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Recent research in rhetoric of health and medicine (RHM) has worked to evaluate the effectiveness of patient inclusion initiatives in health policy decision-making. Extending this line of research, this article evaluates the extent to which the U.S. Food and Drug Administration's (FDA) patient and consumer representative programs meaningfully engage patient experiences. In so doing, this study provides directed and summative content analyses of pharmaceuticals policy deliberation at 163 FDA drug advisory committee meetings. The results indicate that the current implementation of the patient and consumer representative programs do not adequately ensure that patient experiences are being included as a part of advisory committee deliberation or subsequent pharmaceuticals policy. Additionally, the results presented support the growing concern that attempts to include patient perspectives in health policy may actually further marginalize patient populations.

Keywor ds: patient participation, health policy, perspectivalism, Food and Drug Administration (FDA)

Since at least the 1980s, a great deal of scholarship in rhetoric, bioethics, and related fields has argued that patients must be meaningfully incorporated into health policy deliberation and decision-making.[1] This scholarship echoes long-standing calls for patient inclusion from a wide variety of patient advocacy organizations (Bastian, 1998; Burton, 2005; Earp, French, & Gilkey, 2008; Tomes, 2006; Traulsen & Almarsdóttir, 2005; Wilkinson, 2008). A principal goal of these scholarly and advocacy efforts is to ensure that patient concerns are adequately represented in policy forums traditionally dominated by biomedical researchers, healthcare practitioners, and industry concerns. Including patient perspectives, it is argued, serves not only to make policy deliberation and decision-making more ethical, but also to improve outcomes. In other words, the recognition that patients have important perspectives to offer and experiences to draw from beyond those available to biomedical researchers, healthcare providers, or industry stakeholders requires their integration into deliberation and decision-making (Teston, Graham, Baldwinson, Li, & Swift, 2014; Tomes, 2006; Wilkinson, 2008). These repeated calls for including patient voices suggest that while medical expertise and industry participation are often essential elements, they cannot fully encompass, and may often occlude, the full range of insights needed for optimal health policy decision-making.

At the same time, however, there is a growing recognition that normative recommendations for patient inclusion efforts aimed at including patient perspectives may actually serve to further marginalize patient populations (Mol, 2002; Graham & Herndl, 2014; Teston et al., 2014). Indeed, it has been compellingly argued that the focus on patient perspectives on medical conditions inadvertently privileges biomedical models of disease. Furthermore, such scholarship contends that even when patient perspectives are included as relevant data in various policymaking and deliberative spaces, these perspectives are often treated as less objective and therefore less valid than other forms of evidence (e.g., randomized controlled trial data). It is therefore essential that efforts to investigate and evaluate various approaches to patient inclusion address the problems of perspectivalism in patient participation initiatives.

[1]See for example, Barham (2011); Brunton, Jordan, & Fouche (2008); Coplan (2011); Hunink et al. (2014; Lewis (2000); Macpherson (2006); Macpherson (2004); Milewa (2008); Teston et al., (2014); Wilmot (2011).

Emerging methodologies from postcritical rhetoric of health and medicine (RHM) are uniquely poised to offer rigorous evidence-based insights into the nature and effectiveness of initiatives designed to foster patient participation in health policy decision-making. Accordingly, this article offers a content-analytic assessment of the U.S. Food and Drug Administration's (FDA) patient and consumer representative programs, which are part of the FDA's larger drugs advisory committee program. Specifically, we provide rhetorically informed directed and summative content analyses of drug advisory committee discourse. Using the results of these analyses, we offer both 1) an evaluation of the extent to which the FDA's patient and consumer representative programs meet their stated aims of ensuring that patient experience is included in deliberation and decision-making, and 2) an exploration of the ramifications of our study for perspectival approaches to patient inclusion in RHM and allied areas of inquiry.

The Problem of Perspectivalism

Perspectivalism is endemic to both rhetorical theory and the RHM field. It is also largely enthymematic. Subsequently, it can be rather difficult to achieve the necessary intellectual purchase on perspectivalism in the advancement of rhetorical theory. Yet this is a critically important task, because as we will show, perspectivalism has recently become the subject of compelling critiques in both rhetoric and allied disciplinary areas. In addressing this issue, we will begin with a brief overview of perspectivalism in rhetorical theory and RHM. We will then proceed with an explication of recent criticism from science, technology, and medicine studies, and finally, we will describe how both the endemic nature of perspectivalism and its criticism occasion the current study.

Since the return of neo-Sophistic rhetoric in the middle of the last century, our reconstructed history and attendant metanarratives of rhetorical theory place perspectivalism at the center the discipline. As both Michael Mendelson (2002) and Susan Jarratt (1991) detail, the Protagorean doctrine of antilogic and the *dissoi logoi* occupy critical places in our intellectual tradition. Indeed, they are largely considered the founding theoretical insights of contemporary rhetorical theory. As Mendelson notes, Protagorean antilogic operates fundamentally on the twin foundations of relativism and perspectivalism—as reified in the human-measure doctrine (pp. 3–4). This doctrine, built on an ocular metaphor, privileges the epistemology of the

viewing subject in the context of a collective. But perspectivalism is not just epistemological—it and its principle techne—the dissoi logoi—were also central to the democratic project of the Sophists (Jarratt, 1991, p. 41). As Takis Poulakos (1997) describes it, "When looked at not as a philosophical treatise but as a rhetorical summons, the 'man-measure' proclamation announces the advent of a new epoch in which it will be human beings—not the gods, not the tyrants—who will decide the fate of the polis . . ." (p. 48). Furthermore, as Nathan Crick (2012) notes, a more-or-less straight line can be drawn from the twin perspectivalisms (epistemological and democratic) of ancient Greece to contemporary analogs. Specifically, Protagorean perspectivalism is reified in both Robert Scott's (1967) rhetoric-as-epistemic and rhetorical approaches to democratic theory that serve as more contemporary foundations for rhetorical inquiry.

The function of perspectivalism is well-established in contemporary postmodern rhetorical epistemologies (Graham & Herndl, 2013; Teston, Graham, Baldwinson, Li, & Swift, 2014; Graham, 2015). Perspectivalism is the principal antidote to scientific authoritarianism; it is the wedge that opens up space for alternative bodies of knowledge developed in non-scientific traditions. Contemporary theories of deliberative democracy are built on a fundamental presumption of perspectivalism as well. Individuals and constituencies have different values and opinions born of competing ideological and epistemological traditions. Robert Danisch (2012) explains that,

> The "human-measure" principle invites citizens to understand themselves as the guiding force behind their own well-being and the well-being of the community, and to understand their beliefs, decisions, and values as the forces that lead to community action and community standards. . . . Protagoras argues that the very process that allows citizens to be citizens requires positive participation through rhetorical practice for the purpose of furthering the aims of the polis by contributing as best one can to the process of socialization. This is why democracy is the preferred system of governance for those that are committed to social practice accounts of language. (p. 10)

Put another way deliberation—dissoi logoi—is the process by which community perspectives are attenuated to one another and democratic decisions can be made.

In RHM, patient inclusion initiatives arise from both senses of perspectivalism at the same time. The authoritarianism of Western biomedicine fails to adequately account for patient experiences in its understanding of health and disease. Likewise, health policy, as an ostensibly democratic (rather than technocratic) process, requires a diversity of perspectives to ethically populate deliberative events. Indeed, patient inclusion advocates frequently ground their arguments in perspectival theories of democratic representation. Accordingly, the goal of most research in patient and stakeholder inclusion is to assess and evaluate "ways to gather input from relevant patient groups and publics to make better quality decisions that reflect these groups' preferences and values" (Abelson, Giacomini, Lehoux, & Gauvin, 2007, p. 40). Mechanisms that effectively capture patient perspectives are understood to lead to desired ethical and policy outcomes. Correspondingly, failure to adequately capture these perspectives is generally understood to result in less desirable outcomes including, but not limited to, health guidelines and policies that are not appropriate for affected patient populations (Sunstein, 2003; Macpherson, 2004).

In RHM specifically, the discipline's endemic perspectivalism is reified in epistemological and emancipatory efforts to privilege the patient voice both as part of clinical decision-making and health policy. Indeed, the centrality of perspectival theories of health citizenship to the RHM project is well-articulated in the introduction to a recent special issue of the *Journal of Medical Humanities* on public engagement with health and medicine.

> A rhetorical perspective on publics thus advances a participatory, dialogic model wherein citizens self-organize around issues of interdependent concern in a public sphere that need not be limited to geographical space. Emphasizing mutual spheres of influence and interchange, such a perspective encourages us to consider the "rather fluid network of exchanges" shaping health and medical knowledge and practices (Edbauer, 2005, p.19). From this perspective, we can appreciate biomedical and health discourses and practices as the result of complex sets of interacting rhetorical performances that bridge public, private, institutional, and technical concerns. (Keränen, 2014, p. 104)

In RHM, perspectivalism is frequently operationalized by recurrent foci on patients' ability to speak to experience and spaces marginalized by or

inaccessible to clinical and biomedical practices. Indeed, a number of scholars in RHM and related areas have advocated for and focused on the importance of patient expertise, perspective, and lived experience. The unique perspective of the patient, according to such scholars, must be addressed in order to fully capture the rhetorical work in health and medical contexts.[2]

Accordingly, rhetoricians of health and medicine have argued that the patient perspective is not only key to understanding conditions, experiences, and diseases, but is also critical for ethical treatment, care, and policy. The unique power of patient perspectives is authorized by their unique experiences through which they have special access to spaces that physicians cannot reach. "Patient expertise," as Judy Segal (2005) explains "is not an imitation of medical expertise; it is a different expertise" that not only offers "special knowledge of a patient's quality of life" but adds to the "physician's special knowledge of the patient's medical facts" (p. 147). Similarly, Lora Arduser (2017) has argued patients "[have] more knowledge, or at least a different kind of knowledge, that the doctor can benefit from" (p. 84). Likewise, as Lisa Meloncon (2018) reminds us, patients' lived experiences and identities are dependent on the different spaces of their lives such as home or work—spaces to which only patients themselves have access (p. 106). Specifically, patients' "lived experiences in the different spaces of their lives (home, work, doctor's office, online community) reflected the different identities they performed. . . . For example, the mother of a child with a chronic life-threatening condition explained her intense need and desire to participate in these online spaces because it gave her strength to perform the different roles that she needed to on a daily basis" (p. 106). Scholarship in RHM leverages this notion of unique access within a perspectival framework to authorize alternative perspectives in the face of biomedical dominance. For example, Amy Koerber (2009) reports that the participants in her study valorized the "unique perspective that the distinctly nonmedical knowledge of an organization such as La Leche League provides to breastfeeding women" (p. 93). In so doing, she demonstrates how mothers seize on the notion of special access to warrant counter-rhetorics of breastfeeding.

[2] See for example, Epstein's (1996) work on lay expertise, Majdik & Keith's (2011) discussions of patient expertise, and Gouge's (2018) commentary on the importance of lay-experts in online forums (p. 128).

Ultimately, however, perspectivalism is not simply a core theoretical commitment of RHM. Its operationalization in the subdiscipline comes with attendant predictive theses. That is, it is a central assumption of RHM that the inclusion of patients in clinical and health policy decision-making will invariably catalyze an increase in the amount of time spent discussing those unique domains to which patients have access and doctors do not. Correlatively, it is understood that the inclusion of patients' perspectives in deliberative spaces will necessarily lead to more ethical outcomes. Yet a small but growing body of scholarship in RHM and allied areas of inquiry strongly critiques perspectivalism, arguing that that these predictive presumptions are not borne out in practice. That is, despite the centrality and ubiquity of perspectivalism in the discipline and subdiscipline, there are now significant concerns about the extent to which the doctrine actually achieves its emancipatory aims with respect to health and medicine.

Specifically, philosopher of medicine Annmarie Mol has been a significant critic of the role of perspectivalism in academic and emancipatory initiatives that target medical and health policy spaces. Mol's *Body Multiple* (2002) offers a compelling corrective to the principle theoretical intervention offered by social scientists aiming to address the marginalization of patients. As she writes,

> [S]ocial scientists have made it their trade to listen for feelings when they interview patients. And they have persistently and severely criticized doctors for neglecting psychosocial matters, for being ever so concerned about keeping wounds clean while they hardly ever ask their patients what being wounded means to them. In addition to attending to blood sugar levels, bad arteries, wounds, and other physicalities, or so social scientists have been arguing in all kinds of ways, physicians should attend to what patients experience. This is how they have come to phrase it: in addition to *disease*, the object of biomedicine, something else is of importance too, a patient's *illness*. Illness here stands for a patient's interpretations of his or her disease, the feelings that accompany it, the life events it turns into. (p. 9)

The disease/illness dichotomy is now, of course, quite well known and a recurrent feature of social scientific and rhetorical scholarship on health

and medicine. It also underwrites much of the available scholarship on the importance of patient representation. Patient interpretations of and perspectives on their diseases exceed available biomedical knowledge. Therefore, the argument goes, it is essential that these interpretations and perspectives are included in clinical decision-making and policy deliberation as a part of ethical practices in both of these spheres.

However, as Mol (2002), S. Scott Graham (2015), and Christa Teston et al. (2014) argue, perspectivalism may actually serve to replicate the inequitable power structures patient inclusion efforts are designed to correct. Despite perspectivalism's preeminence in relativist postmodern epistemologies, it is a fundamentally modernist conceit. The focus on the differential perspectives of viewing subjects inadvertently authorizes a modernist theory of a singular, objective reality about which there can be multiple viewpoints. This is a notion Christopher Gad and Casper Bruun Jensen (2010) rightly dismiss arguing that, "Reality is manipulated in many ways and does not lie around waiting to be glanced at" (p. 71). As Mol (2002) and Teston et al. (2014) argue, the tacit modernism of perspectivalism actually serves to further marginalize the patient voice in health policy deliberation. Teston et al. note that, "perspectivalism is operationalized by the disease/illness dichotomy . . . [and] reifies the notion of a true objective disease" (p. 159). Patient voices are typically marginalized in biomedical decision-making because their subjective experience of the condition is considered less important or less relevant than the objective biomedical account of that condition.

Indeed, Teston et al.'s (2014) analysis of FDA advisory committee meetings identifies this as a recurrent feature of the discourse. They highlight numerous places in the evaluated transcripts where patient illness narratives are rejected in favor of biomedical accounts of disease. They cite a particularly powerful example from a member of the Oncologic Drugs Advisory Committee: "I was once taught that the plural of anecdote is not data. So we each have one story of somebody who felt better while responding, but if the facts don't support that, then that's not something that we can rely on" (Teston et al., 2014, p. 158). Although the disease/illness dichotomy has been used successfully to authorize patient participation in some spaces, it does not adequately address the authority hierarchy between biomedical and patient accounts. Insofar as the illness is a perspective of the patient, it continues to be interpreted as lesser than the biomedical science of the disease.

In light of the theoretical concerns highlighted by Mol (2002) and the growing evidentiary foundation established by Teston et al. (2014), it is critical that RHM conduct the kind of scholarship that can validate (or invalidate) their theoretical presuppositions about perspectivalism. If our normative recommendations are inadvertently exacerbating the unethical conditions we aim to correct, it is essential that we know this so that we may explore new foundations of inquiry that can better serve our emancipatory aims. Accordingly, in this article, we offer quantifications of rhetorical analyses designed to evaluate the extent to which patient participation predicts the kinds of discursive outcomes our perspectival theories suggest. In so doing, we build on developing postcritical and quantitative rhetorical traditions that are designed both to contribute more directly to external stakeholders and to evaluate the potential limitations of disciplinary lore.[3]

Methods

In 1962, the FDA began chartering independent expert advisory committees to assist with safety and efficacy evaluations of new prescription drug products (Rettig, Earley, & Merrill, 1992). More recently, advisory committee remits have expanded to include 1) providing independent evaluations of newly proposed pharmaceutical products and devices, 2) offering independent assessments of newly proposed uses for existing pharmaceutical products and devices, and 3) evaluating proposed methods for investigating pharmaceutical products and devices (U.S. FDA Advisory, 2014). These committees (which bring together interdisciplinary experts, industry representatives, and patients alike) are charged with deliberating about both the state of relevant medical science and the needs of patient communities, all with the aim of making actionable policy recommendations.[4]

For their first 30 years of existence, advisory committees were staffed exclusively by biomedical experts, but in 1991, the FDA began integrating consumer and patient representative programs into its committee programs (Tomes, 2006; Traulsen & Almarsdóttir, 2005). According to the FDA, a primary role of patient representatives is to "provide [the] FDA with the

[3] For discussions on the problems of disciplinary lore and the lack of a robust dataset supporting theoretical suggestions, see Kimball (2013) and Graham (2017).
[4] It should be noted, however, that although the FDA frequently ratifies these recommendations, it is not bound to do so.

unique perspective of patients and family members affected by a serious or life-threatening disease" (U.S. FDA About, 2014). Similarly, consumer representatives are described as a key resource for "ensuring that FDA obtains the points of view of consumers" (FDA Activities, 2014).

In order to evaluate the effectiveness of the FDA's patient and consumer representative programs in meeting their stated aims, our study adapts and extends early efforts in this area, operationalizing them as part of rhetorically grounded directed and summative content analyses (Hsieh & Shannon, 2005). As mentioned above, this project was intentionally designed as part of the emerging postcritical, upstream rhetorical research tradition which aims for more direct engagement with the rhetors we study. As noted positively by Caroline Gottschalk Druschke (2017) and critically by Leah Ceccarelli (2014), postcritical rhetorical scholarship can look markedly different from research that relies more heavily on traditional rhetorical methods. Attenuating rhetorical findings to the epistemic standards of extra-disciplinary audiences often requires re-engaging the insights of our work through quantitative methodologies that carry more value outside of rhetorical boundaries. Doing so also provides the opportunity to address the increasingly recognized problem of unvalidated lore in RHM and technical communication (Kimball, 2013; Graham, 2017). That is, in many areas of the discipline, we lack robust data sets demonstrating that tacit disciplinary theories and insights—for example, perspectivalism—actually lead to the outcomes assumed—inclusive health policy deliberation.

The postcritical approach adopted here takes its inspiration from prior quantitative efforts to validate rhetorical insights, including those of Celeste Condit (1999) and S. Scott Graham et al. (2015). In particular, we follow the approach of Graham et al.'s statistical genre analysis, which works to bring rhetorical and quantitative insights into mutual alignment. Specifically, the aim is "to offer encompassing conclusions about larger data sets without losing the craft character of rhetorical inquiry" (p. 72). In working to meet this difficult balance, our approach here began with lengthy traditional rhetorical analyses of discourse wherein the development of coding categories and the subsequent quantification was resisted as long as possible. However, in keeping with the postcritical tradition, the ultimate quantification of the data is a critical part of our goal to offer findings in ways that the medical community may find more inherently persuasive.

Our analytic approach focused on patient participation in different aspects of drug advisory committee deliberation. The lead author of this

study, while working with a different team of rhetoricians on a related project, explored how patient participation was realized in drug advisory committees and to further evaluate the reception of patient perspectives expressed at these meetings. The results of this research, which appear in Teston et al. (2014), classifies deliberation based on the sites of practical engagement and experiential loci from which the discourse emerges. The goal of the rhetorical inquiry was to develop a coding schema that might address some of Mol's (2002) concerns with respect to the disease/illness dichotomy and the normative suggestions of patient inclusion advocates who argue that perspectival democratic approaches will provide air time, as it were, for the unique experiences of patients.

Teston et al.'s (2014) rhetorical analysis builds explicitly on Mol's work in *The Body Multiple* (2002), wherein Mol provides an ethnographic account of different approaches to atherosclerosis, each one grounded not in an identity, perspective, or disciplinary paradigm, but rather the local, material sites of practice. For Mol, the atherosclerosis of the surgical ward (where it is an issue of clot matter) is different than the atherosclerosis of the physical therapy clinic (where it is a function of walking distances) even though both physical locations are populated by similar populations of biomedical experts and patients. Graham and Herndl (2013) extend Mol's focus on specific physical loci of practice and develop a theory of "practical regimes of engagement" to account for the same variability that would have historically been treated under notions of disciplinary paradigms or differential perspectives. Reflecting on the clinical practices of pain medicine, they write,

> Diagnosis occurs equally in the exam room, the laboratory, the library, the internet etc. It is a spatially distributed practice. Additionally, the physical location "exam room" is, in many cases, the exact same location used for both diagnostics and opiate pharmacology, but each practice articulates the exam room to a different set of physical locations. Diagnostics articulates itself to all the previously mentioned locations. In contrast, opiate pharmacology articulates the exam room to the same locations as diagnostics but also to the pharmacy and the patient's medicine cabinet at home. (p. 114)

Of course, both the analysis of Teston et al. and the analysis presented here are rhetorical activities. That is, they evaluate texts and discourse and do

not ethnographically study the physical spaces identified by Graham and Herndl. Subsequently, these analyses seek to understand how the discourses of patients in health policy forums work metonymically to stand for identified practical regimes of engagement.

To illustrate, both of the following excerpts from the current data set refer to activities having to do with different physical locations (a literal laboratory in the first place, and the distributed spaces of a clinical trial in the second place).

> DR. TUNKEL: There is a meningitis model. The rabbit model has been in existence since the early 1970s. Merle Sande actually initiated that model at the University of Virginia, and it's a reproducible model in which meningitis can be introduced in rabbits. And it's such that you can do repeated sampling of cerebrospinal fluid in which you can measure, let's say, concentrations of systemically administered monoclonal antibodies and look at response and permeability. Blood-brain barrier. So that model is out there. And, again, based on what Dr. Munford said, I think utilizing a rabbit model alone, given the fact that some of the CNS findings were in both animals, I think would be very reasonable. (U.S. FDA Anti-Infective, October 27, 2009)
> DR. PLATTS-MILLS: It's worse than that. You can see it in immunotherapy trials. We think that they remember everything that they've been told, and they not only take medicines once they're in the trial and coming, but they can tell whether you've washed your bedding and you've done those things, which they would never normally comply with. But once they're in the trial, this kind of placebo effect is a major effect in all these trials. (U.S. FDA Pulmonary-Allergy, November 18, 2009)

Despite the differences in physical location, both passages were interpreted as belonging to laboratory regimes of engagement. In both cases, the discourse emerges from the practices of biomedical science and, in so doing, represents certain spaces and domains of practice. Similarly, we interpreted patient discourse as referencing activities that occur in the home (e.g., at the medicine cabinet) and discourse about significant life events (bar mitzvahs, birthdays, etc.) as belonging to those patient regimes of practical engagement that are mostly inaccessible to biomedical practices.

Specifically, the four-part coding schema that emerged from our rhetorical inquiry (Table 1) identifies deliberation grounded in 1) laboratory practices, 2) patient home life, 3) patient-provider encounters, and 4) the

Table 1. Sites of practice coding schema

Code	Description and Example
Lab	Discussion grounded in laboratory practices including evidence-based medicine, clinical trials, pharmacokinetics, pathologies, hazard-ratios, etc.
	DR. SEPKOWITZ: I have two different questions. One, if there's a vast difference in the Coombs Seropositivity, seroconversion between the two groups? A study drug, for instance, the ceftriaxone, although, that was not clinically relevant, do you have a biologic explanation for that and are you concerned? I think it's 10-point-something percent versus four-point-something percent. (U.S. FDA Anti-Infective, September 7, 2010)
Home	Discussion grounded in the everyday lived experience with a disease such as interacting with the prescription drug label or managing symptoms, side effects, or psychosocial impacts of disease/drugs.
	DR. SAUL KAPLAN: I do think it is an access issue. If it requires up to three injections per joint per affected finger and you can only do one at a time, people don't come in with one affected joint. They come in with multiple joints, multiple fingers, both hands. So I think—and you have to come back the next day after the injection, so I wouldn't belittle the access point. I think these are—multiple visits are going to be involved. More visits with this procedure potentially than with surgery. (U.S. FDA Arthritis, September 16, 2009)
Clinic	Discussion grounded in practices within the exam room and patient-provider encounter—primarily diagnosing, treating, and prescribing.
	DR. GARDNER: I think a problem with this question is our answer to the previous question, which is how would people—if we can't identify who might be placed on the drug safely, then deciding that if they're not gaining—or if they're not losing weight within three months seems spurious here. So I think we're stepping on our own toes with our previous answer. We don't know who would use it, but if they do use it then we should make sure that they're losing weight. (U.S. FDA Endocrinologic and Metabolic, September 9, 2010)
Market	Discussion grounded in issues of economic access to effective drugs including matters of affordability, economic free choice, and the intricacies of insurance coverage.
	MR. SNARSKY: But Novartis took me off ffree support because I'm now getting Social Security and I'm out of—I'm making too much money at $9,000 a year, and they can't give me the drug anymore, whereas other drug companies are supplying me with free drugs. I'm concerned about the cost of this drug. (U.S. FDA Arthritis, June 21, 2011)

prescription drugs market. *Lab* codes referred to biomedical research practices, broadly, while *home* codes were applied to passages that occurred in a wide range of physical locations but where the coded deliberation discussed events of the patient's personal life experiences. *Clinic* is the coding category that perhaps most consistently refers to discourse grounded in a more limited range of physical locations—those of patient-provider encounters in hospitals, clinics, and/or private practices. In contrast, *market* is the most diverse category, referring to the large range of economic practices surrounding obtaining drug products.

A four-category schema is, admittedly, not the most granular analytic instrument. Certainly, the rich complexity of advisory committee discourse could be more completely captured with a more expansive coding schema. However, given the relatively narrow aim of this article—to provide an initial evaluation of the predictive theses of perspectivalism in RHM and to assess how well these FDA programs meet their stated aims—this is an appropriate first step. Furthermore, we believe that a more granular schema would principally offer subdivisions of these four categories. That is, coding for more specific markers of patient engagement would involve coding for issues that occur in patient home life or as part of market considerations. Our data, therefore, provide a high-level aggregation of patient engagement content markers relative to more biomedical or clinical-practice concerns. In so doing, we can more efficiently evaluate the effects of patient participation on the broad range of possible content markers that might signal effective participation.

Following the rhetorical analyses, the coding team applied the schema to 163 transcripts of drug advisory committee meetings held by 13 different drug advisory committees between 2009 and 2012. The research team coded all utterances made by drug advisory committee members, including those of regular medical expert members, patient representatives, consumer representatives, and industry representatives. Codes were assigned regardless of speaker affiliation or identity status. For example, no determination was made as to whether speakers were medical experts or patients in assigning either lab or home codes. Advisory committee member discourse was selected as the data set as it is a) the most direct indicator of shifts in discussion content as a result of changes in patient or consumer representation and b) the most variable part of advisory committee meetings. FDA and drug sponsor presentations, for example, follow a very tightly prescribed format.

The utterance or "talking turn"[5] was selected as the primary unit of analysis. Coding was applied exclusively, and multiple codes could be applied to each unit. This, in turn, created code collocates that were used in the subsequent analysis. The following are sample home-market and home-clinic collocates, respectively:

> MR. DUBBS: Prescribing of this drug, will that be covered by insurance? Is this drug going to be the same price as a drug without niacin? And I'm not taking exception to the objective of the company in formulating this product. I'm just wondering. It's only going to be helpful if you get it into the user's hands who needs it at the time they need it and they don't abuse it. Is an insurance company going to cover it the same as they do a prescription for regular oxycodone? Has that been looked into, the marketing aspects of it? (U.S. FDA Anesthetic and Analgesic, April 22, 2010)
> DR. FEINBERG: Judith Feinberg, no. Actually as a person with MS, I would very much like to have the opportunity to take this drug if I needed therapy with it albeit with, you know, appropriate discussion of all the potential risks and everything else. I take care of plenty of people who take Interferon. That's not a lovely drug either. I think this should be available to patients. But they should understand that there are unknowns. (U.S. FDA Peripheral and Central, June 10, 2010)

Three raters independently applied the schema to 1,457 units (which exceeds the minimum reliability threshold of 1090 and approaches the maximum useful sample of 1,459; see Sims & Wright, 2005) in order to assess inter-rater reliability. Applying Cohen's kappa, the average inter-rater reliability was generally high, ranging from .72 to .89 (Table 2). Considering the robust absolute percent agreements, the inter-rater reliability statistics seem suppressed due to cell asymmetry (see Kim, 2017).

After the coding schema was applied, we identified and extracted four primary variables to be used as outcome measures in the analysis. The four variables included two measures of the frequency of content codes in each

[5]Unit boundaries were defined by a change of speaking subjects.

Table 2. Average inter-rater reliability (Cohen's kappa) and absolute percent agreement by code

Code	Average IRR	Absolute Percent Agreement
Market	.84	99.8
Home	.72	95.5
Lab	.89	95.8
Clinic	.73	90.5

category and two measures of the frequency of collocates. Specifically, identified measures were: a) the number of units coded for each coding category in each transcript; b) the count of words coded in each category expressed as a percentage of total coded words in each transcript; c) the number of units coded with one, two, three, or four coding categories and; d) the percentage of units coded with one, two, three, and four coding categories. These variables were selected as primary measures of perspectival predictions. That is, they provide an assessable outcome with respect to the extent that patient inclusion results in a) a greater diversity of discourses representing a greater diversity of practices, and; b) increased deliberation where differing perspectives where attenuated to one another through dissoi logoi.

In addition to completing the directed content analysis, we used the collected advisory committee rosters and transcripts to identify all advisory committee representatives in attendance at each of the 163 evaluated meetings. We further extracted data from transcripts and rosters to identify the official role assigned to each member—expert advisory committee member, patient representative, consumer representative, or industry representative. Using these data, we identified both the exact number of patient and consumer representatives in attendance at each meeting and the percentage of patient and consumer representatives relative to the entire advisory committee. These two measures of patient and consumer representation (number per meeting and percentage of committee) served as primary comparators for assessing the extent to which changes in stakeholder representation predicted changes in deliberative content.

Finally, in order to evaluate the possibility that patient representation efforts were exacerbated by participant membership in multiple constituencies, we also used meeting materials to evaluate whether each patient and consumer representative also qualified as a medical expert. As part of this

analysis, we conducted an iterative series of online search queries using Google, Facebook, LinkedIn, and the Internet Archive Wayback Machine[6] (Internet Archive, 2014). Collected social media archives, resumes, CVs, personal/professional web pages, and company rosters were used to identify if and when a patient or consumer representative held an advanced medical degree, was employed as a healthcare provider, and/or was employed as a medical researcher.

Given the potential for false positives as a result of common names, the identities of patient and consumer representatives in the dataset were authenticated by one of two protocols: 1) primary authentication, or 2) triangulated authentication. In most cases primary authentication occurred when the official FDA drug advisory committee roster or transcribed representative statements specifically identified a potential medical expertise status. In some cases, primary authentication was achieved when a non-FDA source document (e.g., resume, CV, or social media profile) specifically identified the individual in question as a patient and/or consumer representative during the time period assessed. In the absence of primary authentication, patient and consumer representatives' background information was deemed eligible for inclusion in the dataset when three or more pieces of identifying information could be matched among the drug advisory committee roster or transcript and non-FDA documents. Primarily, triangulated authentication occurred when background research identified an individual with: 1) the same name as the patient or consumer representative; 2) the same city of residence as the patient or consumer representative and; 3) participation in a patient organization focused on the same condition adjudicated at the meeting.

Results and Discussion

Between 2009 and 2012, a total of 984 individuals served as advisory committee members 2,835 times at the 163 evaluated meetings. Of the 984 individuals, 834 served as regular advisory committee members, 79 as patient representatives, 23 as consumer representatives, and 48 as industry representatives (see Table 3). Each committee member served an average of 3.46 times ($SD = 4.10$) in the sample. When the overall frequency is assessed

[6] The Internet Archive Wayback Machine is an online repository of historical web "snap shots." The Archive crawls the web, saving historical versions of web pages in a date-stamped archive.

Table 3. Number of drug advisory committee members and average frequency of service across evaluated meetings

	Number of representatives across evaluated meetings	Average number of meetings served
Regular advisory member	834	3.64
Patient representative	79	2.03
Consumer representative	23	7.52
Industry representative	48	4.52

by member type, patient representatives served 2.03 times ($SD = 1.82$) on average; consumer representatives served an average of 7.52 times ($SD = 5.78$); industry representatives served an average of 4.52 times ($SD = 4.25$) (see Table 2). Occasionally, an individual who had served in one meeting as a consumer representative served at other meetings as a regular advisory committee member.

The collected 984 individual committee members served at a total of 163 committee meetings held by 13 different FDA drug advisory committees. Advisory committee meetings included 8–30 members ($M = 15.75$, $SD = 4.79$). The number of patient and consumer representatives at each meeting ranged from 0 to 2 per representative type; $M = 0.95$, $SD = 0.27$ for patient representatives; $M = 0.98$, $SD = 0.17$ for consumer representatives. Relative to the total number of committee members at each meeting, patient representatives were between 0 and 15% of each roster ($M = 6\%$, $SD = 2.00$), and consumer representatives were between 0 and 13% ($M = 7\%$, $SD = 2.00$).

As would be predicted by the perspectival hypothesis, in keeping with the relative distribution of biomedical experts on advisory committees, meetings are substantially dominated by discussion of technical biomedical matters. The number of advisory committee members' utterances coded as laboratory discussion ranged from 29 to 291 ($M = 171.91$, $SD = 61.29$), followed by the number of discussions coded as clinic, which ranged between 2 and 170 ($M = 58.30$, $SD = 40.03$). In contrast, home and market discussion were the least prevalent content types, with home discussion only present in 0 to 87 ($M = 22.65$, $SD = 18.61$) units per meeting, and market discussion only present in 0 to 19 units per meeting ($M = 3.04$, $SD = 3.60$).

The relative frequency differences among content types persist when the number of words coded by category is evaluated in percentage terms; content coded as laboratory discussion involves 1.55% to 14.53% ($M = 8.02\%$,

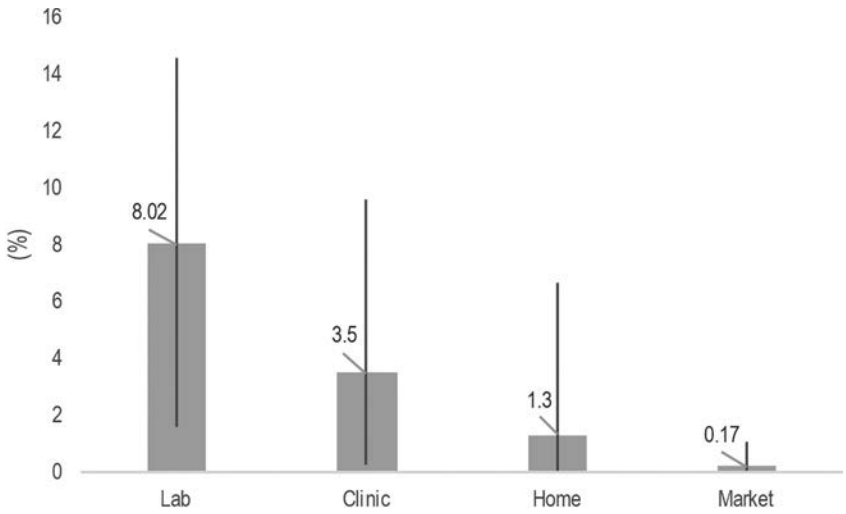

Figure 1. Mean frequency (%) and range of each code across the evaluated meetings

SD = 2.36) of member words transcribed; clinic discussion covers between 0.27% and 9.62% (*M* = 3.5%, *SD* = 2.19) of meeting content; home discussion ranges from 0% to 6.65% (*M* = 1.3%, *SD* = 0.98); market discussion ranges between 0% and 1.07% (*M* = 0.17%, *SD* = 3.60; see Figure 1). The remaining portion of advisory committee deliberation involved introduction of members, procedural issues, and other administrative discourse.

Assessing Content

If the FDA's patient and consumer representative programs are to be considered effective in meeting both their target aims and the normative mandates of inclusion, relative increases in patient inclusion should correspond with relative increases in content variety. This is the central tenet of perspectivalism in rhetorical approaches to democratic deliberation. Perspectivalism is authorized and operationalized by the core assumption that increasing the diversity of participants—who presumably have diverse perspectives—will necessarily increase the diversity of insights discussed in deliberative events. In the case of FDA advisory committee discourse, the perspectival hypothesis suggests that if the patient and consumer representative programs are effective, we would anticipate significant and

measurable increases in home, clinic, and market codes both by number of coded units and as a percentage of coded content. In terms of number of representatives per meeting, the vast majority of the 163 sampled meetings included only one patient ($n = 151$) or only one consumer representative ($n = 158$). Meetings including either none or two representatives ranged between 1 and 10 across conditions. This disallowed for conducting an ANOVA-based significance test to examine the efficiency of the FDA meetings because the sample statistics (i.e., mean, standard deviation) from such small samples can hardly be considered representative of the population parameters to be estimated. Nevertheless, these patterns warrant attention, as they suggest that the patient and consumer representative programs are not meeting their stated aims of ensuring that the patient-specific concerns are represented.

Figure 2 shows the plots comparing the mean number of units of discussion coded in each content category (i.e., lab, home, clinic, market) for meetings with 0, 1, or 2 patient (left) and consumer (right) representatives. The left plot shows the number of coded references for each category remaining similar for meetings with 0 or 1 patient representative and dropping off when including a second patient representative. This pattern, albeit inconclusive, suggests a failure of the patient representative program. That is, had the FDA initiative been effective, the number of coded references in the home, economic, and clinic categories should have increased along with the number of patient representatives. A pattern that is somewhat closer to the predicted pattern representing FDA success was observed in the consumer representative data, where the number of discussions in all but the laboratory category increased when adding a second non-expert

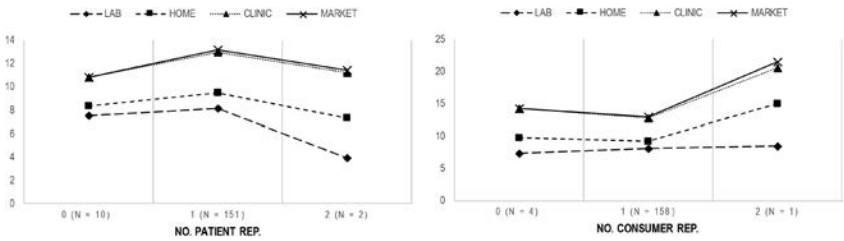

Figure 2. Plots comparing the mean number of discussion per content category for 0, 1, and 2 patient representatives (left) and consumer representatives (right)

member. Nonetheless, the current interpretation of the data is based on the results from a small number of observations and should not be accepted as conclusive or predictive.

Additionally, a positive correlation between number of patient or consumer representatives and the number of collocates would suggest programmatic success and validate another aspect of the perspectival hypothesis. Specifically, democratic theories of deliberation assume that the presence of diverse constituents not only predicts discursive diversity, but also that such diverse perspectives will be attenuated to one another through dissoi logoi. Accordingly, for the purposes of this study, we can interpret an increase in the frequency of collocates as indicative of dissoi logoi where traditional technical forms of data are attenuated to patient experiences. That is, if meetings with a greater number of patient or consumer representatives were more likely to discuss, say, lab or clinic data in terms of home or market experiences, then the patient/consumer representative program could be considered effective in its current implementation. In some ways this is a more important measure of program success than relative changes in the raw amount of home or economic discussion. As it would not occasion effective dissoi logoi, merely adding in increased amounts of patient-centered dialogue in isolation from the technical medical data could suggest a tokenistic implementation of the patient perspective. Similarly, the overall pattern of the data (Figure 3) was not consistent with what one might expect from effective representative programs. Specifically, the data show no apparently meaningful increases in the number of collocates for additional patient or consumer representatives across the four collocate variables. Furthermore, the pattern actually shows a reduction in frequency of collocates for

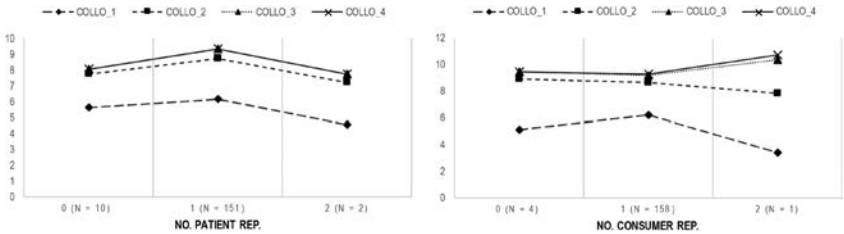

Figure 3. Plots comparing the mean number of discussion for 1–4 collocations for 0, 1, and 2 patient representatives (left) and consumer representatives (right)

meetings with two patient representatives. Again, due to small sample sizes, the current results should be interpreted cautiously.

Correlational Results

In order to provide an additional assessment of the success or failure of FDA patient and consumer representative programs and to address the reliability of the previous test results, the data were restructured to represent patient and consumer representatives' presence as a ratio to the total number of committee members. This measure provides an alternative way of evaluating the potential effects of a relative increase in patient and/or consumer representation. The two major dependent measures, utterances discussing one of the four sites and the collocates, were also expressed in percentages for least square analyses.

The full correlation matrix (see Table 4) corroborates the previous results, showing a mostly negative association between the predictors (i.e., proportion of patient or consumer representatives) and the outcome measures (discursive diversity and evidence of dissoi logoi). According to the logic of perspectivalism, patient and consumer representative programs should show positive correlations across coding and collocate variables. In particular, there were negative correlations between the relative prevalence of clinic discussion and the proportion of both patient representatives

Table 4. Full correlation matrix (N = 163)

	1	2	3	4	5	6	7	8	9
1. PR (%)									
2. CR (%)	.38**								
3. Lab	–.14	–.15							
4. Home	.10	–.14	.004						
5. Clinic	–.16*	–.34**	.32**	.11					
6. Market	–.09	–.22**	–.06	.29**	.12				
7. Collocate (1)	–.11	–.16*	.75**	–.28**	.28**	–.04			
8. Collocate (2)	–.14	–.33**	.58**	.23**	.82**	–.02	.28**		
9. Collocate (3)	–.02	–.06	.12	.70**	.32**	.36**	–.26**	.23**	
10. Collocate (4)	–.11	–.12	.10	.45**	.08	.45**	–.10	.06	.42**

Notes: PR: Patient representative. CR: Consumer representative. *$p < .05$, **$p < .01$.

($r[161]=-.16$, $p<.05$) and consumer representatives ($r[161]=-.34$, $p<.01$). The presence of consumer representatives also predicted a decline in market related deliberation ($r[161]=-.22$, $p<.01$), in the utterances discussing one among the four sites ($r[161]=-.16$, $p<.05$), and in those containing collocates of two sites ($r[161]=-.33$, $p<.01$). These findings run directly contrary to the predictions of perspectivalism. Under that doctrine, rhetoricians anticipate that increased representation from patients and consumers should increase both the relative frequencies of discussion related to domains where patients have access (e.g., clinical and market practical regimes of engagement.) To see these, in fact, decrease in the context of increasing diversity of representation raises significant questions about the efficacy of the patient and consumer representative programs and the power of the perspectival hypothesis.

Patient and Consumer Expertise

The overall results from this study, albeit preliminary, indicate that current FDA selection criteria and program implementation may be failing to satisfy the goals of ensuring that patient experience and concerns are represented in drug advisory committee meetings. One possible reason for this is a noteworthy trend in selecting participants who also identify as medical experts to serve as patient or consumer representatives. Per our expertise analysis, 22 (28%) of the 79 patient representatives and 18 (78%) of the 23 consumer representatives were identified as having medical expertise either in the form of advanced medical degrees or employment as a biomedical researcher or healthcare provider. As a result, 45 (27.6%) of the evaluated advisory committee meetings included a patient representative who was also a medical expert. One hundred and fifteen meetings (70.12%) included a medical expert consumer representative. Importantly, a meager 45 (27.6%) of the evaluated meetings involved public participation where neither the patient representative nor the consumer representative was also a medical expert.

The results presented here remind us both that 1) individuals are complex and mobile, and 2) that the human-measure doctrine is simultaneously collective and individualized. In the first case, as our data indicate, patient and consumer representatives frequently belong to more than one identity community. Selected patient and consumer representatives may be biomedical researchers, healthcare providers, advocacy professionals, and so forth.

Subsequently, they may have the ability to speak on behalf of multiple perspectives. Accordingly, there is no guarantee that they will speak from the perspective associated with the one part of their identity they were selected to represent. This underscores Poulakos' (1997) critical insight that the human-measure doctrine

> calls upon citizens to understand themselves as the sole arbiters of individual and communal well-being, and to regard their beliefs, deliberations, and decisions as the only sources of historical agency. The process of interaction evoked above, of a citizen's self-interest shaping and being shaped by the collective interests of the community, points to a political conception of rhetoric that helps us address the contradictory claims about education attributed to Protagoras. (p. 48)

Although, rhetoricians like to focus on the collective dimension of perspectivalism, it is ultimately individuals pursuing their self-identified interests that shape the technai of dissoi logoi. Assigning someone to speak on behalf of a particular identity community in no way guarantees that they will represent that constituency over the other identity communities to which they also belong.

Implications for FDA Advisory Committees

Within RHM, analyzing discursive practices at FDA drug advisory committees has become something of a cottage industry. By their very nature and their transcripts' ready availability for download at FDA.gov, drug advisory committee meetings have proven amenable to a wide variety of rhetorical research projects. Indeed, these transcripts have been used as a proving ground for: 1) generating new theories on burdens of proof in argumentation (Paroske, 2012); 2) developing understandings of the role of technical evidence in policy discourse (Teston, 2017) and; 3) exploring the impacts of financial conflicts of interest on discursive practices (Graham et al., 2015). Additionally, there has been increasing attention paid to the role of patient participants at drug advisory committee meetings (Teston et al., 2014; Teston & Graham, 2012; Card, Kessler, & Graham, 2018).

These prior analyses of FDA patient participation initiatives do indicate significant cause for concern. Segal's (2015) analysis of a patient-focused

forum describes an open door for industry "astroturfing" run amok, and Teston et al. (2014) show how medical experts on advisory committees systematically reject the value of patient insights for policy decision-making. More recently, Card, Kessler, and Graham (2018) demonstrate that patient representatives without medical expertise contribute to advisory committee deliberation far less frequently than credentialed medical experts. Ultimately, the results presented in this article further reinforce a troubling body of evidence with respect to the success of FDA patient inclusion efforts.

First, our findings indicate that patient inclusion, as currently deployed by the advisory committees, fails to ensure content diversity. This result is not entirely surprising as it is consistent with other research in democratic science-policy deliberation (Callon, Lascoumes, & Barthe, 2009; Wynne, 1992) and prior studies of FDA advisory committees (Teston et al., 2014). The assumption that patient inclusion will necessarily lead to content diversity fails for multiple reasons. Current advisory committee design and selection criteria already significantly privilege the role of biomedical experts and laboratory practices. Simply adding patients and informed consumers to meetings and charging them with representing a certain perspective is insufficient to overcome these structural issues. Indeed, our findings are consistent with those of other social scientific research that has studied tokenistic inclusion in deliberative bodies, most notably corporate boards of directors (Page, 2007). Adding one or two additional marginalized individuals to a deliberative body of 10 to 20 traditionally powerful individuals, it turns out, is not likely to encourage equal participation across a diversity of perspectives or experiences. This should, perhaps, be an issue of special concern regarding patient representatives. The inhibitory effects of tokenism may be magnified when consumer representatives are indistinguishable from regular advisory committee members. Additional research should be conducted to further evaluate this question.

Furthermore, insofar as advisory committees include representatives who are charged with providing a unique patient perspective, we question the extent to which it is appropriate for these representatives to also be biomedical experts. In the assessed data set, two consumer representatives also served as regular advisory committee members. This suggests that, at least for some consumer representatives, there is no meaningful difference in hiring criteria. To be clear, our presentation of these findings is not meant

to suggest that these individuals should be ineligible to serve on drug advisory committees. Rather, we are concerned that their assigned role as patient or consumer representatives might be inappropriate to the goals of these programs. Specifically, our data suggest that careful attention should be directed toward the consumer representative program.

Indeed, an important and unaddressed question is whether a consumer representative program as something different from a patient representative program makes sense for the drug advisory committees. While a consumer representative is a distinct and meaningful category for other FDA advisory committee programs (i.e., those for food and tobacco science), we wonder whether there is a meaningful difference between consumers and patients in terms of prescription drug products and medical devices. If there is an important distinction between the two programs for drug advisory committees, then it would be that consumer representatives are charged with representing the patient voice more in terms of economic issues than home life concerns. However, our data indicate a significant negative correlation between the proportion of consumer representatives in attendance at advisory committee meetings and the amount of market-based discussion. Moreover, as a result of the biomedical literacy requirements mentioned in the introduction, the consumer representative program is populated overwhelmingly by medical experts.

Insofar as the current advisory committee practices are engineered to primarily elicit discussion of laboratory and clinical practices, individual representatives who work across multiple domains of practice are seemingly encouraged to focus on privileged domains. While we would recommend that the FDA explore significant procedural revisions to eliminate this concern, we recognize that current legal requirements for FDA decision-making criteria ensure a primary focus on laboratory practices (Graham, 2015). Therefore, it may be appropriate to consider collapsing the consumer representative program into the patient representative program, at least for drug advisory committees. In so doing, the FDA could simultaneously work towards addressing the issue of tokenism and our concern that, for drug advisory committees, patients and consumers may not be meaningfully different.

We would recommend that the agency reconsider both the appropriateness of dual role individuals for these positions and the general policy to limit representation to a single individual in each category. The FDA should further consider adopting an evidence-based approach to assessing

patient and consumer inclusion programs. The FDA already has a vibrant drug advisory committee program which could support a more experimental approach. That is, the FDA might explore systematically varying selection criteria and representative numbers across advisory committee meetings and assessment outcomes in terms of relative increases in patient voice and collocate patterns. Implementing the results of such assessments could lead to the development of robust representation programs that ensure that the patient voice is adequately represented in deliberation and decision-making about pharmaceutical policy.

Ramifications for Rhetorical Inquir

Perspectivalism is endemic to rhetorical inquiry broadly and the RHM project, specifically. It is a central facet of both epistemic and democratic initiatives in the discipline. Crick (2012) describes our disciplinary democratic commitments as a "radical expression of a radical faith" (p. 1), but these commitments might also be understood as foundational disciplinary lore. While certainly faith and lore can be powerful integrative exigencies and useful tools with which to shape disciplinary inquiry, the postcritical project must question the extent to which faith and lore can or should serve as principal foundations of our normative recommendations. In keeping with the postcritical tradition, this article argues that interventional efforts in RHM must be grounded in a solid evidence base that warrants the recommendations we make. This is both a critical ethical commitment and a potentially more effective way to reach audiences of other stakeholders.

Importantly, the data presented in this article significantly challenge the perspectival hypothesis and further illustrate the limitations of that hypothesis for patient inclusion efforts. Ultimately, perspectival theories of patient representation assume that, as the FDA puts it, patients have a "unique" patient perspective and consumers have a specific "consumer point of view" (FDA Activities, 2014). Insofar as these are assumed to be structural features of identity, the FDA can assume that ensuring a diverse range of identities represented in drug advisory meetings will necessarily result in a content diversity. However, as our findings demonstrate, this is clearly not the case. The logic of perspectivalism frees the FDA from the obligation to address the inherent advisory committee structures and directives that prevent broader representations of sites of practice, experience, and concerns in deliberative spaces like drug advisory meetings.

The assumption that simply bringing patient or consumer representatives to the table satisfies calls for inclusion is not only problematic for its reliance on perspectival theories of participation; it also elides the complexity of individual participants who may belong to more than one stakeholder community. While these are significant problems both for theoretical understandings of patient participation and practical initiatives like the patient and consumer representative programs, they do not obviate the need to ensure that key stakeholders are meaningfully incorporated into the decision-making process. Therefore, in the light of the problems of perspectivalism presented in this article, we argue that it is incumbent upon RHM scholars to actively develop non-perspectival approaches to patient inclusion efforts, approaches that do not tacitly endorse the disease/illness dichotomy, problematic collocations of identity and perspective, and ineffective FDA inclusion efforts.

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References

Abelson, Julia, Giacomini, Mita, Lehoux, Pascale, & Gauvin, Francois-Pierre. (2007). Bringing 'the public' into health technology assessment and coverage policy decisions: From principles to practice. *Health Policy*, *82*, 37–50.

Arduser, Lora. (2017). *Living chronic: Agency and expertise in the rhetoric of diabetes*. Columbus: Ohio State University Press.

Barham, Leela. (2011). Public and patient involvement at the UK National Institute for Health and Clinical Excellence. *The Patient: Patient-Centered Outcomes Research*, *4*, 1–10.

Bastian, Hilda. (1998). Speaking up for ourselves: the evolution of consumer advocacy in health care. *International Journal of Technology Assessment in Health Care*, *14*, 3–23.

Brunton, Margaret, Jordan, Claire, & Fouche, Christa. (2008). Managing public health care policy: Who's being forgotten? *Health Policy*, *88*, 348–358.

Burton, Bob. (2005). Drug companies told that sponsoring patients' groups might help win approval for their products. *BMJ*, *331*(7529), 1359.

Callon, Michel, Lascoumes, Pierre, & Barthe, Yannick. (2009). *Acting in an uncertain world*. Cambridge, MA: MIT Press.

Card, Daniel J., Kessler, Molly M., & Graham, S. Scott. (2018). Representing without representation: A feminist new materialist exploration of federal pharmaceuticals policy. In Amanda K. Booher & Julie Jung (Eds.), *Feminist rhetorical science studies: Human bodies, posthumanist worlds* (pp. 183–204). Carbondale: Southern Illinois University Press.

Condit, Celeste. (1999). *The meanings of the gene: Public debates about human heredity*. Madison: University of Wisconsin Press.

Coplan, Paul M., Noel, R. A., Levitan, B. S., Ferguson, J., & Mussen, F. (2011). Development of a framework for enhancing the transparency, reproducibility and communication of the benefit–risk balance of medicines. *Clinical Pharmacology & Therapeutics*, *89*, 312–315.

Crick, Nathan. (2012). *Democracy and rhetoric: John Dewey on the arts of becoming*. Columbia: University of South Carolina Press.

Druschke, Caroline Gottschalk. (2017). The radical insufficiency and wily possibilities of RSTEM. *Poroi*, *12*(2), article 6. https://doi.org/10.13008/2151-2957.1257

Earp, Joanne A. L., French, Elizabeth A., & Gilkey, Melissa B. (2008). *Patient advocacy for health care quality: Strategies for achieving patient-centered care*. Sudbury, MA: Jones and Bartlett Publishers.

Epstein, Steven. (1996). *Impure science: AIDS, activism, and the politics of knowledge*. Berkeley: University of California Press.

Food and Drug Administration Activities for Patient Participation in Medical Product Discussions; Establishment of a Public Docket. 79 Fed. Reg. § 65410 (2014, November 4). Retrieved from https://www.federalregister.gov/documents/2014/11/04/2014-26145/food-and-drug-administration-activities-for-patient-participation-in-medical-product-discussions?utm_content=next&utm_medium=PrevNext&utm_source=Article

Gouge, Catherine C. (2018). "No single path": Desire lines and divergent pathologies in health and medicine. In Lisa Meloncon & J. Blake Scott (Eds.), *Methodologies for the rhetoric of health and medicine* (pp. 115–137). New York: Routledge.

Graham, S. Scott. (2015). *The politics of pain medicine: A rhetorical-ontological inquiry*. Chicago: University of Chicago Press.

Graham, S. Scott. (2017). Data and lore in technical communication research. *Communication Design Quarterly*, *5*(1), 8–25.

Graham, S. Scott, & Herndl, Carl. (2013). Multiple ontologies in pain management: Toward a postplural rhetoric of science. *Technical Communication Quarterly*, *22*(2), 103–125.

Graham, S. Scott, Kim, Sang-Yeon, DeVasto, Danielle M., & Keith, William. (2015). Statistical genre analysis: Toward big data methodologies in technical communication. *Technical Communication Quarterly*, *24*, 70–104.

Hsieh, Hsiu-Fang, & Shannon, Sarah. E. (2005). Three approaches to qualitative content analysis. *Qualitative Health Research*, *15*(9), 1277–1288.

Hunink, Myriam M., Weinstein, Milton C., Wittenberg, Eve, Drummond, Michael F., Pliskin, Joseph S., Wong, J. B., & Glasziou, Paul P. (2014). *Decision making in health and medicine: integrating evidence and values*. Cambridge, UK: Cambridge University Press.

Internet Archive Wayback Machine. (2014, March 1). Retrieved from https://archive.org/web/

Keränen, Lisa. (2014). Public engagements with health and medicine. *Journal of Medical Humanities*, *25*(2), 103–109.

Kim, Sang-Yeon. (2017). Intercoder reliability techniques: Cohen's kappa. In Mike Allen (Ed.), *The SAGE encyclopedia of communication research methods*, (pp. 736–738). Thousand Oaks, CA: SAGE.

Kimball, Miles A. (2013). Visual design principles: an empirical study of design lore. *Journal of Technical Writing and Communication*, *43*(1), 3–41.

Koerber, Amy. (2009). Rhetorical agency, resistance, and the disciplinary rhetorics of breastfeeding. *Technical Communication Quarterly*, *15*(1), 87–101.

Lewis, C. (2000). Advisory committees: FDA's primary stakeholders have a say. *FDA Consumer Magazine, 34*(5), 30–34.

Macpherson, Cheryl Cox. (2004). To strengthen consensus, consult the stakeholders. *Bioethics*, *18*, 283–292.

Macpherson, Cheryl Cox. (2006). Healthcare development requires stakeholder consultation: palliative care in the Caribbean. *Cambridge Quarterly of Healthcare Ethics*, *15*, 248–255.

Majdik, Zoltan P., & Keith, William M. (2011). Expertise as argument: Authority, democracy, and problem-solving. *Argumentation*, *25*(3), 371.

Meloncon, Lisa. (2018). Bringing the body back through performative phenomenology. In Lisa Meloncon & J. Blake Scott (Eds.), *Methodologies for the rhetoric of health and medicine* (pp. 96–114). New York: Routledge.

Milewa, Timothy. (2008). Representation and legitimacy in health policy formulation at a national level: Perspectives from a study of health technology eligibility procedures in the United Kingdom. *Health Policy*, *85*, 356–362.

Mol, Annemarie. (2002). *The body multiple: Ontology in medical practice*. Durham, NC: Duke University Press.

Page, Scott E. (2007). *The difference: How the power of diversity creates better groups, firms, schools, and societies*. Princeton, NJ: Princeton University Press.

Paroske, Marcus. (2012). Overcoming burdens of proof in science regulation: Ephedra and the FDA. *Rhetoric and Public Affairs*, *15*(3), 467–497.

Poulakos, Takis. (1997). *Speaking for the polis: Isocrates' rhetorical education*. Columbia: University of South Carolina Press.

Rettig, Richard A., Earley, Laurence E., & Merrill, Richard A. (1992). *Food and Drug Administration Advisory Committees.* Committee to study the use of advisory committees by the FDA. Division of Health Care Policy. Institute of Medicine.

Segal, Judy Z. (2005). *Health and the rhetoric of medicine*. Carbondale: Southern Illinois University Press.

Segal, Judy Z. (2015). The rhetoric of female sexual dysfunction: faux feminism and the FDA. *Canadian Medical Association Journal*, *187*(12), 915–916.

Sims, Julius & Wright, Chris C. (2005). The kappa statistic in reliability studies: Use, interpretation, and sample size requirements. *Physical Therapy*, *85*, 257–268.

Teston, Christa. (2017). *Bodies in flux: Scientific methods for negotiating medical uncertainty.* Chicago: University of Chicago Press.

Teston, Christa B. & Graham, S. Scott. (2012). Stasis theory and meaningful public participation in pharmaceutical policy-making. *Present Tense: A Journal of Rhetoric in Society*, *2*(2), 1–7.

Teston, Christa B., Graham, S. Scott, Baldwinson, Raquel, Li, Andria, & Swift, Jessamyn. (2014). Public voices in pharmaceutical deliberations: Negotiating "clinical benefit" in the FDA's Avastin hearing. *Journal of Medical Humanities*, *35*, 149–170.

Tomes, Nancy. (2006). The patient as a policy factor: a historical case study of the consumer/survivor movement in mental health. *Health Affairs*, *25*, 720–729.

Traulsen, Janine M., & Almarsdóttir, Anna Birna. (2005). Pharmaceutical policy and the lay public. *Pharmacy World and Science*, *27*, 273–277.

U.S. Food and Drug Administration (2014, January 12). Advisory committee consumer representatives. Retrieved from http://www.fda.gov/AdivsoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/default.htm

U.S. Food and Drug Administration. (Updated 2014, September 23). FDA advisory committees: Drugs. Retrieved from http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/default.htm

U.S. Food and Drug Administration. (2014, September 18). About the patient representative. Retrieved from http://www.fda.gov/ForPatients/About/ucm412709.htm

Wilkinson, Emma. (2008). Patient organisations aim for greater collaboration. *Molecular Oncology*, *2*, 200–202.

Wilmot, Stephen. (2011). Evidence, ethics and inclusion: a broader base for NICE. *Medicine, Health Care and Philosophy*, *14*, 111–21.

Wynne, Brian. (1992). Misunderstood misunderstanding: Social identities and public uptake of science. *Public Understanding of Science*, *1*(3), 281–304.