Promotion, Protection, and Entrepreneurship: Stakeholder Participation and Policy Change in the 21st Century Cures Initiative

HANNA K. BRANT
University of Missouri-Columbia

NATHAN MYERS
Indiana State University

KATHERINE L. RUNGE
University of Colorado-Boulder

The Energy and Commerce Committee in the U.S. House of Representatives developed the 21st Century Cures Act through a fact-finding process that involved many different stakeholders in the biotechnology field. This effort can be viewed as an example of policy entrepreneurship in that the committee was trying to accelerate the development of new drugs and treatments. Some members of the committee were very active in this process, while others were less engaged. This article investigates what factors influenced individual legislators’ participation level in the initiative. We consider whether there is evidence that legislator characteristics and the types of groups actively involved in the initiative contributed to some important viewpoints going unaddressed. The evidence supports a contention in the literature that legislators approach biotechnology with a promotional focus as opposed to placing an emphasis on protecting the public from harm, which may have led to potentially problematic changes in areas such as informed consent.

Acknowledgements: The authors wish to thank the Center for Genomic Advocacy and the Center for Student Research and Creativity at Indiana State University for providing financial support for this research. Thank you to Dr. Chia-An Chao at Indiana State University for allowing us to use the Biotechnology Development Index variable, which she was integral to creating. This variable will be further explicated in a future paper. We also acknowledge the work of Sarah Rusie in collecting data necessary for that variable. The authors would also like to thank the editors of Politics & Policy, and acknowledge the journal’s anonymous reviewers who provided helpful and constructive feedback. An earlier version of this article was presented at the 2016 meeting of the Midwest Political Science Association in Chicago, IL.
Keywords: Policy Change, Policy Entrepreneurship, Promotional Focus, Stakeholders, Protection, Participation, Biotechnology, 21st Century Cures Initiative, Legislators, Informed Consent, Policy Entrepreneurs, Bipartisan Momentum, U.S. Congress, Responsible Use of Emerging Technology.

Related Articles:

Related Media:

El comité de Energía y Comercio de la Cámara de Representantes de los Estados Unidos desarrolló la Ley de Curas del Siglo 21 a través de un proceso de investigación que involucró a muchas partes involucradas en el campo de la biotecnología. Este esfuerzo puede ser visto como un ejemplo de emprendimiento polítnico por parte del comité para acelerar el desarrollo de nuevos medicamentos y tratamientos. Algunos miembros del comité fueron muy activos en este proceso, mientras que otros fueron menos comprometidos. Este estudio investiga qué factores influyeron en el nivel de participación de los legisladores individuales en la iniciativa. Consideramos si existe evidencia de que las características del legislador y los tipos de grupos que participan activamente en la iniciativa contribuyeron a que no se abordaran algunos puntos de vista importantes. La evidencia apoya la afirmación en la literatura que los legisladores abordan la biotecnología con un enfoque promocional en lugar de poner énfasis en proteger al público del daño, lo que puede haber llevado a cambios potencialmente problemáticos en áreas como el consentimiento informado.
In July 2015, the U.S. House Energy and Commerce Committee unanimously passed H.R. 6, the 21st Century Cures Act. Described by some pundits as the most significant piece of health-care legislation since the Patient Protection and Affordable Care Act, the 21st Century Cures Act has the potential to significantly cultivate the U.S. biotechnology sector. The law was born from a strategically orchestrated campaign of activities by the House Energy and Commerce Committee, which included several hearings and a number of roundtables around the country. This article explores whether the 21st Century Cures initiative and the legislation it ultimately produced was the product of bipartisan effort diffused throughout the committee, or the effort of a few key policy entrepreneurs. We also consider whether the nature of the entrepreneurship emphasized the promotion of the biotechnology industry over its regulation, which may have affected the types of external groups represented and left some potential policy concerns unaddressed.

This article focuses on the members of the House Energy and Commerce Committee during the 21st Century Cures initiative to investigate whether the bipartisan momentum behind the legislation was diffused or concentrated within the committee. This is examined through a content analysis of legislators’ relative participation in the 21st Century Cures hearings and roundtables. Regression analysis is used to test for relationships between members’ level of participation in the hearings, as a measure of entrepreneurship, and several independent variables measuring personal and political factors that could affect their level of interest in biotechnology. In addition to the content analysis, evidence from the hearings is also qualitatively examined to investigate connections between the representatives and the external participants, the policy positions expressed by the external participants, and the degree to which these policy positions became part of the legislation as passed.

Coupled with investigating the legislators, the witnesses that appeared during the 21st Century Cures hearings are also considered in regard to whether or

---

1 The U.S. House of Representatives passed the final version of the bill on December 8, 2016. It was signed into law shortly thereafter.
not they represented a broad and representative cross section of biotechnology stakeholders and addressed a full range of prominent biotechnology issues. Content analysis of the media coverage of biotechnology issues highlighted by the 21st Century Cures initiative is also used to gauge the diversity of stakeholders and views taken into account. The issue of whether the content of the 21st Century Cures initiative represents a well-rounded perspective on key biotechnology issues is considered through an analysis of reactions in the popular media and via Twitter. We take particular note of criticisms of the 21st Century Cures Act presented in social media and whether those views were raised during the hearings and roundtables. This analysis is intended to promote more discussion and research concerning whether or not congressional policy makers are promoting responsible use of emerging technology. This research also contributes to the contention in the literature that the participation of outside groups is largely confined to those organizations that support a committee’s positions.

**Previous Government Approaches to Biotechnology Policy**

Academic literature in the field of genomic policy describes the history of efforts to regulate genomic research. Such efforts have been undertaken by the federal government as well as interdisciplinary groups of stakeholders. There is considerable agreement that the field would benefit from more interdisciplinary collaboration to try to address questions and challenges posed by genomic research (Gottweis 2005; Hoffman and Sung 2005; Sharp, Yudell, and Wilson 2004).

**Relationship between Government and the Biotechnology Industry**

While much of the early federal policy making in the biotechnology field was aimed at protecting the public from possible unforeseen consequences, considerable emphasis has been placed at the state level on using biotechnology as an engine for economic development. Cozzens and others (2005) noted that every U.S. state uses science and technology as part of its economic development strategy. State governments began to develop an extensive array of programs in the 1980s to promote collaboration among universities and industries, commercial development of new technologies, the start-up of new firms, and technological modernization existing firms (Feller 1992).

Mintrom (2009) asserts that, since WWII, states have provided the infrastructure for scientific research while the federal government has provided funding for specific projects. States have tried to create infrastructure to attract large amounts of federal dollars into their jurisdiction. This promotion of scientific research has been found to have positive outcomes for economic
development. Bagchi-Sen, Lawton Smith, and Hall (2004) noted that, to increase the volume of venture capital, as of 2004, 28 states had publicly supported seed or venture capital funds to invest in bioscience-related companies. Furthermore, five states had funds that could only be invested in bioscience companies: California, Massachusetts, North Carolina, Ohio, and Wisconsin.

Harris (2015) noted efforts to create supportive environments for biotechnology in the states, including both tax credits and state funding, as well as increased civil and/or criminal penalties for destruction of biotech property. Ten states—California, Arizona, Hawaii, Iowa, Louisiana, Kansas, Massachusetts, North Carolina, Oklahoma, South Dakota, and Virginia—have both types of policies. Brown (1988) noted that states have tended to focus on how to ensure the growth of the biotechnology industry without also giving appropriate consideration on how to control or monitor it. Policy-making efforts to increase biotechnology industry at the state level may have encouraged more focus at the federal level as well.

**Effect of State Policy Making on Federal Policy Making**

The promotion of biotechnology as an economic development strategy at the state level was aided by the product-based federal regulatory system surrounding biotechnology, which put medical biotechnology under the purview of the House Energy and Commerce Committee (Sheingate 2006a). Due to economic conditions and political pressure, the dominant congressional focus on medical biotechnology shifted from moral and ethical concerns to a renewed focus on economic applications. This may have been a result of members of Congress looking to states as laboratories of democracy and attempting to encourage the economic development activity occurring at the state level. Members of Congress may have also experienced political pressure from the state level to facilitate this activity, or been influenced by personal interests.

Legislators’ attitudes toward biotechnology policy would be expected to affect congressional hearings on the issue. While groups participating in hearings concerning medical biotechnology were once diverse, the tendency of committees to invite participants to testify at hearings that support their existing viewpoint (see Jones, Baumgartner, and Talbert 1993) resulted in less attention to ethicists and those concerned with the potential risks of biotechnology. Jones Baumgartner, and Talbert (1993) also argue that committee bias can only result in a larger institutional bias when a single committee holds a policy monopoly over the issue. As biotechnology has come to be viewed in a largely economic context, the Energy and Commerce Committee has developed such a monopoly within the House.

In Sheingate’s (2006a, 2006b) work on congressional committee activity regarding medical biotechnology, he came to three main conclusions: such activity was once spread out over multiple committees, was more concerned with medical than economic benefits, and involved interest groups interested in
ethical and consumer concerns. Medical biotechnology hearings were less dominated by industry concerns than more agriculturally focused hearings. However, recent work in the area of biotechnology (see Harris 2015) shows that biotechnology has become increasingly viewed in an economic development context, a shift which is supported by regulatory and oversight changes at the federal level. In essence, Congress shifted its orientation from a protective one to a promotional one in the area of biotechnology, with representatives acting as policy entrepreneurs to promote the development of new biotechnology innovations.

Biotechnology Policy and Entrepreneurship

Sheingate (2006b) recommended studying whether individuals on committees with complex jurisdictions are more entrepreneurial than individuals on committees with more limited jurisdictions. This research will follow from this recommendation by studying the characteristics that influence the level of entrepreneurship members of the Energy and Commerce Committee demonstrated during the 21st Century Cures hearings and development of the legislation. We hypothesize that characteristics of individual legislators will be associated with their level of active participation in the committee processes.

Kingdon (1995) defined a policy entrepreneur as someone who is in or out of government, in elected or appointed positions, or part of a research organization or interest group. Their defining characteristic is willingness to devote time, energy, reputation, and resources in hopes of a future return. Success as a policy entrepreneur would presumably be linked to effectiveness as a legislator. Volden and Wiseman (2014) note five habits of highly effective law makers, including: developing an agenda based on their background, experience, and expertise; developing an agenda focused on district needs; being accepting of compromise when working with opponents; and assembling many allies both inside and outside the institution. Of particular note for this discussion, they also wrote that effective legislators should behave in an entrepreneurial manner in positions of power such as chairmanships.

Wawro (2010) noted Hall’s (1996, 233) definition of policy entrepreneurs as: “a special case of [legislative] participation, one where the individual ranks at the high end of the formal and informal participation scales.” Some may theorize that legislators engage in so much activity to attract electoral support, but Wawro found no significant evidence to support a relationship between entrepreneurship and campaign support from Political Action Committees (PAC). Neither did Wawro find evidence that campaign contributions were made with the understanding that legislators would engage in entrepreneurship in the future. Wawro’s research also contradicted assertions that increase entrepreneurship could harm a legislator’s chances for reelection, finding that general legislative activity was often forgotten. Specific actions taken to benefit the district were more of a factor in voters’ decisions. Wawro also found, in regard to
electoral success, that constituents of Republican legislators were more likely to respond favorably in an election to higher levels of entrepreneurship. Another analysis indicated that Democrats had a somewhat lower probability of being reelected if they were more entrepreneurial, with Republicans experiencing no effect. However, neither of these relationships were statistically strong.

Mintrom and Norman (2009) noted that the work of policy entrepreneurs to achieve policy change can be decisive in situations where contextual factors are working against the passage of a policy. They highlighted the importance that policy entrepreneurs demonstrate social acuity, team building, problem definition, and the ability to lead by example, such as using pilot projects to illustrate possible success. Mintrom (1997) cited the role of policy entrepreneurs in the consideration and passage of school choice in 26 states as evidence of their effectiveness. Research by Weissert (1991) found that legislators associated with salient issues were perceived to be more effective. Similarly, policy entrepreneurs are more likely to be effective if they are working with highly salient issues or are successful in increasing the salience of those issues. Roberts and King (1991) described four categories of activities “public entrepreneurs” engage in: creative/intellectual (generate/broker ideas), strategic (approaches for action), mobilization/execution (move a policy through the legislative/administrative agenda), and administrative/evaluative (active involvement in the implementation and assessment of policy). The members of the Energy and Commerce Committee are in a position to engage in all of these activities, however, we emphasize the first three categories of activities. It is worth noting that all of the tasks described above involve working cooperatively effectively with other policy makers. A study by Reingold (1996) found that the vast majority of legislators recommended the use of cooperative strategies to be effective, with very few recommending the use of coercive strategies. This seems applicable advice for policy entrepreneurs as well. Fiorina and Shepsle (1989, 32-3) as cited by Wawro (2010, 4) describe policy entrepreneurs as coordinating resources and actions to accomplish goals that would otherwise not be possible. Hall (1996, 91) notes that this requires actively collecting and processing information on both the effects of the policy proposed and the policy preferences of those in leadership (as cited in Wawro 2010, 6). If a policy entrepreneur is successful in producing a good policy, they should also work to communicate its availability and benefits to the public (Kirzner 1973, 136 cited in Wawro 2010, 11-2).

Roberts and King (1991) noted that the concept of policy entrepreneurs can be applied to different models of policy making, including Kingdon’s (1995) idea of policy streams, where entrepreneurs help to link problems, ideas, and politics. The 21st Century Cures process could be seen as an example of Kingdon’s process at work, with members of the committee acting as entrepreneurs linking problems (need for economic development and new health technology), policy ideas (proposals for streamlining the regulatory process for biotechnology), and politics (bringing together a bipartisan coalition around reform).
Mintrom and Vergari (1996) noted that policy entrepreneurs should develop strategies for presenting their ideas to others, as demonstrated by the 21st Century Cures initiative’s use of hearings and roundtables. A study by Anderson, Box-Steinffenmeier, and Sinclair-Chapman (2003) found that legislators who introduce bills and speak on the floor exhibit greater effectiveness, but those behaviors need to be modulated. In other words, it is beneficial not to do too much. It is important to consider, with this in mind, that there may be such a rush to take advantage of a window of opportunity created by the convergence of problems, policies, and politics in regard to biotechnology policy that some important points of view may be crowded out. There may be diminishing returns from talking too much and not listening enough.

Research Focus

The 21st Century Cures Act (H.R. 6) was passed in the House of Representatives on July 10, 2015 on a vote of 344-77.² The bill was remarkable for the level of bipartisan support it received in a time of strong partisanship in Congress. The bill was introduced by Representative Fred Upton (R-MI) on May 19, 2015 and had 230 cosponsors (U.S. House of Representatives 2015b). Cosponsors included all members of the House Energy and Commerce Committee. Of those voting against the legislation, 70 representatives were Republicans and seven were Democrats. One of the bill’s cosponsors and Energy and Commerce Committee member, Anna Eshoo, ultimately voted against the bill (U.S. House of Representatives 2015a).

The underlying question in this research is, given the number of House members sitting on the Energy and Commerce Committee, why were some members so much more active in the process as compared to other members? Also, did the factors encouraging greater levels of activity affect who was invited to participate in the hearings and the ultimate content of the legislation? Given the focus on biotechnology as an economic development tool at the state level as well as the product-oriented approach to genomic legislation at the federal level, this article will begin by statistically testing for relationships between legislators’ characteristics and their level of participation in the 21st Century Cures hearings. Characteristics include law-maker party affiliation, ideology, whether a member of Congress comes from a state active in the biotechnology field, and whether they accepted campaign contributions from the biotechnology sector. Statistical testing will be supplemented with a more qualitative review of the evidence.

The discussion surrounding the passage of the 21st Century Cures Act and the content of the final legislation did include topics not directly associated with biotechnology innovation, such as the use of electronic health records. Members

²The final version of the legislation passed the U.S. House of Representatives on December 8, 2016.
may have been influenced in regard to their views on the bill and their participation in the process by these other topics. However, press releases and statements made by members of Congress largely focused on the biotechnology innovation aspects of the bill when promoting it to constituents. In a later discussion of press releases accessed through Lexis-Nexis regarding the bill, it is noted that of 47 press releases from members of the Energy and Commerce Committee, only eight of those releases made reference to issues other than biotechnology. These issues included Medicare payments and reimbursement, loan repayments for students going into medicine/research, requiring drug manufacturers to share information with consumers, testing/repurposing existing drugs for off-label uses, and interoperability of electronic health technology.

Also, in terms of the content of the bill, the majority of the legislation is targeted at promoting biotechnology innovation. Titles I and II of H.R. 6 as enacted are strongly focused on biotechnology innovation and/or being able to more effectively deliver treatments derived from the technology using electronic medical records. Title III focused on issues such as delivering treatments through the use of electronic health records and other technological innovations, as well as improving care through more education for doctors. Title IV focused on policies regarding how Medicare and Medicaid would reimburse providers for new treatments and equipment stemming from technological innovation. Even those groups participating as witnesses during the process of developing the bill that were not directly associated with biotechnology innovation stood to benefit financially from the expansion of the industry. The promotion of innovative “cures” for medical conditions is credited with giving the legislation its bipartisan character. This can be seen in a press release from Representative John Sarbanes (D-MD) released after the initial passage of the bill in the House of Representatives:

The bill will increase biomedical research and accelerate the approval process for new medical devices and prescription drugs, giving patients more access to life-saving treatments.

The level of bipartisan support for this bill is a testament to its tremendous promise - affording practitioners improved health care technologies and providing patients with better medical care. I want to commend Chairman Upton [R-MI] and Ranking Member Pallone [D-NJ] for coming together to advance this significant piece of legislation.

Importantly, this bill would give young science researchers more opportunities to pursue cutting-edge and potentially life-saving medical studies. With the 21st Century Cures Act, we can offer crucial resources to the next generation of researchers as they embark on groundbreaking projects to strengthen the American health care system. (Sarbanes 2015)

While other elements came to be incorporated into the legislation as passed, notably mental health-care reform, the biotechnology elements appear to have been the driving force.
Given the view that legislators in support of the 21st Century Cures Act sought to promote the biotechnology industry, this research will also examine the contention in the literature that the participation of outside groups is largely confined to those organizations which support the committee’s positions. We examine this descriptively by dividing the participating organizations in the 21st Century Cures process into different groups and evaluating the degree to which they participated. We focus on the groups outlined by Sheingate (2006a): producer groups, public interest organizations, medical professionals, members of Congress, academic and private scientists, other government representatives, and executive branch officials.

Finally, we conduct qualitative analyses of the responses to the 21st Century Cures Act in the news media and social media to evaluate whether the act passed by the full House incorporated all relevant viewpoints. This is examined by coding for criticisms that were overlooked or neglected in the drafting of the 21st Century Cures Act. This qualitative analysis ties back to the statistical findings by looking at whether the exclusion of some groups and the neglect of some issues may be the result of variables influencing committee members that affected the outcome of the legislation.

Methodology

This research utilizes the case study method, as it will examine a particular example of policy making in significant detail using a variety of different documents and evidence. Content analysis is used to examine some of these documents to produce a dataset to generate descriptive findings and to perform regression analysis.

We investigate the hearings and roundtables of the 21st Century Cures initiative to generate evidence regarding what variables influenced legislators’ level of policy entrepreneurship and the degree to which the initiative incorporated a full range of viewpoints. This research fits the definition of a case study as articulated by Yin (1989, 23) as cited by Luton (2010, 123). First, it “investigates a phenomenon within its real-life context” (123). Second, “the boundaries between the phenomenon and the context are not clearly evident” (123). Third, “multiple sources of evidence are used” (123).

A case study approach is appropriate for this research because it is intended to use multiple forms of qualitative data to explore these linkages. The specific topic of the 21st Century Cures initiative is useful for exploring the connections between theory and practice, because it illustrates the many complexities involved when trying to balance issues like safety and innovation. All of the evidence used in the case study is integrated by its focus on policy entrepreneurship during the initiative, wherein external stakeholders were invited to participate in the hearings and roundtables by the entrepreneurs, and how the policy recommendations of the entrepreneurs influenced the legislation passed in the House.
Data

The data used in this research come primarily from the website for the 21st Century Cures initiative, hosted by the U.S. House of Representatives Energy and Commerce Committee. Documents collected from the Committee’s website include transcripts of formal congressional hearings on biotechnology issues related to the 21st Century Cures Act, as well as videos of roundtables hosted by the Energy and Commerce Committee in different American cities to discuss biotechnology issues. Agendas of committee meetings are also used to focus on external participants who provided testimony at these meetings, as were news articles regarding the initiative featured on the website. Additional qualitative data were collected from the 21st Century Cures Twitter page (Path2Cures) and news articles collected through Lexis-Nexis and Google News searches.

Transcripts of 21st Century Cures hearings were coded independently by two of the authors. The transcripts were coded for substantive contributions from members of the House Energy and Commerce Committee. Substantive contributions were defined as any question or comment addressing biotechnology issues that served to advance the discussion and were coded as frequencies. Roundtables were similarly coded by the co-authors using videos of the proceedings, transcripts were not available. In total, there were six hearings conducted from May 20, 2014 to September 19, 2014 and six roundtables from May 6, 2014 to July 23, 2014. Sixty-three individual House members are accounted for in the dataset. The vast majority of these House members sat on the Energy and Commerce Committee, although there were some members who participated in an *ex officio* capacity or because of a particular interest in the subject matter.

Once the frequencies of substantive contributions were coded for hearings and roundtables, separate participation scores were created for each type of meeting. Separate scores were generated because the roundtable events were held around the country, thus making it difficult for many members of the committee to attend. For both types of meetings, the total number of substantive comments and questions made by each House member were divided by the number of hearings and roundtables attended by the member, keeping in mind that some members’ schedules did not allow them to attend every hearing. The two participation scores were then weighted, with hearings receiving a heavier weighting at .7 and roundtables receiving a lower weighting at .3. To create the dependent variable, the weighted participation scores for hearings and roundtables were then added to create a total participation score for each member of the committee or congressional participant in the hearings/roundtables.

---

3 The site for the 21st Century Cures initiative can be found at https://energycommerce.house.gov/cures
4 Only 54 were members of the committee.
Correlation between the coding of the two authors was tested at each phase of the calculation process. The Pearson’s $r$ correlation for the final weighted participation scores was .93. This participation score represents the dependent variable for the forthcoming regression analysis. This variable measures the individual entrepreneurship of U.S. House members as defined as effort to help develop the final 21st Century Cures legislation. As statements made by the leaders of the Energy and Commerce Committee announcing the 21st Century Cures initiative indicate, the committee approached this as an opportunity to promote the biotechnology industry in the United States. Therefore, our study begins with the assumption that greater participation in the committee’s efforts represents greater commitment to the committee’s stated objectives.

Our goal for the first portion of the research was to test the theory suggested in the literature and the popular media that the promotion of biotechnology was a bipartisan issue. We collected data on two independent variables to test this theory. One was a binary variable indicating whether a congressional participant in the hearings was Republican (1) or a Democrat (0). The partisan affiliation of the members was determined by reviewing their respective congressional webpages. Keeping in mind the previous research that indicates attitudes toward biotechnology may have more to do with ideology than partisan affiliation, we have included a measure of conservative ideology. For this measure, we employed the first dimension values, measuring a representative’s level of support for government intervention in the economy, from the DW-NOMINATE data produced by Carroll and others (2015). Given this, we derive the following hypotheses:

**Hypothesis 1:** If a congressional participant is coded as being Republican (1), they will have a higher level of participation in the 21st Century Cures hearings and roundtables.

**Hypothesis 2:** If a congressional participant is less supportive of government intervention in the economy (i.e., more conservative), then they will have a higher level of participation in the 21st Century Cures hearings and roundtables.

In addition to partisanship and ideology, we hypothesize that a House member’s position in relation to the committee may have an effect on their level of participation. We include two variables to address this issue. One measures whether or not a House member held a seat on the Energy and Commerce Committee at the time of the 21st Century Cures proceedings (1 = held a seat, 0 = did not hold a seat). The other variable measures whether a participant was in a majority or minority leadership position on the committee at the time of the proceedings (1 = in leadership, 0 = not in leadership). Those who held seats on the committee with leadership positions are presumed to have more incentive for legislative success. Therefore, we propose the following hypotheses:
Hypothesis 3: If a congressional participant held a seat on the Energy and Commerce Committee, then their level of participation will be greater.

Hypothesis 4: If a congressional participant held a leadership position on the Energy and Commerce Committee, then their level of participation will be greater.

Another hypothesis considered was that congressional participants from states with strong biotechnology industry would be more likely to be active in the 21st Century Cures hearings. Therefore, we included a biotechnology development index (BDI) score for the state that each congressional participant in the hearings represented.

This state biotechnology index score was computed by collecting data on five different measures of biotechnology development in a state, standardizing the measures, and then calculating the geometric mean for those measures. The BDI is made up of five indicators. (1) The number of life sciences research and development employment as a percentage of total state employment, (2) the number of life sciences manufacturing employment as a percentage of total state employment, and (3) the number of life sciences establishments as a percentage of total establishments are taken from 2012 data from the U.S. Bureau of Labor Statistics. The fourth indicator, from the National Institutes of Health, measures each state’s federal funding for biotechnology research and development, data were normalized using gross state product. A fifth indicator, the number of biotechnology laws passed up to and including 2012, was collected from the National Conference of State Legislatures. The total number of bills was divided by the total number of state legislators in each state.

The following formula was used to normalize each of the indicators:

\[
\frac{\text{State Value} - \text{Minimum Value of 50 States}}{(\text{Max. Value of 50 States} - \text{Min. Value of 50 States})}
\]

Then, the BDI was calculated based on the geometric means of the five biotechnology indicators (Chao and Myers forthcoming). For some representatives, the biotechnology industry may not be relevant to their particular district, even though it is for the state as a whole. If members are single-minded seekers of reelection (Mayhew 1974), then we would expect members to be aware of their state’s policy climate to aid their reelection goals.

Davidson and Oleszek (2002) note that as House members gain seniority in their positions they tend to cultivate specialization in particular areas. Greater seniority and increased expertise can lead to greater legislative success. This may help members of Congress to pursue other statewide offices down the road. Representatives from states with a more active biotechnology industry would be expected to have more incentive to actively promote that industry legislatively. Therefore, we hypothesize:
Hypothesis 5: If a congressional participant represents citizens in a state with a higher level of biotechnology development, then their level of participation will be higher.

A final hypothesis considered is that House members who received electoral support from the biotechnology industry in the form of campaign contributions would tend to be more active during the 21st Century Cures hearings. Data on the campaign contributions made in 2014 by the Biotechnology Industry Organization to congressional participants in the 21st Century Cures hearings were collected from the website Open Secrets. It is anticipated that those representatives receiving campaign support from the biotechnology industry will more strongly advocate for positions favorable to the biotechnology industry.

Hypothesis 6: If a congressional participant received a higher level of campaign contributions from the biotechnology industry, then their level of participation will be higher.

An interaction variable for the biotechnology index score and the level of campaign contributions was also calculated, as it was suspected that the influence of one of the variables on the dependent variable may be influenced by the level of the other.

Hypothesis 7: If a congressional participant is from a state with a higher level of biotechnology development and received a higher level of campaign contributions from the biotechnology industry, then their level of participation will be higher.

Descriptive statistics for these variables are provided in Tables 1 and 2 below. Republicans had slightly greater representation on the committee than Democrats (35-28). The bulk of the committee participants was comprised of members of Congress with seats on the committee that did not hold a leadership position on the committee. The DW-NOMINATE ideology score was .228 (minimum of −.597, maximum of 100). The average participant received $825.40 in campaign support from the biotechnology industry (compared to a maximum of $5,000) and came from a state with a BDI score of .215, compared to a maximum of .598. The average interaction between a state’s level of biotechnology development and its campaign contributions was 162.91, compared to a maximum of 1,364. The number of substantive statements or questions was 3.62 per meeting, as compared to the maximum of 25.08.

Analysis

Due to findings in the literature regarding the bipartisan nature of biotechnology policy and the fact that the 21st Century Cures Act was unanimously
passed out of the Energy and Commerce Committee and received an overwhelming majority in the full House, we first ran a bivariate correlation in SPSS Version 22 (IBM Corp., Armonk, NY) using partisan affiliation variable as the independent variable and overall participation as the dependent variable.

The results of the bivariate correlation, with a coefficient of -.006 and significance level of .962, support the literature and the contention in the popular media that support for the biotechnology industry is not conditioned by partisan affiliation. Our next step was then to conduct a multivariate regression analysis to test for the influence of the other independent variables on members’ levels of participation. The results of the multivariate analysis with the interaction variable are reported in Table 3. For comparison, the results without the interaction variable are reported in Table 4.5

5 To further test the interaction effects, three additional regression models were run. In one model, campaign contributions to each member were raised by $1,000 and then an interaction was calculated. In the second model, the BDI for each state was increased by the average for all states represented and an interaction was calculated. In the third model, both the contributions and the BDI were raised. In all three models, the interaction, as well as the contribution and BDI variables, was not significant (the coefficient was .0008 in all three cases). Leadership was significant in the model, but the model overall was no longer significant.
The F ratio of 2.88 in Table 3 is statistically significant at the .05 level, indicating that the model has some predictive value in regard to the dependent variable of overall participation. The adjusted $R^2$ of .16 also indicates that the model does have at least modest predictive value. Looking at the results for the individual independent variables, the variable representing the interaction between a state’s BDI score and the level of a member’s campaign contributions received from the Biotechnology Industry Organization is the only independent variable found to be statistically significant at the .01 level. None of the other independent variables approach statistical significance. The coefficient for the interaction variable (contribution*BDI) indicates a positive relationship with the dependent variable, meaning that a higher interaction value was related to a
higher degree of participation. In the analysis without the interaction variable (see Table 4), the leadership variable took on statistical significance, but the overall model was no longer significant based on the F ratio.

This finding lends support to previous research by Sheingate (2006a) indicating that Congress’ approach to biotechnology issues has shifted from a more protective orientation to one that is more promotional in nature. The significance for the BDI/campaign contributions interaction variable indicates that members were significantly more active in the 21st Century Cures process when they (1) represented a state with a higher level of biotechnology development and (2) received electoral support from the national organization representing the biotechnology industry.

This finding, viewed in light of the stated objectives of the 21st Century Cures initiative at the outset and a reading of the transcripts of the 21st Century Cures hearings, indicates that those members who took a more entrepreneurial, or active, role in the hearings and roundtables were those with more constituents with direct ties to the biotechnology industry and who had some direct ties to the biotechnology industry through the campaign finance system. Therefore, it stands to reason that those members that were most active in the hearings tended to support the positions taken by the biotechnology industry in regard to streamlining the regulatory process and reducing barriers to the conduct of research. Conversely, such members could be considered less likely to raise the type of legal and ethical issues regarding research and regulation that ethicists and other groups would be likely to interject. This suggests that biotechnology is viewed increasingly as an engine of economic development by legislators at the state and federal level.

The Example of California Companies and Legislators

To examine the apparent interaction between a state’s level of biotechnology development and electoral support for members of the Energy and Commerce Committee and its effect on participation in the 21st Century Cures hearings, we will focus on the state of California. As a state, California was ranked third on the BDI previously discussed. California had five representatives on the Energy and Commerce Committee at the time of the 21st Century Cures hearings (tied for the highest number with Texas) and California also had the largest number of external stakeholders participating in the hearings at eleven participants. The California representatives included Lois Capps (D), Tony Cárdenas (D), Anna Eshoo (D), Doris Matsui (D), and Jerry McNerney (D). To examine the role of campaign contributions, we will focus on four stakeholders that operated PAC under the company’s name in 2014: McKesson Corporation (a health information technology company), Qualcomm, Inc. (a mobile technology company), Edwards Lifesciences (a manufacturer of heart valves and heart monitors), and Intel Corporation (a manufacturer of computers and communication technology).
McKesson Corporation, in addition to its primary corporate office in California, has satellite offices in Connecticut, Georgia, Massachusetts, Michigan, Pennsylvania, New Jersey, and Virginia, states that also had representatives on the Energy and Commerce Committee (McKesson Corp. Website n.d.). During the 2014 election cycle, the company gave donations to 31 out of 54 of the committee members, including four of the committee members from California. The PAC’s total of donations to committee members was $185,000 (Open Secrets Org. n.d.). Johnathan Niloff, a vice president and chief medical officer for McKesson Connected Care and Analytics, testified at the hearing “21st Century Technology for 21st Century Cures” on July 17, 2014. During his testimony, Niloff advocated for creating a framework for interoperable health information technology to improve quality, safety, and affordability, and creating a risk-based regulatory framework for health information technology (Energy and Commerce Committee 2014c).

In addition to California, Qualcomm, Inc. has offices in other states with Energy and Commerce representatives: Massachusetts, Texas, Colorado, New Jersey, North Carolina, Oregon, Kentucky, Pennsylvania, and Washington (Qualcomm Website n.d.). The company contributed campaign funds to twelve out of the 54 members of the Energy and Commerce Committee for a total of $22,500 in funds. This included two of the California representatives (Open Secrets Org. n.d.). During the 21st Century Cures process, Qualcomm advocated for policy promoting increased use of advanced telecommunications in health care.

Robert Jarrin, senior director of Government Affairs for Qualcomm, also testified at the July 17 hearing. He called upon the committee to address the lack of Medicare reimbursement for telehealth and remote patient monitoring technologies. Jarrin also called for remote patient monitoring technology and patient-generated health data to be included under the “Meaningful Use” rules for the Centers for Medicare & Medicaid Services electronic health record incentive payment program to encourage the use of this technology with electronic medical records. Another concern was the addition of more broadband spectrum to facilitate the improved functioning of wireless networks (Energy and Commerce Committee 2014c).

Edwards Lifesciences is a California medical device company that manufacturers heart valves and monitors. However, it does not have locations in other states represented on the Energy and Commerce Committee with the exception of Utah (Edwards Lifesciences Website n.d.). The company donated to 14 of the 54 committee members, including two of the members from California, for a total of $25,000 (Open Secrets Org. n.d.). The company’s chairman and CEO, Michael Mussallem, testified at the hearing titled “21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication” held on July 22, 2014. At the hearing, Musallem called for improvement of evidence development mechanisms to reduce costs and delays, creating and improving economic incentives to promote innovation, and accelerating FDA efforts to improve the regulatory process (Energy and Commerce Committee 2014d).
Intel Corporation has corporate offices in the states of Colorado, Illinois, Massachusetts, Minnesota, New Jersey, Oregon, Pennsylvania, and Texas, in addition to their California headquarters (Intel Corp. Website n.d.). In the 2014 cycle, the corporation donated to 17 of the 54 committee members, including all five members from California, for a total of $62,500 (Open Secrets Org. n.d.). Dr. Mark Blatt, the company’s worldwide medical director, participated in the roundtable on “Digital Health Care” on June 24, 2014. Blatt spoke about the company’s OpenNotes programs, which gives patients ready access to their own medical information, including doctor’s notes (Sullivan 2014).

Many of the views expressed by these stakeholders were translated into the 21st Century Cures Act as passed in the House. Title III, Subtitle A of the 21st Century Cures Act is focused on ensuring interoperability of health information technology. Another subtitle related to the delivery of health-care services would require the Administrator for the Centers for Medicare & Medicaid Services to issue a report on the feasibility of providing Medicare reimbursement for telehealth services. Language to create incentives for increased use of patient monitoring software and expand the broadband spectrum was not included in the legislation (H.R. 6; U.S. House of Representatives 2015b).

The act includes provisions to make evidence development more efficient, create an innovation fund, and promote reform in FDA regulatory processes. In the bill’s language regarding interoperability, the Congress affirms the right of the patient to have access to their structured and unstructured medical data (H.R. 6; U.S. House of Representatives 2015b). While one cannot make a precise causal connection between the views expressed by the stakeholders above and the inclusion of these items within the legislation as passed, it does lend support to the idea that representing a state with a thriving biotechnology industry and that industry supporting legislators’ electoral efforts can influence a legislator’s level of engagement and thereby affect the contents of the bill.

It should be noted that some groups expressed concern or opposition to the interoperability provisions during the development of the legislation and after its passage. The American Academy of Family Physicians called for Congress to change the regulations to penalize software vendors, as opposed to the providers who currently bear the burden (21st Century Cures Act Threatens Patient Safety, January 4, 2016). The American Hospital Association (AHA) raised similar concerns regarding providers being unfairly penalized. The organization also expressed the opinion that the bill’s prohibitions against information blocking used an overly broad definition that would potentially find providers in violation for using good business practices or trying to make improvements for patient care. The AHA believes that software vendors and health-care providers should have different definitions of information blocking to ensure that reasonable actions by hospitals are not seen as violations under the new provisions (Leventhal 2015). While these topics may be specific to biotechnology, they are strongly related to providers’ capacity to deliver services based on these innovations.
To explore the relationship between participants and provisions of the bill further, we examined more closely what types of external organizations were invited to participate in 21st Century Cures roundtables and offer testimony at hearings. The coders reviewed the agendas for the 21st Century Cures meetings and made note of all the external organizations that participated. To systematically examine what types of groups were invited to participate and their level participation, we sorted the participants into groups based on categories used in Sheingate’s (2006a) previous work: producers, public interest groups, medical providers, academic/private scientific researchers, and government officials. We also added one additional group, legal perspectives. We then counted the number of times at least one representative from each category was invited to participate. Those findings are provided in Table 5.

Table 5. Number of Times Each Category of External Organization Participated in the 21st Century Cures Hearings

<table>
<thead>
<tr>
<th>Categories</th>
<th>Number of Appearances</th>
<th>Percentage of Total Appearances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Producers</td>
<td>22</td>
<td>43%</td>
</tr>
<tr>
<td>Public interest groups</td>
<td>11</td>
<td>22%</td>
</tr>
<tr>
<td>Medical providers</td>
<td>10</td>
<td>20%</td>
</tr>
<tr>
<td>Researchers</td>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td>Government officials</td>
<td>4</td>
<td>8%</td>
</tr>
<tr>
<td>Legal perspectives</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td></td>
</tr>
</tbody>
</table>

Notes: 

*Producers is defined as private sector businesses involved in the manufacture of biotechnology, pharmaceutical, or other health technology products. For example, Johnson & Johnson, Abbott Molecular, and IBM.

Public interest groups is defined as groups representing the interests of the general public and/or particular classes of patients. For example, American Cancer Society, Pew Charitable Trusts, and National Health Council.

Medical providers is defined as individuals, groups, or organizations actively involved in the treatment of patients. For example, Mayo Clinic, Duke University Health System, and the Cleveland Clinic.

Researchers is defined as organizations whose primary mission is the advancement of medical research. For example, Virginia Center for Translational and Regulatory Sciences, MD Anderson, and Center for Integration of Science and Industry.

Government officials is defined as witnesses presenting the interests of a government agency. For example, Food and Drug Administration (FDA) and FDA’s Center for Devices and Radiological Health.

Legal perspectives is defined as witnesses present to provide legal expertise. For example, Columbia Law School.

To explore the relationship between participants and provisions of the bill further, we examined more closely what types of external organizations were invited to participate in 21st Century Cures roundtables and offer testimony at hearings. The coders reviewed the agendas for the 21st Century Cures meetings and made note of all the external organizations that participated. To systematically examine what types of groups were invited to participate and their level participation, we sorted the participants into groups based on categories used in Sheingate’s (2006a) previous work: producers, public interest groups, medical providers, academic/private scientific researchers, and government officials. We also added one additional group, legal perspectives. We then counted the number of times at least one representative from each category was invited to participate. Those findings are provided in Table 5.

The producer category is comprised of representatives from the biotechnology industry, indicating that their testimony and perspectives made up approximately 41 percent of those offered during the 21st Century Cures process. It should also be noted that those groups categorized as public interest
organizations were primarily organizations representing the interests of patients and the families of patients affected by different medical conditions, so many of the perspectives offered by that group were sympathetic to the biotechnology industry’s calls for relaxed regulation and fewer impediments to research. Medical providers and researchers would be expected to be more neutral, although still with an interest in seeing accelerated efforts toward the development of new drugs and treatments. Those categories of participants who would be more prone to supporting stricter regulatory standards, government officials, representatives of the U.S. FDA, and legal perspectives, representatives of Columbia Law School, only comprised approximately 9 percent of those invited to participate. These findings support Sheingate’s (2006a) contention that the shift in Congress’ orientation toward the biotechnology industry has affected the types of groups brought before Congress to offer testimony on important issues. As illustrated in the discussion of California’s representatives and stakeholders, many participants in the hearings and roundtables were business interests from technology-based industries.

To further consider the diversity of views represented in the process leading up to the passage of the 21st Century Cures Act, the coders examined articles from news and popular media related to the 21st Century Cures process that were linked to on the committee’s website. There were 32 articles available, representing a variety of different types of publications: wire services (e.g., Associated Press), national newspapers (e.g., Wall Street Journal), regional newspapers (Cleveland Plain Dealer), magazines (e.g., U.S. News and World Report), websites and blogs (e.g., Breitbart News Network), specialty outlets (e.g., BIOtech Now), think tanks (e.g., Manhattan Institute of Public Policy), advocacy outlets (e.g., Parkinson’s Action Network), and the general popular media (Popular Mechanics).

The coders first reviewed the number of articles available from the 21st Century Cures Act that quoted the following types of stakeholders related to the 21st Century Cures process: business interests, elected officials, nonelected government officials, researchers, and medical providers. The findings of the two coders are provided in Table 6.

### Table 6. Number of Articles from the 21st Century Cures Site Quoting Different Groups

<table>
<thead>
<tr>
<th>Groups</th>
<th>Number of Quotes (Coder 1)</th>
<th>Number of Quotes (Coder 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elected officials</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Business interests</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Nonelected government officials</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Researchers</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Medical providers</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>


This descriptive qualitative review of the articles finds that elected officials were the most commonly quoted among the five groups, which is expected given that the articles are hosted on a congressional website touting a congressional initiative. Second to elected officials in terms of representation in the articles are business interests. This is not surprising given the conservative and pro-business orientation of many of the sources represented. However, the fact that many of the publications have such an orientation and that representatives of the biotechnology industry are quoted in a substantial portion of the articles could be viewed as additional evidence of the 21st Century Cures initiative taking a more promotional stance toward the biotechnology industry.

The coders also investigated how many of the articles featured on the website referred to particular institutions and relationships: partnership between government and business, involvement of academic institutions, and involvement of nonprofit organizations. Data on the number of articles providing such references are included in Table 7.

Despite discrepancies between the two coders, the findings of both coders indicate that at least half of all the articles hosted on the 21st Century Cures website refer to a partnership between government and business. The fact that the Energy and Commerce Committee would choose to highlight these particular articles lends some credence to the idea that Congress is taking a more promotional stance in terms of the biotechnology industry rather than a protective one in terms of a more regulatory focus. The idea of such a partnership can also be seen in documents published by the Energy and Commerce Committee at the outset of the initiative, which focused significant attention on what the government can do to help bring new biotechnology products to market more efficiently (Energy and Commerce Committee 2014a).

A third aspect of the news articles that the coders examined was the number of articles containing rhetoric that was critical of or skeptical toward the use of genetics, genomics, and/or the biotechnology industry. Coder 1 reported no such references in the articles featured and Coder 2 reported only one. These descriptive results suggest a lack of diversity in the viewpoints expressed in the articles profiled on the website. Given the emphasis on biotechnology industry perspectives in the 21st Century Cures hearings and roundtables, this could also speak to a lack of adequate diversity in the perspectives represented in the 21st Century Cures initiative as a whole. This suggests that the committee was

<table>
<thead>
<tr>
<th>Institutions/Relationship</th>
<th>References (Coder 1)</th>
<th>References (Coder 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partnership between government and business</td>
<td>26</td>
<td>17</td>
</tr>
<tr>
<td>References to academic institutions’ involvement</td>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>References to nonprofit organizations’ involvement</td>
<td>11</td>
<td>4</td>
</tr>
</tbody>
</table>
promoting a pro-business media narrative that emphasized the benefits of biotechnology, while deprioritizing the risks involved.

A more general review of news articles using Lexis-Nexis found similar favorable coverage for the bill. A search was conducted using newspapers available through Lexis-Nexis using the search term “21st Century Cures Act” and the date range January 1, 2014 to July 6, 2015. A total of 18 news items were returned, primarily consisting of newspaper editorials, editorials authored by legislators involved with the initiative, and letters to the editor. Sixteen of the articles were expressly in support of the legislation and two expressed opposition or criticism. The largely favorable coverage of the bill could be attributed to the significant effort leaders of the Energy and Commerce Committee made to shape the messaging and packaging of the bill.

Given the statistical and qualitative evidence that the Energy and Commerce Committee may have taken a promotional stance toward the biotechnology industry, our research also investigated concerns expressed regarding the 21st Century Cures Act that may have been, at least in part, the result of a lack of diversity of perspectives during the hearings and roundtables. Tweets were captured from the Twitter page of the 21st Century Cures initiative (Path2Cures) and reviewed for expressions of opposition or criticism toward the bill. The sample included 2,448 tweets that were sent between May 19, 2015 and July 5, 2015. One of the investigators manually reviewed the tweets to determine which were supportive and which were negative. The negative tweets were then reviewed to determine the nature of the criticism. The following themes reoccurred in the tweets in the account during that time period:

- Opposition to changes to the 340b federal prescription drug bill (this language was eventually stripped from the bill).
- Concerns about reduced safety standards for medical testing.
- Concerns about interoperability standards between electronic health record systems.
- Concerns about increased access to patient records.
- Concerns about lowering standards for obtaining informed consent from research participants.
- Concerns about extending drug exclusivity.
- Concerns about a lack of transparency in regard to what the bill entailed and how it would be implemented.

The three issues most closely associated with biotechnology are safety standards, informed consent requirements, and drug exclusivity. The articles found in the Lexis-Nexis search addressed safety issues, but not drug exclusivity and informed consent.

A Google News search was conducted for the same time period using the search terms “21st Century Cures”+ “informed consent,” “21st Century Cures”+ “safety standards,” and “21st Century Cures” + “drug exclusivity.” An article published in Medical Device Daily on September 10, 2014, prior to
the proposal of the official legislation, noted that the draft bill contains language calling for a shift toward the use of centralized Institutional Review Boards (IRBs) as opposed to continuing to use local review boards (Serebrov 2014). Some were concerned that such a change could lead to less oversight over medical, clinical, and drug trials because the centralized IRBs will have more protocols to contend with and will not be as close to or have as much access to researchers as local IRBs. Avorn and Kesselheim in a *New England Journal of Medicine* article dated June 25, 2015, expressed concern that some aspects of the pending bill could bring back problems once considered resolved by the medical establishment. One such aspect they identified was allowing informed consent requirements to be waived in circumstances where the testing was considered to present no more than minimal risk (Avorn and Kesselheim 2015). Changing informed consent standards is an example of an issue that could have received more consideration in the 21st Century Cures Act development process had ethicists and others had more of an opportunity to participate, as Sheingate (2006a) notes they once did (although it should be noted that Kesselheim did testify at the 21st Century Cures hearing regarding the modernizing of medical trials). In regard to drug exclusivity, Gaffney wrote a May 13, 2015 article on the subject published by the Regulatory Affairs Professionals Society concerning the Orphan Product Extensions Now (OPEN) Act. This act would grant pharmaceutical companies the ability to extend drug exclusivity on a product for six months if the product is approved to treat conditions affecting fewer than 200,000 people in the United States (Gaffney 2015). The OPEN Act was not included as a part of the final version of the 21st Century Cures Act.

While not discussed as extensively as many other topics, there were a number of references to informed consent during the hearings and roundtables. During the hearing “Modernizing Clinical Trials” on July 9, 2014, Representative Tim Murphy (R-PA) inquired as to whether Health Insurance Portability and Accountability Act (HIPAA) laws were imposing an undue obstacle on medical research. One witness expressed the opinion that it may be worth reviewing HIPAA regulations in regard to research to explore ways to gain better access to medical information while protecting patient privacy, particularly when there is no more than minimal risk to the patient. Another witness noted that efforts are being made to find ways to re-obtain consent from participants in tissue research to use the information in other research. A third participant noted the utility of allowing electronic medical records to be searchable among different research sites to identify participants that would be valuable to a particular study at another research site without compromising the privacy of individual patients (Energy and Commerce Committee 2014b). In another hearing on September 19, 2014, Dr. Janet Woodcock, director of the Center for Drug Evaluation and Research at the FDA, noted in regard to clinical trials that it can be difficult to recruit an already sick individual into an antibiotic clinical trial because the informed consent process can be lengthy
and doctors are hesitant to delay treatment (Energy and Commerce Committee 2014e).

In testimony at the same hearing, Paula Brown Stafford, the vice president for clinical development at Quintiles, called for reform of informed consent policy to allow research participants to be recruited through social media, while protecting participants from being discriminated against by what they reveal on-line. Stafford also recommended in her testimony that the committee explore policy changes such as the use of centralized IRB and standardized informed consent forms to facilitate quicker start times for research projects. This would prevent an identical research protocol from having to be approved at multiple sites and allow on-site IRBs to focus on issues specific to that particular study. Stafford noted that centralized IRBs have proven effective in Europe (Energy and Commerce Committee 2014e).

While informed consent was not extensively discussed during the 21st Century Cures hearings and roundtables, changes in policy such as the use of centralized IRBs and waiving of informed consent for minimal risk research can affect many aspects of medical research. While one can see some evidence that the presence of advocates for these policy changes at the hearings and roundtables influenced their presence in the legislation as passed, similar to health information technology interoperability and other issues noted earlier, what is equally notable is that the proceedings were lacking in the presence of bioethicists or other specialists to argue the other side. This has had the effect of undermining the legitimacy of the legislation in some corners.

Discussion

Previous research by Sheingate (2006a) indicated that policy making surrounding biotechnology was moving from a protective, or regulatory, focus to an economic development focus. Quantitative and qualitative evidence from the 21st Century Cures Act development process provides support for this idea. Regression analysis suggests the possibility that a legislator representing a state with a significant degree of biotechnology development and receiving campaign contributions from the biotechnology industry influenced their level of participation in the hearings and roundtables for the 21st Century Cures initiative. An examination of external participants from the State of California lends some qualitative evidence to this conclusion, indicating that biotechnology or other health-related firms involved in the 21st Century Cures initiative that operated PAC saw several of their policy recommendations included in the bill passed in the U.S. House of Representatives. Qualitative analysis of other documents associated with the initiative also indicated an emphasis on the role of the biotechnology industry in the development of the legislation.

Results of the content analysis provided in the first part of the article provide evidence that those legislators who both received campaign finance support from the biotechnology sector and came from states with a more
developed biotechnology industry were more engaged in the development and debate surrounding the 21st Century Cures Act. This indicates that legislators were motivated both by a combination of electoral self-interest and a desire to promote the industry of their state during the process.

One would anticipate then, based on previous work by Sheingate and others, that legislators would manage the hearings and events surrounding the bill in a manner that would promote the biotechnology industry. This was examined in the second portion of the present article. The composition of the witnesses that participated in the 21st Century Cures hearings was consisted largely of representatives of the biotechnology industry and related Producers, and even those witnesses who were not representatives of the industry were largely favorable to the bill. Numerous issues with the bill, in regard to privacy and safety, were identified in the social media, but not addressed in the hearings. This reinforces the conclusions regarding legislator motivation from the first part of the article, and suggests that because of those motivations the hearings functioned as promotional rather than fact-finding efforts.

This emphasis on promotion rather than protection may have serious implications for patients and research participants, as suggested by concerns expressed regarding the lowering of informed consent standards. While centralized IRB and lowered informed consent standards for studies considered lower risk may help to expedite research and the development of new treatments, observers have noted possible increased risks this could pose for patients and research participants.

This article is not intended to defend or dispute the validity of such concerns. It is, rather, meant to investigate whether the 21st Century Cures process was structured in a manner that allowed such concerns to receive due consideration. It could further be asked to what degree electoral support from the biotechnology industry and state interests influenced the structure. Based on the qualitative findings, it appears that groups representing such ethical issues were not fully integrated into the discussion, and there was a lack of substantive conversation on these issues during the hearings and roundtables. One could argue that more representatives with concerns about patient and research participant protection should have been invited to testify. One could make the same argument concerning the interoperability concerns discussed earlier, which some believe could have unintended negative consequences for health-care providers and may negatively affect patient care.

This article contributes to the literature on congressional policy making in the field of biotechnology by lending support to previous work by researchers like Sheingate indicating that members of Congress are taking an increasingly promotional role in regard to the biotechnology industry. This focus is resulting in a lack of consideration for important ethical issues involving the protection of patients, research subjects, and the public in general. Just as the promotional messages surrounding the bill focused on the promise of biotechnology innovations, concerns expressed about the bill focused on increasing drug exclusivity,
erosion of informed consent standards, and patients and research subjects being exposed to dangerous products. As biotechnology innovation grows, so do the risks involved. This article adds to the literature suggesting that a more appropriate regulatory balance needs to be struck.

The goals of finding better treatments for cancer and being able to more efficiently produce safe and effective vaccines are shared by many Americans. However, even in the face of pressing public health concerns, it is important to recognize the dangers of expediency in these pursuits. Concern for those afflicted with disease should be balanced with concern for those who could be harmed during clinical trials or by a defective drug that reaches the marketplace. Entrepreneurship is important, but promotion should be balanced with protection. Members of Congress and other elected representatives, in particular, have a responsibility to consider all sides of a policy issue, even when they themselves have a particular point of view. Only if such viewpoints are considered can the public be assured that their elected representatives have done their due diligence to minimize potential negative outcomes. This is also important if Congress wants to assure the American people that they have not been captured by a particular industry. Furthermore, regardless of Congress’ decision, the American people should be given access to a full range of information, and testimony during hearings allows for this.

Future research could also examine the inclusion of ethical or protection-oriented perspectives in other ongoing policy discussions involving the biotechnology industry. While this is a case study of a particular policy initiative and therefore not generalizable, it is certainly possible to expand this research and investigate whether the trend of prioritizing promotion ahead of protection holds true across other initiatives. At the same time, it is important to consider which elected officials are engaging in entrepreneurship in the promotion of such policies. Along these lines, it would also be possible to examine transcripts of previous hearings regarding biotechnology issues using similar content analysis techniques to investigate whether the findings from this article are supported and if there is evidence of a historic trend.

As noted by the leaders of the Energy and Commerce Committee, biotechnology holds tremendous potential to improve millions of lives in the United States and around the world. It is important that the U.S. Congress takes a leadership role in this area. However, this research and other research in the field speak to the importance of considering whether an elite or pluralist perspective to policy making best serves the American people. This research suggests that some perspectives were not given appropriate consideration during the 21st Century Cures discussions. One could argue that those who were asked to participate in the hearings and roundtables know the intricacies of the policy area best and are the most equipped to weigh the level of risk involved. However, one could also make the case that given the history of abuses arising in the United States and around the world from science proceeding without proper checks that those speaking to such concerns should be given a fair and thorough
hearing. This is an important debate in politics and policy, as decisions made by legislators today may mean the difference between the type of scientific revolution promised by the 21st Century Cures Act or a future backlash against such science that could ultimately set back the discovery of medical breakthroughs.

About the Authors

**Hanna K. Brant** is a PhD student in the Political Science Department at the University of Missouri. Her research interests include members of Congress, legislative behavior, political careers, and gender and politics.

**Nathan Myers** is an associate professor of political science/public administration at Indiana State University. Dr. Myers is also a founding member of the Indiana State’s Center for Genomic Advocacy. His research interests include public health emergency preparedness and response, biotechnology policy, and bureaucratic politics. Dr. Myers has previously published research in *Journal of Health Politics, Policy, & Law, Politics & Policy, Administration & Society, California Journal of Politics and Policy, Public Integrity,* and *Journal of Health and Human Services Administration.*

**Katherine L. Runge** is a PhD student in the Political Science Department at the University of Colorado. Her research interests include American political behavior, campaigns and elections, and gender and politics. Her teaching interests include American politics and gender and politics.

References


