Recombinant Comments

Analyzing the Public Response to Proposed rDNA Products

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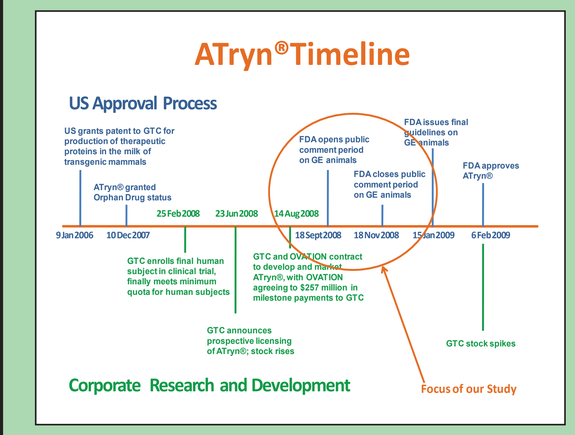
Abstract

A significant issue in the public understanding of science is the way in which citizens use digital media to influence policy making on cutting-edge research and emerging technologies. Because online communication allows for broad participation over a short period of time, it may enable a more democratic participation in science policy making. Yet at the same time, it may also reaffirm some of the patterns of public discourse that existed prior to online forums.

In this study, we examine the public comments on the Food and Drug Administration's proposed guidelines for ATryn®, the first drug manufactured from nonbacterial recombinant DNA, that is, human-animal gene splicing. Using qualitative content analysis software NVivo, we identified "categories of concern" in the online public comments that are characteristic of the public's response to new biotechnologies, and we further linked these comments to categories of stakeholders. Our preliminary conclusions suggest that consumers tend to focus on transparency in labeling of genetically modified products, animal rights groups tend to focus on animal welfare issues, and universities and other public institutions tend to focus on both the scientific significance surrounding the ATryn®, as well as the ethical implications involved in the study.

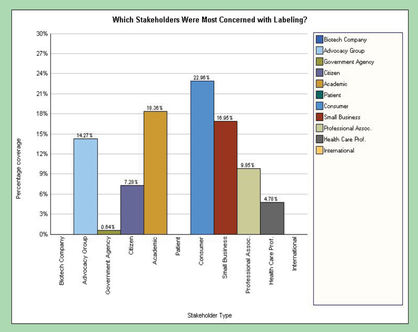
Analysis

After the FDA began discussing the labeling of organic food in 2001, the issue of labeling transparency flourished as a topic of debate. The timeline below indicates the focus of our research during the development of ATryn®—a transgenic pharmaceutical derived from a particular human protein spliced into goats. As the economic and political counterparts show, the drug was pushed through patenting even before the FDA had implemented a comment period on the proposed guidelines to regulate it. The timeline suggests that the FDA's approval was a foregone conclusion. Our research investigates the entire conversation held in the docket and all the tributary conversations that stakeholders held while the docket was open.

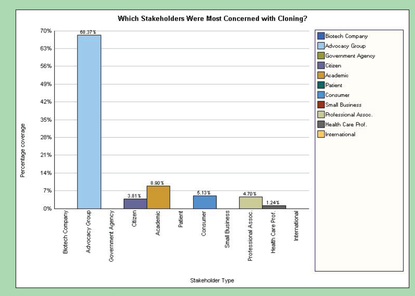


The political and economic counterparts of this timeline are part of our project's foundation. Diverse interests and opinions reflect a variety of motivating factors for speaking out about labeling transparency as a benefit or burden. Through our effort to organize responses and seek patterns throughout the discussion, we discovered the opinions and motivations of stakeholders and how each stakeholder related to the others.

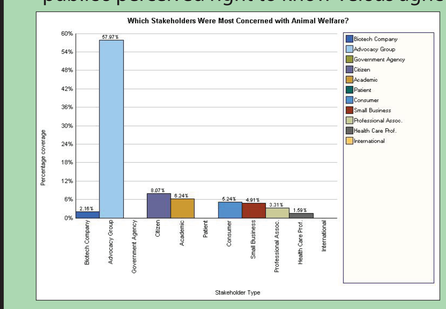
Results



Labeling is presented by many individuals and advocacy groups as a "rights" issue, as the Labeling graph (left) indicates. Often when a professional organization or industry comments, they focused on the interagency collaboration they feel is needed in regulating Genetically Engineered (GE) biologics. These comments seem to represent a focus on transparency issues. The most lucid and complete explanation of the problem with the FDA's "new animal drug" designation occurs in a response from an advocacy group—the Center for Science in the Public Interest.



The very title "Recombinant Comments" suggests a method that involves finding correlations among different sets of comments. The abundance of content in the public comments on consumer concern over GE food safety and labeling seems prescient. We observed that cloning and animal welfare were discussed much differently depending on the Stakeholder Type, as the Cloning graph (right) and the Animal Welfare graph (below) indicate. The National Animal Identification System (NAIS), the USDA's effort to track animals through the US human food chain, is relevant here as another example of the conflicts arising over the public's perceived right to know versus agricultural producers' interest in self-regulation.



The controversy over the "new animal drug" designation involves greater secrecy than the approval process for GE crops, as biotechnology companies are not required to submit all of the underlying data; thus the process is less transparent to the public. Some people consider this a loophole that allows veterinarians, rather than food safety or environmental experts, to evaluate the safety of the construct. Designation also requires a separate review process for each new GE product, placing a greater administrative burden on biotech companies. In addition, the FDA refused to offer more time for discussion, despite 15 requests within the docket for an extension of the commenting period. Extensions were granted previously for a docket concerning GE alfalfa, as well as an organic food labeling docket. While our research offered answers to a wide variety of specific queries, the docket as a whole helped reveal the frames through which certain stakeholders view science in the public sphere. Through further research and the continued use of NVivo software, future dockets will offer more opportunities to investigate the public's diverse opinions and understandings of science and expose the motivations and agendas of various stakeholders.

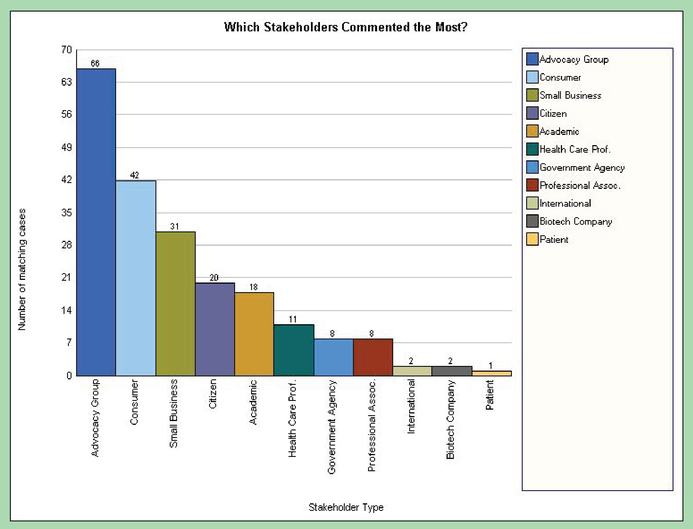
Methods

The FDA's approval of ATryn® is significant for two reasons. Not only is ATryn the first drug made from a genetically modified animal, but its approval sets a precedent for how the government will regulate the sort of drug it is. On September 18, 2008, the FDA opened a public forum asking for comments concerning whether or not transgenic foods should be labeled. The first step to investigating the public comments was to acquire a resource for coding different respondents, opinions, and discussions. After compiling all of the responses into a docket—a single document containing all 214 coded responses sequentially-we began working with NVivo software, a program capable of coding diverse content in great quantity. We then arranged all of the responses into certain "stakeholder" categories: Advocacy Group, Academic, Biotech Company, Citizen, Consumer, Government Agency, Health Care Professional, International, Patient, Professional Association, and Small Business.

We were attempting to treat each case as an individual speaking on his or her own behalf rather than representing some larger organization or agency. In the few cases in which an individual self-identified in two ways, we categorized that individual on the basis of the first self-identification. For example, an individual who self-identified as both a "health professional" and "consumer" was coded as "health care professional."

Our first task was to determine what is being discussed most and which group is commenting most. The Tag Cloud below created by the NVivo software represents the 50 most frequently used words in the docket; it offers a visual representation of the most discussed topic within the entire docket:

We learned ways to use the technology to investigate the types of discussions these stakeholders developed. By coding for certain terms in the entire docket and pooling responses into a specific "Stakeholder Type," we were able to begin organizing responses into groups to visualize which groups were commenting most, as well as the issues and opinions each group offers. The chart below illustrates which Stakeholder Type had the most total responses. Advocacy Groups and Consumers represent the majority of total comments in the docket.



The forum was meant to allow interested citizens and organizations an opportunity to discuss whether ATryn should be designated as a "new animal drug," but through our analysis of the docket of responses we discovered that many other issues were being brought to the table. As we designated each response a Stakeholder Type, we saw that groups were using the forum as a chance to tackle a variety of food issues: cloning, animal welfare, labeling transparency, and more. After bolstering our ability to utilize NVivo, our analysis allowed us to chart the frequency and diversity of responses for each group.

References

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Acknowledgments

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