Paper #209

The Influence of Institutional Background on the Approval of Engineered Systems

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Abstract

Success of engineered systems and devices is contingent upon their approval by expert committees. For example, advisory panels to the Food and Drug Administration make crucial recommendations regarding the approval and diffusion of medical devices in the United States. Systems and devices are subject to opinions and institutional bias that might drive decision outcomes in an unfavorable direction. Computational linguistics algorithms, such as Latent Semantic Analysis, provide a quantitative metric for the dynamics of the multi-stakeholder decision making underlying approval meetings. Insights from the analysis can lead to recommendations for how such committees might be structured to improve system performance with minimal cost and rework.

Introduction

Large-scale engineered systems must successfully pool knowledge and expertise from many domains if they are to be effective. Furthermore, any large-scale engineered system must receive the approval of several stakeholders, many of whom have differing requirements, and hence different perceptions, of the system and its functionality. Examples include design reviews that large-scale engineered systems must pass (consider, for example, the PDR and CDR cycles within the aerospace domain). These approval activities are aimed at bringing in additional expertise, and, ideally, improving the ultimate design. In general, committee decision making can

have a large impact upon a device or system of devices, affecting the system's architecture before it enters the market. Methods developed in this work for understanding differential institutional perception can be extended to similar studies in other domains of interest to engineers. Furthermore, the question of how to design decision-making processes that successfully leverage different perspectives is one that is extensible to a range of technology and policy activities across both public and private sectors.

In the United States, the FDA is responsible both for determining the safety and efficacy of medical devices and for promoting medical device innovation (Merrill 1994). The most uncertain, and therefore difficult, of these devices are reviewed by expert advisory panels, aimed at generating scientifically and empirically sound, i.e., "evidence-based," recommendations. A device's approval, and future diffusion, often rests upon the panel's assessment of the device's safety. These panels are aimed at producing a recommendation, informed by the expertise and knowledge of panel members, which can supplement the FDA's "in-house" decision process. Multiple experts are consulted so that the group decision's efficacy can take advantage of many different institutional perspectives. Panel members' values and institutional contexts may differ, leading to different readings of the evidence, and therefore different recommendations (Gelijns, Brown et al. 2005). It is difficult to determine whether panel recommendations promote FDA's mission of promoting both safety and innovation, particularly since there is no alternative against which a panel's decision may be compared. This suggests that, in order to determine the FDA's ability to differentiate between devices, we must be able to distinguish how specific innovations are perceived by actors at the regulatory level of the health care system.

Most large-scale engineered systems are situated within a complex regulatory environment involving multiple stakeholders. (Nelson 2005) notes that systems situated within highly-regulated sectors, such as health care and the military, are much more subject to professional and political judgment, and less subject to market forces, than are many other sectors of the economy. In health care, (Gelijns, Brown et al. 2005) notes that this leads to an inability to make strictly evidence-based decisions for the following reasons:

1. A given data-set may be interpreted differently by different experts, especially in the presence of high uncertainty. Unless these experts can learn from one another, good decision-making might be impaired.
2. Patterns of technological change are difficult to predict, particularly when innovations are ultimately used for different purposes than originally intended.
3. Even in the case of clear evidence, decision-makers may disagree on its implications due to differing value systems.

This suggests that a device's determination as safe or efficacious depends strongly on the opinions of advisory panel members. (Douglas and Wildavsky 1982) argues that these are largely shaped by the perceptions, and hence, the knowledge and expertise, of risk assessors. Institutions that might impact decision-making include membership in a particular profession, specialty, or bureaucratic organization (Freiman 1985; Savage and Robertson 1999; Savage 2004; Gelijns, Brown et al. 2005).

Medical Device Approval in the FDA

The task of approving medical devices for the US market falls to the Food and Drug Administration's Center for Devices and Radiological Health (CDRH). Figure 1, sourced from (Maisel 2004), provides an overview of the process by which a device is reviewed for approval by CDRH. The grant of a 510(k) or Pre-Market Approval (PMA) by the FDA allows a device to

be marketed. These approvals often act as *de facto* monopolies for the device involved because any competitor must demonstrate additional safety or efficacy of the new device as compared to the initial baseline in order to receive approval. Advisory panels review devices "as needed" (Parisian 2001). Devices brought to committees for review are generally those which the FDA does not have the "in-house expertise" to evaluate. As such, the devices under evaluation by the committees are likely to be the most radical innovations facing medical practice, and those facing the most uncertainty. Furthermore, advisory panel members are "by definition, the world's experts who are engaged in cutting-edge bench science, clinical research and independent consulting work" (Sherman 2004). Advisory panels therefore serve to bring needed expert knowledge and political credibility with industry and consumer advocate groups to the FDA device approval process. Audience members will include representatives of the media, consumer advocate groups, the financial community, and competitor companies, all of whom are looking for information regarding how the medical device might perform on the market (Pines 2002). Panel recommendations, and the judgments and statements of individual members, therefore carry significant weight both inside and outside the FDA.

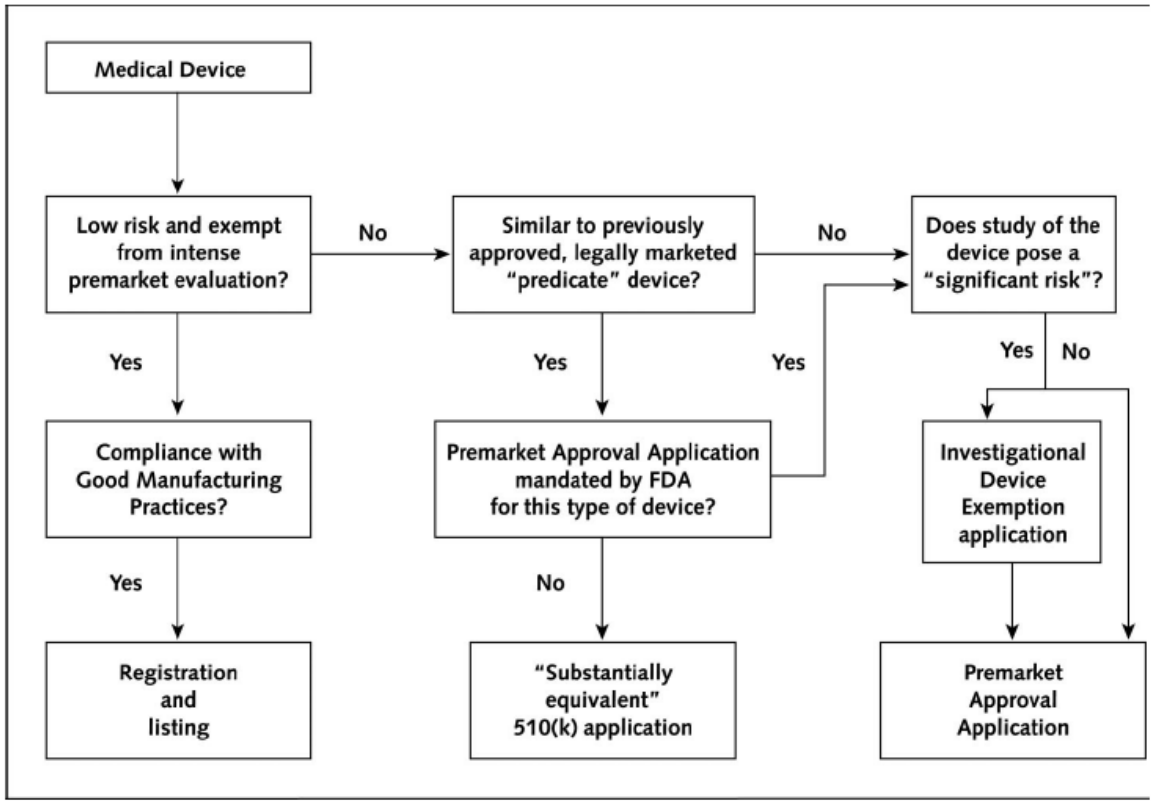

Figure 1: Medical devices are classified into three categories based upon risk to the patient. Diagram sourced from (Maisel 2004)

Although FDA advisory committees are aimed at producing "evidence-based" recommendations, differential interpretation of the evidence allows room for debate, and concomitant accusations of bias. Panel members' professional experiences might allow for intuition that can seem to go against the indications shown by the data. (Friedman 1978) expressed a concern that this constitutes a form of "specialty bias," especially when multiple specialties are involved. On the other hand, this view presupposes that a reading of the data that is entirely uninformed by past experience is best, which seems to obviate the role of expertise in advisory panel decision making. Others argue that conflicts of interest should be mitigated in advisory panels. On the

other hand, a prominent study recently found only a minor correlation between conflict of interest and voting patterns, with no actual effect on device approval (Lurie, Almeida et al. 2006). A distinction must be drawn between decision-making that is based on evidence and decision-making that is driven by one "orthodox" reading of the evidence.

Methodological Approach

We have stated that group membership may affect perception of data (Douglas 1986). This is reflected in the fact that each institution, and indeed, each specialty, possesses its own unique language and jargon. This is particularly true in medical and academic disciplines, where conceptual precision is required to communicate within the specialty. (Nelson 2005) notes the importance of written and oral language as a means of encapsulating and transferring tacit knowledge. On the other hand, an outsider to the institution may be unable to understand the discourse. Casting "organization [as] the mobilization of bias", (Cobb and Elder 1983) recognizes institution-specific symbolism in language, noting that the choice of terminology in defining a problem may be seen as a means of mobilizing support. Furthermore, the linguistic definition of a problem dictates, to some extent, its solution. Choosing to use specialized technical words serves to narrow the range of subjective meaning of otherwise ambiguous terminology (such as "safety" or "efficacy" in FDA's context) thereby implicitly redefining the problem according to a given speaker's particular interest. Determining the speaker's intention in using both precise and "symbolic" language can allow insight into their institutional frame of reference.

Latent Semantic Analysis. One way of determining actors' institutional frames is to analyze the associations that they make between specific words. As a means of analyzing terminology in context, we turn to latent semantic analysis (LSA) – a natural language processing tool which was developed for purposes of information retrieval and topic grouping (Deerwester, Dumais et al. 1990; Landauer, Foltz et al. 1998). LSA was initially created to address the issues of synonymy and polysemy in information retrieval. Synonymy refers to the use of different words to represent the same concept (e.g., spice and seasoning), whereas polysemy refers to the representation of different concepts by the same word (e.g., bat that flies vs. bat that hits the baseball). LSA addresses the synonymy issue through the use of Singular Value Decomposition and dimensionality reduction. This will be explained as follows: We would like to associate words together that have similar meanings. For the purposes of LSA, we assume that words which have similar meanings tend to appear within the same contexts; i.e., words with similar meanings will co-occur either with each other or with the same sets of words. For example, one might encounter the following sentences:

d_1: Pepper and salt add seasoning to the salad.
d_2: Pepper and salt are the two spices found most often in American restaurants.

These two sentences both contain the words "pepper" and "salt". From a brief overview of both documents, we would be able to infer that pepper and salt are seasonings (as in the first document), and that pepper and salt are spices. We would like to be able to infer that spices are seasonings.

The LSA Algorithm. Consider a corpus of documents, D, containing n documents $d_1 \ldots d_n$. Consider, as well, the union of all words over all documents, W. Suppose there are $m<n$ words, $w_1 \ldots w_m$. We may therefore construct a "word-document matrix", **X**, with dimensions m x n, where each element in the matrix, x_{jk}, consists of a frequency count of the number of times word j appears in document k.

We conceive of the original word-document matrix as a "noisy" representation of word-word similarity (or equivalently, document-document similarity). One source of this "noise" is the use of multiple words to represent the same concepts. We would therefore like to recover the original associations, or concepts, implicit in each word. Singular Value Decomposition (SVD) with dimensionality reduction is a commonly used algorithm for the reduction of statistical noise. Using the above analogy, LSA performs noise reduction on the original word-document matrix.

The Singular Value Theorem in linear algebra states that any matrix may be represented as the product of three matrices, $\mathbf{X} = \mathbf{W}\ \mathbf{S}\ \mathbf{D}^{\mathbf{T}}$, where **X** is the word-document matrix derived above. In this case, **W** is a m x m matrix of singular unit vectors, each of which are, by definition, mutually orthogonal. Each of these singular vectors corresponds to a word. Similarly, **D** is a n x n matrix of mutually orthogonal singular unit vectors. Each of these vectors corresponds to a document. Finally, **S** is a m x m diagonal matrix of decreasing, non-negative singular values, with each element corresponding to a linear combination of weights associated with each singular vector.

Without loss of generality, let *r* be the rank of **X**. In order to reduce the noise in **X**, we would like to reduce the rank of **X** such that $r' < r$ corresponds to the number of latent concepts within the corpus. We therefore set the smallest (r-r') singular values to 0, generating **S'**. The value of *r'* must be chosen by the user, although values of *r'* between 100-300 seem to work well for information retrieval purposes (Landauer, Foltz et al. 1998). The resulting matrix, $\mathbf{X'} = \mathbf{W}\ \mathbf{S'}\ \mathbf{D}^{\mathbf{T}}$, is a rank *r'* approximation of **X** that can be represented as having *r'* mutually orthogonal singular vectors. Words and documents, which were previously represented by linear combinations of *r* mutually orthogonal singular vectors, are now represented as linear combinations of *r'* mutually orthogonal vectors, such that the locations of words and documents in the vector space represented by **X'** approximate the corresponding locations of words and documents in **X** in a least-squares sense. If we were to treat **X'** as a Euclidean space, the normalized inner product (i.e., the cosine between) of two word-vectors (represented as rows of the matrix **W S'**) can be thought of as the projection of each word upon a set of axes each of which corresponds to a latent concept. Therefore, this value would correspond to the two words' degree of synonymy (or similarity for documents). LSA is therefore able to capture higher-order relations between synonymous words (e.g., words that do not directly co-occur, but that mutually co-occur with a third word as in the spice/seasoning example above).

A query to LSA will return those words which are closest in the **X'** metric space – namely, those words which co-occur most often with the query word, or with those words that occur with the query word, etc. In principle, these words are synonymous with the query word.

LSA Implementation. We have implemented LSA in Python 2.5 and MATLAB. Python 2.5 was used to parse an FDA Advisory Panel meeting into a word-document matrix, which was then imported into MATLAB. Singular value decomposition and log-entropy weighting (Dumais 1991) were executed using built-in MATLAB functions, generating an LSA space. Finally specialized functions were written to perform the coherence analyses described below.

Other applications of LSA have included automated student essay evaluation (Landauer and Dumais 1997), measurement of textual coherence (Foltz, Kintsch et al. 1998), knowledge assessment (Rehder, Schreiner et al. 1998), information visualization (Landauer, Laham et al. 2004), the quantitative analysis of design team discourses (Dong, Hill et al. 2004), and the construction of a theory of human learning and cognition (Landauer and Dumais 1997). In particular, (Dong 2005) has used LSA to study conceptual coherence in design and the process by which members of a design team agree upon a common design representation. This work begins

by extending Dong's techniques to the realm of advisory committee decision-making, and is ultimately meant to contribute a data-driven methodology that may provide insight into the effects of institutional background on decision-making for complex engineered devices and systems.

Application to Medical Device Approval

Medical advisory panels may be viewed as teams (McMullin and Whitford 2007). Although they are not designing an artifact, as in Dong's work, such panels must produce a policy recommendation that will have a strong impact upon the success or failure of the technical system under review. LSA may be used to study coalition formation within medical advisory panels, by studying the respective coherence of one actor as compared to another. In general, we suggest use of LSA for the analysis of team or committee dynamics.

The use of LSA to measure textual coherence can provide insight into the extent to which different speakers within an advisory panel meeting are using terminology in the same way. Coherence analysis was first implemented in (Foltz, Kintsch et al. 1998), and extended to design teams in (Dong 2005). In a design team, designers must be "on the same page". This means that they must be speaking in words that are sufficiently similar as to be comprehensible to each other, i.e., speaking similar professional languages. LSA does allow for the analysis of relative linguistic homogeneity, thereby enabling a determination of the extent to which designers are "on the same page" relative to one another through a coherence metric.

The combined analyses of coherence and changing synonymy associated with certain words can provide insights into the role of institutions in setting voting patterns. We may be able to determine, for example, whether coherence is higher between members of a given profession than between voting members or industry-representatives. This could provide empirical evidence of the role of group decision processes in enabling the transfer of knowledge required for effective committee decision-making.

Preliminary Results

We show results from a preliminary analysis of a meeting of the Circulatory Systems Devices Advisory Panel Meeting held on April 22, 2005 (Gross 2005). In this panel meeting, the Circulatory System Devices Advisory Panel discussed and made recommendations regarding the approval of the "PAS-port", a device aimed at reducing the risk of stroke inherent in coronary artery bypass (Maisel 2005). This device was under review for 510(k) approval when its predicate device was pulled from the market. This had the effect of prompting the FDA to create new requirements for similar devices. Since the predicate device was now invalid, the PAS-Port device was brought to the advisory for review, despite the fact that the sponsors had initially not planned to execute full-fledged clinical trials. The device's sponsors used observational data from two clinical trials conducted outside of the United States, and therefore under different conditions than those that might have been required by the FDA had they been conducted under an Investigational Device Exemption (IDE) for a PMA. As a result, there were several questions regarding the viability of the data (and hence, the sponsor's contention that the device was safe). Among these were the following:

1. The sponsor's presentation attempted to combine the results of two clinical trials conducted under different conditions. Thus, there was a question of whether the data could be pooled to yield meaningful results.

2. Following the failure of the predicate device, the FDA increased the lower bound for the confidence interval surrounding a proposed device's patency rate (i.e., the rate at which a vein graft would remain un-blocked). This implied that a statistical test with higher power was required. Nevertheless, these new requirements occurred after the sponsor had already run the clinical trials.
3. The data were collected outside of the United States, and therefore, was not supervised by the FDA. Rather, the studies were designed for European clinical trial reviewers.
4. The device under study was improved between clinical trials, thereby leveraging the experience of the designers to improve its safety and efficacy, but simultaneously contributing to the non-comparability of the two trials.

Coherence Analysis. The following analysis confirms our intuition upon reading the meeting transcript, and is suggestive of a direction for future work. Figure 2 shows an analysis of the meeting described above. For the purposes of this analysis, actors were categorized into four bins: Voting members; FDA; Sponsors; and Non-Voting Members. Each point in a given time series is calculated as the cosine of the angle between the running average of all utterances generated by a specific group (the "group centroid"), and the final group centroid of the voting members. Note that the sponsor's coherence with respect to the voting members' final position drops dramatically. It is interesting to note that the FDA's coherence also drops with respect to the voting members. This is likely due to the fact that the voting members ultimately chose to ignore the FDA representatives' statistical analysis indicating that the data could not be pooled. Nevertheless, all members agreed that the data were not pooled correctly.

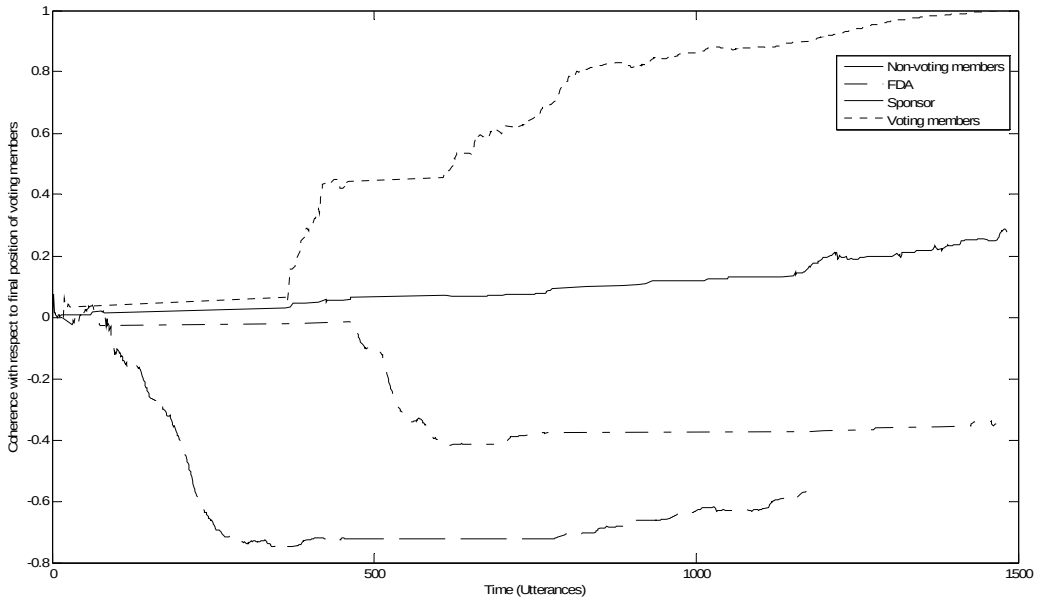

Figure 2: Coherence of group centroid with respect to final centroid of voting members. The horizontal axis, representing the utterance number in the discourse, represents progress through the discourse. The vertical axis is coherence as measured with respect to the final position of the voting members. Each curve corresponds to a different group present at the meeting (Non-voting panel members, FDA representatives, sponsors, and voting members).

Figure 3 further examines the sponsor's coherence measured with respect to the final position of the voting members in semantic space. Note that the greatest drop occurs at the time of the presentation of the data suggesting that it was indeed a disagreement on the interpretation and viability of the data that led the voting members to ultimately choose not to approve the device. Although there was some disagreement regarding the viability of pooling the two clinical trials together (captured in the Statistical Methods Presentation), most of the discussion focused on the interpretation of the data rather than on the methods used to reach that interpretation.

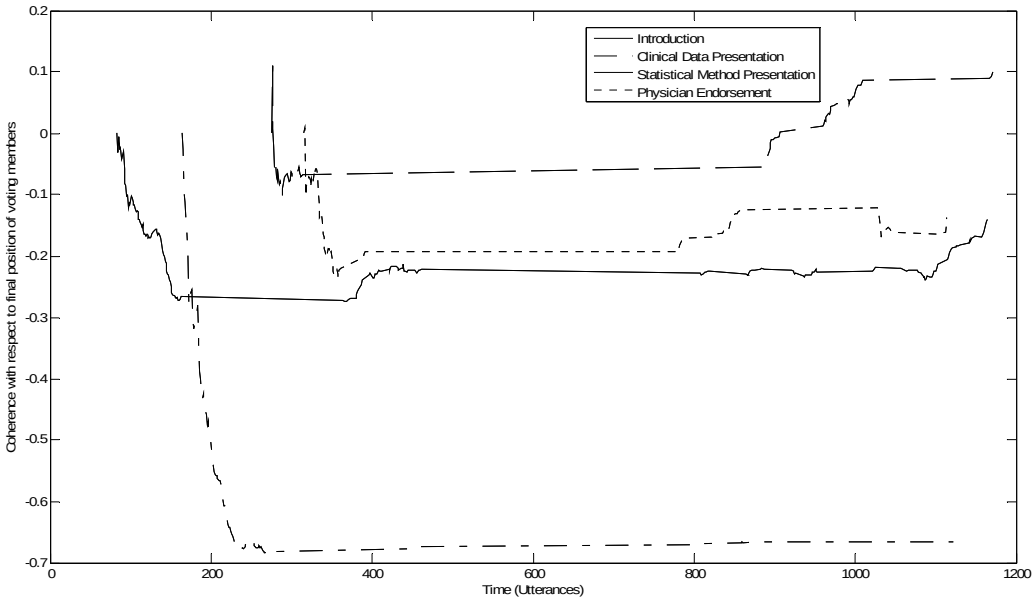

Figure 3: Breakdown of sponsor's presentation by speaker/section. Each curve corresponds to a different speaker, each of whom presented a different phase of the sponsor's talks (introduction, clinical data, statistical method, and physician endorsement).

Evaluation of Results

Implications for FDA. One could argue that the panel rightly rejected a device that was not demonstrated to be safe. On the other hand, no device is entirely safe or entirely unsafe. The question is rather one of the extent to which this device might benefit compared with its unknown risks to population safety. The coherence analysis seems to indicate that the results were presented in such a way as to focus the committee's attention on the question of whether or not the data met the 80% lower confidence bound FDA safety requirement, rather than on interpretation of the data within the context of the specific disease being treated.

The analysis seems to indicate that the FDA's questions regarding clinical trial design had an impact on directing the line of questioning that the panel members followed. Given that the device was neither evaluated as a PMA nor as a 510(k), the *ex ante* standard of review for the device was unclear. In the absence of a clear standard, the advisory panel was convened to make a recommendation regarding the device's safety and efficacy based upon their expertise. Rather than focusing directly upon the device and whether or not it might fail, they instead discussed the validity of the clinical trials. There was comparatively little discussion about the meaning of the

data and the actual safety and efficacy of the device. This is understandable given that none of the panel members had a direct experience with the device due to conflict of interest rules. Rather, the discussion focused on the uncertainty surrounding the data, and the need for a larger sample size to meet the *ex post facto* requirements imposed by the FDA. In the absence of specific expertise with this device, decisions must be made upon the basis of data. The panel therefore ultimately recommended that the device not be approved because of this uncertainty. Nevertheless, each panel member expressed appreciation for the operation of the device and a desire to see it on the American market once a clinical trial that was sufficiently powerful to meet the new FDA regulations was carried out.

Advisory committees were initially chartered to draw upon the practical expertise of practitioners and researchers in the field. The non-binding status of their recommendations could further enable them to make potentially controversial recommendations. Rather than making a value-based policy recommendation – namely, attempting to determine the appropriate balance between the probability that the device might fail and the probability that it might save lives, based upon the data presented, the advisory panel chose to make its decision upon the basis of an exogenously defined lower confidence interval bound that was put in place after the clinical trials had already been conducted. The panel's focus on the analysis was sufficiently powerful to meet the FDA's criteria seems to have sidestepped the larger question of whether the FDA's new rules should necessarily have applied to this device. This is therefore an implicit choice to delegate decision-making power to the necessarily risk-averse institutional rule created by the FDA following the failure of the predicate device.

FDA has, in the past, been described as a "risk-averse" agency. Although the Medical Device Amendments of 1976 were designed to simultaneously promote safety and innovation, FDA seems to be moving more towards the "drug model" of device approval, requiring statistically rigorous clinical trials. This has negative implications for FDA's ability to promote device innovation as per its legal requirement (Merrill 1994).

Implications for the Methodology. The results described in this analysis are preliminary, and only provide an initial insight into studies of the effects of institutional framing within group decision making for system review. Nevertheless, this analysis seems to have captured the main concerns of voting members when reviewing the PAS-Port device. Future work will focus upon expanding the methodologies employed above. Although the results are suggestive, other techniques may be employed to gain new insights from the data.

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Biography

David Broniatowski is a graduate student at MIT pursuing a Ph.D. in Engineering Systems. A member of the SEAri research cluster, his research focuses on the impact of multi-stakeholder decision-making on the diffusion of innovations in health care. His work experiences include positions at the Center for Strategic and International Studies, the XPrize Foundation, NASA Headquarters, and the Avidyne Corporation. David received an S.B. (2004) degree and an S.M. (2006), both in Aeronautics and Astronautics, as well as an S.M. (2006) in Technology and Policy, all from MIT.

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Acknowledgements

The authors gratefully acknowledge the funding for this research provided by the MIT-Portugal Program. David A. Broniatowski is a member of the Systems Engineering Advancement Research Initiative (http://seari.mit.edu), a research initiative within the Engineering Systems Division at the Massachusetts Institute of Technology. SEAri brings together a set of sponsored research projects and a consortium of systems engineering leaders from industry, government, and academia.