) continued the argument given by McDermott in the House over whether the bill actually improved efficiency or whether it just gave pharmaceutical companies the freedom to do as they wished. The debate also revealed instances of compromise where Senators had their personal ideas, wishes, or bills placed within the 21st Century Cures Act. Additionally, several senators highlight the efforts of Congress to work together to compromise in order to find the best solutions to accelerate discovery, delivery, and development of drugs.

1. Conflict

Warren in the Senate reiterated the argument given by McDermott in the House. Warren stated that the bill,

> "was a typical Washington deal a deal that ignored what voters want, and held a bunch of commonsense, bipartisan health proposals hostage unless Congress also agreed to pass a giant giveaway to drug companies…. This bill is not about doing what the American people want. This bill is about doing what drug companies and donors want" (Congressional Record 162, S6591).

Merkley said similarly that,

> "What is in this bill is a provision that loosens the rules governing how companies market

> their drugs and the anti-fraud laws that go along with them- headache pills being advertised on television as a cure for the common cold and hair loss, perhaps. This is just what Big Pharma wants: freedom, freedom to mislead consumers about what drugs actually have been proven to do. I will tell you what else is in this bill. It allows people to sell untested treatments and drugs without final FDA approval that has demonstrated the treatments are safe. Two big factors deregulating responsible provisions for Big Pharma are in this bill" (Congressional Record 162, S6593).

However, Warren and Merkely's opinions were not commonly shared and the other speakers spoke strongly in favor of the bill.

2. Compromise

This bill demonstrated significant compromise because it included sections that were important to individual senators. Johnny Isakson (R-GA) stated, "For me, it is personal for two or three reasons. One reason is the pediatric rare disease provision. The second reason is there are things I worked on for a long time that are coming to full fruition. One of the measures is home infusion" (Congressional Record 162, S6611).

Jack Reed (D-RI) gave a similar speech in support of the bill stating that:

> "This bill also includes my legislation, the Garrett Lee Smith Memorial Reauthorization Act, which supports youth suicide prevention grants for schools, elementary schools through college where children and young adults spend most of their time, to be able to reach at-risk youth. I am especially pleased that, for the first time, this bill will allow funding to be used for mental health treatment on college campuses, the most effective way to prevent suicide" (Congressional Record 162, S6790).

These compromises were strategic as they allowed the bill to receive sufficient support in order

to pass the Senate.

Lamar Alexander, the leading proponent of the bill on the Senate side (R-TN) emphasized the compromises made by both parties in both houses throughout the process of passing the bill.

> "We have had an unusual opportunity in this to work across the aisle with Chairman Upton, Representative Pallone, Representative DeGette, and others in the House of Representatives and their staffs. I want to especially thank Speaker Ryan and Senator McConnell. Speaker Ryan did a triple somersault to try to find a funding mechanism that would satisfy both Democrats and Republicans, and Senator McConnell made time on the floor for it. Not everyone is satisfied with the funding mechanism, but we are all voting for it because this is such an important bill" (Congressional Record 162, S6793).

On December 7, 2016, the Senate agreed to the House amendment by a Yea-Nay vote of 94-5, passing the bill. Then, on December 8th, 2016 the bill was presented to President Obama. On December 13th, the President signed the bill and it became Public Law No 114-255 (Congress.gov).

Conclusion

The question that this project sought to answer was "In a partisan environment, what characteristics of political compromise lead to the passage of legislation?" The results of this project confirm that the 21st Century Cures Act passed with overwhelming bipartisan support because of political compromises between Democrats and Republicans. The case study of the 21st Century Cures Act identified two important characteristics of political compromise that lead to the passage of legislation: the use of strategic planning and experienced leadership.

I. Did Political Compromise Exist

A. Where Political Compromise Occurred

Political compromise is identified by this project in three main areas: the bipartisan committees used to develop the ideas for the act, the use of preexisting bills as provisions, and the resolving of disputes.

First, the committees that created the ideas for the bill were designed to foster bipartisanship. In 2012, Barton created the first committee to find new cures for the United States with equal numbers of Republicans and Democrats. Later, Upton created the 21st Century Cures Initiative as a bipartisan measure to expedite the discovery, development, and delivery of new and innovative treatments to patients everywhere. These committees demonstrate Barton and Upton wanted there to be political compromises between the Republicans and Democrats. Their goal was to create a piece of legislation that would be bipartisan by having both sides create the legislation.

Second, the text of the act heavily relied on preexisting bills. H.R. 6 is related to 46 other bills from both sides of the aisle. Throughout the development and progression of the act through Congress, many of these bills were incorporated either partially or fully as provisions of the 21st

Century Cures Act. The included bills were strongly supported by certain legislators. This shows that Upton compromised by allowing other bills to become part of the 21st Century Cures Act in order to garner support.

Finally, political compromise occurred throughout the 21st Century Cures Act's progression through resolving disputes. Whenever someone spoke against the act, Upton and other legislators in support of the act would highlight other positive provisions the act contained. This convinced legislators that initially spoke against provisions in the act to retract their objections and ultimately vote in favor of the act. These legislators did this so that the provisions they did agree with would pass. What these compromises mean is that both Republicans and Democrats agreed to some unfavorable sections so that the provisions that they were strongly in support of would be able to pass through Congress.

As a result of political compromises, the resulting act contains some initiatives that are desirable to Republicans, some that are desirable to Democrats, and some that desirable to both parties, which led to the overwhelming passage of the 21st Century Cures Act. The political compromises that occurred throughout this bill were strategic as they allowed the bill to receive sufficient support in order to pass.

B. Types of Political Compromise

The research showed that there were two types of political compromise throughout the passage of the 21st Century Cures Act. The first type of political compromise is where both parties met in the middle to reach an agreement. This is seen through the bipartisan committees where Republicans and Democrats worked together to develop provisions that both parties supported. Another example is the rewording of amendments so that both parties supported them. The second type of political compromise is horse-trading: political bargaining in exchange

for votes. Some of the provisions that were added to the act were included to gain votes from certain legislators. For example, Upton included restrictions for abortion to the act, despite many Democrats' disagreement, in order to gain more Republican votes. These two types show that political compromise can yield different results. It can lead to negotiation and eventual agreement or each party including some provisions that they oppose in order to be able to include some provisions that they support.

II. Characteristics of Successful Political Compromise

While there are many characteristics of political compromise, the two that most strongly contributed to the passage of the 21st Century Cures Act are the use of strategic planning and experienced leadership.

A. Strategic Planning

The analysis of the foundation for the bill showed that political compromises were made from its initial creation. Barton and Upton planned strategically so that political compromises would occur in order to ensure that the greatest number of people would support the legislation.

The idea for the bill first began in 2012 although it was not introduced until 2015. In 2012, Barton created the bipartisan task force with equal number of Republicans and Democrats from the Energy and Commerce Committee and the Appropriations committee. When Upton created the House Energy and Commerce Committee's version of the committee, it also had the intent of being bipartisan. This allowed both parties to have influence on the bill in order to introduce a version that could be supported by both parties.

The committee also held hearings representing all parties that would be interested in the bill in order to identify the root problems with the current research, development, and delivery processes and to represent the most commonly agreed to solutions. This helped ensure that the

bill would be supported by a majority of the stakeholders: patients, advocates, doctors, non-profits, pharmaceutical and biotechnology companies, research institutes, academics, and government organizations.

Barton, Upton, and their colleagues created a plan from the beginning to get a pharmaceutical drug related bill through Congress. These committees demonstrate that Barton and Upton knew that bipartisanship would be necessary to pass pharmaceutical drug legislation. They planned for bipartisanship through creating these committees to discuss what the issues were with the discovery, development, and delivery of new cures and treatments and to resolve any early disputes. Barton and Upton wanted there to be political compromises between the Republicans and Democrats so that the bill would have strong support on both sides.

B. Experienced Leadership

1. Fred Upton as the Sponsor

The selection of Fred Upton as the sponsor for the 21st Century Cures Act proved to be the most influential factor that contributed to the passage of the act. Four components made Upton such a strong sponsor: influence, interparty relations, experience, and compromising mindset.

a. Influence

Upton, at the time, was the Chairman of the House Energy and Commerce committee. His position of leadership gave him significant influence to introduce a piece of legislation, helped him garner support within the committee, and allowed him to assure that the act would at least make it out of committee. Having a position of leadership also helped him gain support for the act when it was discussed in the House.

b. Interparty Relations

Upton is also a more liberal Republican (GovTrack). Therefore, Upton has the ability to satisfy both parties. As a Republican, he is able to introduce legislation that would be supported by his party. As a more liberal Republican, he is able to introduce more moderate ideas that would be easier for Democrats to support. Upton is well known for working with both parties on legislation. He, therefore, had the connections needed on both sides of the aisle to gain support and to help mediate political conflict and help lead political compromise.

Because of Upton's ability to introduce more moderate legislation and his connections on the other side of the aisle, Upton was able to convince Diana DeGette to be his first cosponsor. This was a strategic move as DeGette helped Upton garner support from Democrats for the 21st Century Cures Act.

c. Experience

Upton's experience was instrumental in navigating the bill through the political landscape of Congress. He has in depth procedural knowledge, due to his 29 years in Congress, which helped the act progress. He amended H.R. 34 to have the text of H.R. 6 to overcome the barrier of H.R. 6 not being given time on the Senate floor. Upton's knowledge of Congressional proceedings was critical to the passage of the 21st Century Cures Act. He also is experienced in introducing pharmaceutical drug legislation, which contributed to his ability to guide the bill through Congress.

Upton also is skilled in creating political compromise, which allowed him to overcome partisan obstacles. He guided conversation away from controversial points or amendments using rhetoric to focus on the overall positive results of the bill. This turned political conflict into political compromise. He also had a strong willingness to compromise. Upton understood when

amendments to the act would be supported by the majority and made those changes in order to secure more votes for the bill.

d. Compromising Mindset

Upton exemplifies Gutmann' research on how a politician can create bipartisanship through political compromise. Gutmann states that politicians must be able to create political compromises both within their party and the opposing party. Upton, with his political background and connections, was well suited to make compromises on both sides of the aisle. He was skilled at doing so throughout the progression of the act. Additionally, in order for political compromise to occur, Gutmann states that a politician must have a compromising mindset, which is defined as when politicians adapt their principles to respect their opponents' opinions. Upton is an example of a leader that has a compromising mindset because he was able to see the value in ideas introduced by the Democrats. He demonstrates, through his actions, speeches, and statements, how leaders with compromising mindsets go about creating political compromise.

2. Influential Cosponsors

The first cosponsor of the bill was Diana DeGette (D-CO) who helped lead the 21st Century Cures Initiative with Upton. She is a Democrat, although she is a more moderate Democrat who at times leans conservative (GovTrack). She, thus, was able to appeal to Democrats to gain support for the bill while still working well with Republicans. She holds a position of leadership as the Chief Deputy Whip, which means that she has significant influence with the Democratic Party. She, like Upton, used rhetoric throughout her speeches to encourage representatives to vote in favor of the bill due to the greater good of its intent despite points of disagreement. This message was particularly useful in convincing Democrats to vote for the bill

when discussing areas of the bill that were conservative leaning, such as the rider that placed limits on using funding for abortion.

The act also had three other influential original cosponsors: Frank Pallone (D-NJ), Joseph Pitts (R-PA), and Gene Green (D-TX). Pallone was the Ranking Member of the House Energy and Commerce Committee. Pitts and Green were also very powerful members of the House Energy and Commerce Committee. The act had an equal number of original cosponsors on both sides of the aisle that spoke adamantly in favor of it throughout its progression through the House. Additionally, the act has 226 other cosponsors, which showed that the sponsor and original cosponsors worked hard to make sure that the act was widely supported throughout the House of Representatives.

3. Support of Key Leaders in the Senate

The Senate created a bipartisan initiative designed to be the counterpart to the House's efforts. Senators Lamar Alexander (R-TN) and Patty Murray (D-WA), chairmen and Ranking Member of the Committee on Health, Education, Labor and Pensions respectively, were the two senators chosen to lead the initiative. These two senators were extremely influential and thus helped gain support for the 21st Century Cures Act when it passed into the Senate. Alexander and Murray, in fact, both spoke in strong support of the 21st Century Cures Act for the last two speeches of the Senate hearing of the bill before it passed the Senate. This shows their commitment and ability to influence the Senate to help the bill pass.

Additionally, Vice President Joe Biden's support strongly contributed to the passage of the 21st Century Cures Act. Before Biden's support, the act was struggling to gain momentum in the Senate (Karlin-Smith). After the incorporation of Biden's Cancer Moonshot initiative, Biden was invested in the passage of the act. His initiative was very personal to him as his son, Beau,

died from brain cancer less than a year earlier. With Biden's imposing presence, the act was put onto the Senate's agenda and was introduced into the Senate (Karlin-Smith). When the act was discussed in the Senate, Biden presided, a rare occurrence, showing how strongly he supported the act (Congressional Record 162, S6696). Biden's support for the act helped convince Senators, particularly Democratic senators, to pass the act.

III. Limitations and Next Steps

The 21st Century Cures Act was used to understand how drug legislation, a partisan issue, can be passed with overwhelming bipartisan support. The findings from this study of the act are applicable to any type of policy that legislators seek to pass in the current hyperpartisan environment of Congress. This project found that the use of strategic planning and experienced leadership in political compromises led to the passage of this act. The success of these strategies in passing the act was evident through the 392-26 vote in the House and 94-5 vote in the Senate.

However, the project does not address two key questions that should also determine the success of the bill: whether this bill accomplishes what it initially set out to do and whether provisions of the bill have been implemented. The first question is if political compromise leads to bills that accomplish the same goals as initially intended? The initial intent for the bill was to expedite the discovery, development, and delivery of new and innovative treatments and cures. Based on general statements given by representatives and senators, it seems the intent for the bill remained the same. However, an in depth analysis of the different iterations of the text of the bill would be necessary to determine whether the intent changed. The second question is when different provisions will take place in the future and if the law has had any effects so far? To answer this question, research would have to be done into the enactment dates and to see if those provisions have been implemented.

This project has implications for future research. Studying how political compromises were made in the 21st Century Cures Act revealed characteristics of successful political compromise. Understanding these characteristics can help in the analysis of other bills to understand why they do or not pass. It can also help Congress understand how to overcome the partisan divide in passing legislation.

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Appendix

Fig. 1 FDA Drug Approval Process Infographic