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Conflicted scientists: the "shared pool" dilemma of scientific advisory committees

Katherine A. McComas, Leah Simone Tuite and Linda Ann Sherman

Science advisors play a critical role in government policy making, yet these advisors are often equally attractive to regulated industry. Despite efforts to manage conflicts of interest among science advisors, allegations of conflict frequently plague advisory committee deliberations or outcomes. This article examines what we term the "shared pool" dilemma using data collected from 92 members of 11 US Food and Drug Administration advisory committees. The results suggested science advisors were generally positive about their experiences on advisory committees and viewed the committee process as impartial. Written comments suggested that advisors linked the neutrality of the process to the success of the FDA's conflict-of-interest procedures. Even so, the advisors acknowledged the challenges associated with recruiting disinterested *and* qualified scientists to serve on advisory committees, reflecting the shared pool dilemma. Many advisors seemed more troubled about advisors participating when they lacked expertise than when they had minor conflicts of interest.

1. Introduction

Scientific advisory committees are an integral part of regulatory decision making, providing a low-cost supplement to government expertise and non-partisan review in an area ripe for special interest lobbying (Hilgartner, 2001; Jasanoff, 1990). In 2003, over 200 US federal expert advisory committees provided scientific and technical guidance for 18 federal agencies, including the Department of Health and Human Services, National Science Foundation, National Aeronautics and Space Administration, Department of the Interior, Department of Defense, and Department of Homeland Security, and operation costs exceeded $287 million (US General Services Administration, 2003a). In an era of government budget downsizing, scientific advisory committees will likely become even more vital to government agencies unable to staff regular positions for such evaluations.[1]

Two requisite elements of scientific advisory committees are member expertise and neutrality. In a poll of 975 advisory committees, which included both expert and non-expert committees, government officials charged with committee oversight stated that their committees' most significant program outcomes were advancing scientific research and building trust in government (US General Services Administration, 2003b). To accomplish

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these objectives, science policy advisors must be experts in their respective fields to ensure the quality of their advice. The perceived credibility, legitimacy, and fairness of the advisory committee process equally rest, however, on the perceived neutrality of committee membership. In addition to achieving balance in membership, this neutrality entails committee members being free from real or potential conflicts of interest. In other words, members should not have financial, professional, or personal stakes in the outcome that could influence them to act in a biased manner during committee deliberations or voting.

At first glance, satisfying this precondition may not appear so difficult; however, a closer look reveals the crux of a dilemma—namely, that the qualities that make science advisors attractive to government agencies also often make them equally appealing to regulated industry (US Food and Drug Administration, 2002). Frequently, regulated industry courts the very scientists most qualified to serve on advisory committees to work as consultants or members of speakers' bureaus. Alternatively, scientists having the greatest experience with the products that come before committees for review, such as product manufacturers or users, are disqualified from participating owing to a potential to benefit from the failure or success of the product or policy decision. This explains, for instance, why individuals who own blood banks do not generally participate on the US Food and Drug Administration's (FDA) blood products advisory committee or why plastic surgeons are sometimes controversial members of medical device panels (see, e.g., Rowland, 2003): either situation poses a real or potential financial conflict of interest that requires screening. A third scenario entails qualified scientists working for institutions (e.g., universities or research centers) receiving industry funding or grants, which also raises a potential financial conflict of interest. Although the federal government still provides the lion's share of research dollars to universities, industry-supported research has been steadily increasing in academic settings in recent years (National Science Board, 2002). Any of the above scenarios can give rise to real or potential conflicts of interest among scientists and result in what we term the "shared pool" dilemma of scientific advisory committees.

This article examines the shared pool dilemma of scientific advisory committees. It begins by analyzing more closely the assumptions underlying the dilemma, particularly those related to expertise and conflict of interest. It then offers interview data collected from FDA advisory committee members who answered a series of questions related to their experiences with conflicts of interest and advisory committee procedures. Although not the only science advisors who undergo conflict-of-interest review, FDA experts are arguably in a unique position to comment on conflict-of-interest procedures. First, the FDA has relied on advisory committees to assist with its regulatory decision making for several decades and employs one of the federal government's most extensive conflict-of-interest review processes for its advisory committee members. Despite the FDA's efforts to reduce even the appearance of conflicts of interest among advisory committee members (US FDA, 2002), there are several recent examples when committee impartiality has been questioned (Cauchon, 2000; Rowland, 2003; Willman, 1999). Constant reminders in headlines, as well as lengthy conflict-of-interest review procedures to which each member must submit, arguably increase the salience and relevance of conflict-of-interest issues to FDA advisory committee experts. By incorporating science advisors' views into an examination of the shared pool dilemma, our intent is to understand more fully the challenges and constraints associated with the science advisory process. Because the perception and management of the shared pool dilemma influence who serves on science advisory committees, this article may provide additional insight into how the credibility and legitimacy of the science advisory process is actively constructed and maintained.

2. Shared pool dilemma

The concept of a limited number of scientific or technical experts that are equally attractive to government agencies and the industries these agencies regulate, i.e., the shared pool dilemma, rests on at least two assumptions: (a) that a finite number of qualified experts exists for any given topic, and (b) that the mere presence of a real or potential conflict of interest may result in a member acting in a biased manner. There are arguments for and against the validity of these assumptions, which we examine in turn.

Meaning of expertise

In simplest terms, the assumption of a finite number of experts necessitates a closed system, where no new experts emerge or where current experts have somehow "cornered the market" on the production or possession of new knowledge. In contrast, one could argue that universities train new students and grant thousands of advanced degrees annually. One could also point out that technological innovations frequently revolutionize scientific methods of data collection and analysis, making former methods obsolete or simply out of date and opening the door for new experts to emerge. In defense of these assumptions, however, the claim may well be valid that at any given moment, a finite number of experts having the requisite knowledge, experience, and training to participate effectively on an advisory committee exists. Furthermore, with regard to expertise, one could argue that most scientists only achieve "expert" status after long, established careers, which can include tenure at a respected university, an impressive publication record, a successful track record of obtaining extramural funding, and other public service or private consulting activities. Finally, it could be unwise to discount the institutional memory or time-tested experience of scientists who have been working in their respective disciplines for many years, which is arguably vital to the development of expert pools.

Certainly, the meaning of expertise is itself a contested terrain. Much of the debate surrounding expert qualifications appears in legal scholarship, which examines the use and social construction of expertise in courtroom settings (Jasanoff, 1995; Risinger, 2000; Smith and Wynne, 1989). Other discussions of expertise revolve around public involvement in risk-based decision making (e.g., Krimsky and Plough, 1988; Renn et al., 1995; Sclove, 1995). Much of this literature examines expert/non-expert dichotomies or interactions (i.e., scientists talking with non-scientists or lay audiences), as well as the dominance of "expert systems" over non-expert or local sources of knowledge in risk management and policy making (e.g., Fischer, 2002; Wynne, 1992). Some of the most detailed research on the science advisory process examined the techniques by which the National Academy of Sciences actively worked to manage the perceived credibility and expertise of two of its expert advisory committees whose neutrality and competency came under public scrutiny (Hilgartner, 2001). This research also suggested that the meaning of expertise for science policy advisors is frequently ambiguous and left largely to the discretion of committee administrators to define.

The Federal Advisory Committee Act itself sets no standard for expertise, stating that the appointment of science advisors and consultants remains at the "sole discretion" of the appointing agency (Federal Advisory Committee Management, 2001). A brief review of how a sample of federal agencies select their advisory committee members provides some insight into how they exercise their discretion. To constitute its Science Advisory Board, for example, the US Environmental Protection Agency (EPA) recruits individuals that are "recognized, non-governmental experts in their respective fields" (EPA, 2004: 1). In

addition to scientific experts, the EPA also includes members from industry and environmental groups. The Performance Measurement Advisory Council of the Office of Management and Budget (OMB) recruits members that are both "outstanding" and "objective." Balance and expertise are key, and the OMB gives weight to "viewpoint diversity, expertise in performance measurement, and professional qualifications" (Daniels, 2002: 37,462). The US Department of Defense (DOD) similarly emphasizes balance among member viewpoints and requires that members have "demonstrated professional or personal qualifications relevant to the committee's work" (DOD, 2003: 3). Finally, the FDA obliges its voting members to have:

> expertise in the subject matter with which the committee is concerned and have diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise to handle the problems that come before it. . . . (Food and Drugs, 2003: 18)

In addition to scientific experts, FDA advisory committees include patient, consumer, and industry representatives, although industry representatives are non-voting members.

This cursory review suggests that federal agencies seek balance, expertise, and training when populating their advisory committees; however, there appears to be no set standard for expertise. As a result, agencies arguably enjoy some latitude when recruiting their experts, which could serve to ease rather than exacerbate the shared pool dilemma.

Explicating conflict of interest

Another assumption underlying the shared pool dilemma is that members having a conflict of interest are prone to act in accordance with that conflict. Arguably, the reality is much less certain since many factors will likely come into play. To examine this assumption further, some background on the meaning of conflict of interest proves helpful.

Generally speaking, a conflict of interest entails having not only a "stake" or "vested interest" in the outcome but also the power to influence it. A standard scenario involves a situation where an individual or institution has decision-making authority and

> (1) P [the individual or institution] is in a relationship with another requiring P to exercise judgment in the other's behalf and (2) P has a (special) interest tending to interfere with the proper exercise of judgment in that relationship. (Davis, 2001: 8)

Key aspects of this definition requiring further elaboration are relationships, interests, and the proper exercise of judgment. According to Davis (2001), *relationships* can be personal, professional, or financial, but they must involve a connection between "P" and another party that explains that party's reliance on "P." *Interests* refer to "any influence, loyalty, concern, emotion, or other feature of a situation tending to make P's judgment (in that situation) less reliable than it would normally be" (2001: 9). Finally, what constitutes as the *proper exercise of judgment* varies among accepted social, cultural or legal norms and is likely to change if rules or norms are revised. For example, a scientist who accepts corporation funds in return for speaking engagements would have a relationship with that corporation. If that scientist were asked to serve on a government advisory committee charged with evaluating, i.e., judging, that corporation's product pending government approval, the scientist would be in a state of conflict. In other words, the scientist's financial or professional interest in that corporation's endeavors could influence him or her to exercise improper judgment or act in a biased manner.

Davis (2001) offered three scenarios to illustrate objectionable aspects of conflict of

interest. In the first case, individuals or parties having a conflict are either unaware of the conflict or ignoring it. Although the latter of these two is less principled and arguably more unethical, in neither case do the individuals or parties take adequate measures to reduce the real or potential conflict. In case two, the conflicted individuals or parties intentionally conceal the conflict, thus behaving immorally according to certain norms of conduct that value disclosure. And in the third scenario, the conflicted individuals or parties acknowledge the conflict but do not remove themselves from the decision-making position. This creates a technical if not moral problem. As Davis argued, "Even as a technical problem, conflict of interest can harm the reputation of the profession, occupation, avocation, or individual in question" (2001: 12).

Conflict of interest and bias have different meanings although people frequently use the terms interchangeably. Davis (2001) clarified that whereas bias suggests the existence of prejudice, conflict of interest refers to the *tendency* toward prejudice. In this sense, having a conflict of interest is similar to someone's having inherited a gene that makes him or her more susceptible to a condition, with no guarantee, however, that the condition will manifest itself. Likewise, the mere presence of a conflict of interest does not mean that an individual or party has acted or will act inappropriately or misuse their authority, but it does indicate that the conditions exist for bias to occur. Or, to continue with an earlier science example, although the scientist who accepts speakers' fees from a particular corporation has a conflict of interest when advising the federal government about the merit of that corporation's research, there is no guarantee that he or she will act inappropriately, e.g., to judge that corporation's work more favorably than extant research warrants.

Even so, the mere presence or specter of conflict of interest can be unsettling. Similar to the presence of the repressed gene, the unpredictable nature of conflict of interest can generate greater uncertainty in the decision-making process and ensuing outcomes, and this unease has resulted in extensive efforts to identify, monitor, and manage real or potential conflicts of interest before any malfeasance can occur. Accordingly, efforts to minimize even the trace of conflict of interest among science advisors can reinforce or even increase public confidence in the neutrality of the process. Consequently, even if government agencies believe that science advisors would refrain from acting in their own interests, the need to avoid the mere perception of conflict likely results in more conservative procedures, which, in turn, could aggravate the shared pool dilemma.

Conflict-of-interest legislation

Efforts to reduce real or potential conflicts of interest in the US federal government date back several decades; conflict-of-interest legislation has been a part of the criminal code since the 1940s. Specifically, Section 208 of Title 18, Acts Affecting a Personal Financial Interest (1948), made it a criminal act for government employees to engage personally or officially in any activity having a direct effect on the employee's financial interest. Because science advisors who participate on advisory committees are typically given "special government employee" or SGE status, the criminal code placed a substantial hardship on government agencies trying to recruit advisors. The Ethics Reform Act of 1989 eased the hardship by including a section related to SGEs. This new section made it legal for individuals as SGEs to participate on advisory committees insofar as their expertise was judged to outweigh the potential financial benefit they could accrue from participation (Ethics Reform Act, 1989). In short, this law adjudicated that not all conflicts of interest were created equally, particularly when weighed against the benefits of participation.

In 1996, the Office of Government Ethics provided further guidance for managing conflicts of interest. Under 18 USC 208(b)(1), federal agencies could issue waivers for SGEs to participate provided that the disqualifying financial interest not be substantial enough to affect the integrity of the SGE's services to the government. Agencies would base judgments according to the dollar value of the financial interest, its value in relation to the individual's overall assets, the extent to which the individual must exercise discretion, and the need for the individual's services in the matter. Exemptions under 18 USC 208(b)(2) related to the relationship of the SGE to the product and the nature and value of the disqualifying financial interest. Finally, 18 USC 208(b)(3) gave agencies permission to authorize SGEs to participate in advisory committees convened under the Federal Advisory Committee Act, which included additional membership requirements. Under this section, agencies would base decisions to grant waivers on the type of interest that disqualifies participation, the identity of the individual whose interests are at issue, the uniqueness of that individual, and the difficulty of finding an alternative individual of similar expertise who does not have a potentially disqualifying conflict of interest. As with the other clauses, the agency responsible for appointing the individual had to certify that the need for the individual's services, i.e., the individual's expertise, outweighed the potential conflict of interest.

More recently, the 1997 Food and Drug Modernization Act contained additional requirements pertaining to FDA advisory committees reviewing clinical investigations or marketing for drugs or biologics (Food and Drug Modernization Act, 1997). Specifically, Section 120 stated that the FDA could not grant a waiver allowing a committee member to review his or her own work.

This review suggests that early conflict-of-interest legislation arguably intensified the shared pool dilemma by adding restrictions on the potential supply of science advisors. Subsequent legislation aimed to decrease the burden on government agencies to locate and recruit science advisors for their advisory committees, yet the importance of maintaining credibility in the public's eye has resulted in extensive procedures and management efforts. Today, the conflict-of-interest procedures the FDA uses, for example, involve multiple levels of review and as many as 11 steps, which include the preparation of financial disclosure, responses to a questionnaire, preparation of waiver, review by the FDA's ethics staff, and final approval by the appointing official (US FDA, 2002). In addition to screening for financial conflicts of interest, the FDA recognizes intellectual conflicts of interest, although these are more difficult to define. In addition to minimizing the potential for bias, these screening procedures arguably help to reassure the public, who cannot see "behind the scenes," that the bureaucracy is determinedly working to maximize committee expertise while protecting the neutrality of committee membership (Hilgarter, 2001).

3. Hypotheses and research question

To examine the shared pool dilemma in greater depth, we launched a collaborative research effort to examine the extent to which FDA science advisors viewed the conflict-of-interest procedures as fair and impartial. As a corollary, we were interested in determining how these perceptions influenced committee members' satisfaction with the advisory committee process. To frame our inquiry, we drew on the theory of procedural justice, which argues that individuals care about the fairness or justice of procedures to which they are subjected (Thibaut and Walker, 1975; Tyler and Folger, 1980; Tyler, 1994; Tyler et al., 1996). Moreover, research has found that the degree to which individuals view procedures as just

influences the degree to which they are satisfied with the process and the people in charge of the procedures, sometimes even when the outcomes are not in their favor (Colquitt, 2001; Lauber and Knuth, 1999; Phillips, 2002; Thibaut and Walker, 1975; Tyler and Folger, 1980). Finally, research has found that when individuals consider the procedures as just, they are also more willing to accept the outcomes or decisions (Arvai, 2003; Tyler, 1994).

On the basis of procedural justice research, we therefore expected that when science advisors perceived the conflict-of-interest procedures as more fair and impartial, they would also be more satisfied with their participation. To allow for the possibility that science advisors could evaluate fairness differently depending on whom one was being fair to, we distinguished between "fairness to the advisor" and "fairness to the public." In sum, we proposed that:

- H1a: Perceived fairness of the conflict-of-interest procedures to the public will positively influence members' satisfaction with participation.
- H1b: Perceived fairness of the conflict-of-interest procedures to committee members will positively influence members' satisfaction with participation.
- H2: Perceived committee impartiality will positively influence members' satisfaction with participation.

In addition to examining the perceived fairness or impartiality of the conflict-of-interest process, we were also interested in the extent to which committee members' views about the conflict-of-interest procedures influenced their satisfaction with advisory committee participation. To frame our study, we drew on group communication research suggesting that satisfaction is influenced by the perceived quality of group members' contributions (Gouran, 1973), as well as the extent of participation in the decision (Cooper and Wood, 1974). In particular, Cooper and Wood (1974) found that group member satisfaction increased when members participated throughout the decision-making process. Research has also shown that the degree to which group members believe that their participation impacts decisions influences their satisfaction (Folger et al., 1979). Folger et al. (1979) also documented a "frustration effect" when individuals who saw their participation as limited were more frustrated overall than individuals not given the opportunity to participate at all. From this research, we posed the following hypotheses:

- H3: When members believe their participation had a greater impact on outcomes, they will be more satisfied with their participation.
- H4: When members believe their participation was more useful, they will be more satisfied with their participation.

We also posed a research question that focused more directly on the shared pool dilemma—namely, how do science advisors perceive and understand the challenges associated with managing real or potential conflicts of interest among advisory committee members?

4. Methods

In cooperation with the FDA's commissioner's office, we collected survey data from FDA advisory committee members at 11 meetings that took place in the Washington DC metropolitan area between February and July 2003. These meetings were selected to represent the four largest centers at the FDA: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Center for Devices

and Radiological Health (CDRH), and the Center for Food Safety and Applied Nutrition (CFSAN). During the data collection period, some of the centers held more meetings than others, so the sample includes a larger proportion of respondents from CDER and CDRH advisory committees. In general, however, CDER and CDRH have more advisory panels than the other centers have.

At each of the meetings, the advisory committee's executive secretary permitted us to distribute envelopes at each advisory committee member's seat. Advisors included voting members, as well as non-voting industry representatives. Each envelope contained a letter describing the research and soliciting participation, the questionnaire, and a business reply envelope. At each meeting, the study's first author was permitted to make a statement at the beginning of the meeting to introduce the study and request participation. In several cases, we made direct contact with committee members to further encourage their participation. Members were encouraged to complete questionnaires before leaving the meeting and drop them in the box marked "FDA Survey" at the meeting registration table; however, they were also told they could return the questionnaire at a later time in the business reply envelope. To encourage openness, responses were anonymous.

The first seven questions used seven-point Likert-type scales followed by space for open-ended comments. The questions were: (1) In general, how impartial do you think the FDA advisory committee meeting process is? (2) How fair to committee members do you think that the FDA's procedures are for managing real or potential conflicts of interest of its advisory committee members? (3) How fair to the public do you think that the FDA's procedures are for managing real or potential conflicts of interest of its advisory committee members? and (4) To what extent do you believe that outside expertise and recommendations offered by advisory committees have an impact on FDA policy making? Questions 5 to 7 asked variations of the following — Overall, how would you characterize your participation in FDA advisory committee meetings: (5) not at all satisfying to very satisfying; (6) not worth my time to very much worth my time; and (7) not useful to the FDA to very useful to the FDA. Members were then asked the number of committees they have participated in as a member, as well as whether they had ever been recused from committee service because of a financial conflict of interest (1 = yes, 2 = no).

As noted above, we provided a space for additional comments under each question, where we encouraged respondents to expand on their answers.

5. Results

Ninety-two out of 139 committee members participating in the 11 meetings returned completed questionnaires. To estimate response rates, we counted the number of advisory committee members present at each meeting. Table 1 lists the meetings we attended, as well as the estimated response rates per meeting. Response rates ranged from a high of 100 percent to a low of 43 percent; the average response rate was 68 percent. In addition to providing numerical data, 50 of these committee members (54 percent) offered a total of 127 written comments. To present the results, we first examine the numerical data and hypotheses before turning to the members' written comments.

Quantitative responses

Table 2 provides the means and standard deviations to the questions, as well as the correlations among questions. On average, respondents reported participating in about eight

Table 1. Meetings and estimated response rates

Meeting	Date(s) (2003)	Members	Responses	Response rates
Oncologic Drugs (CDER)	12 to 13 March	16	11	69%
Blood Products (CBER)	13 to 14 March	12	11	92%
Dietary Supplements (CFSAN)	25 March	8	4	50%
Circulatory System Devices (CDRH)	10 April	12	7	58%
National Mammography Quality Assurance (CDRH)	28 April	13	8	62%
Antiviral Drugs (CDER)	13 to 14 May	17	9	53%
Dental Products (CDRH)	22 May	8	8	100%
Cardio-Rental Drugs (CDER)	29 to 30 May	14	8	57%
Nonprescription Drugs (CDER)	12 June	10	8	80%
Endocrinologic and Metabolic Drugs (CDER)	9 July	14	6	43%
Transmissible Spongiform Encephalopathy (CBER)	17 to 18 July	15	12	80%
Overall response rate for data collection		139	92	66%
Average response rate for 11 meetings				68%

advisory committee meetings; 20 percent reported participating in more than 10 meetings. Most respondents had never been recused from serving on a committee because of a conflict of interest; however, as the number of meetings they participated in increased, so did the likelihood of their being recused at least once.

The numerical data suggested that advisory committee members were very positive about their experiences as FDA experts. On scales with scores ranging from 1 to 7, with higher scores corresponding to more positive assessments, the lowest mean was 5.4 in response to the question about impact on FDA policy making; the second lowest was 5.8 in response to the question about the committee's usefulness to the FDA.

Table 2. Means, standard deviations, and correlations among variables

Variable	M	SD	1	2	3	4	5	6	7	8
1. Impartiality of meeting process	6.1	1.0	—							
2. Fairness of conflict-of-interest procedures to committee members	6.0	1.2	.38* (90)	—						
3. Fairness of conflict-of-interest procedures to public	6.1	1.2	.63* (89)	.63* (90)	—					
4. Advisory committees impact FDA policy making	5.4	1.2	.20 (89)	.08 (89)	.03 (88)	—				
5. Committee participation is satisfying to member	6.1	1.0	.29* (89)	.10 (89)	.15 (88)	.44* (88)	—			
6. Committee participation is worth member's time	6.1	1.0	.29* (88)	.16 (88)	.13 (87)	.35* (87)	.76* (89)	—		
7. Committee participation is useful to FDA	5.8	1.0	.27* (88)	–.04 (88)	.12 (87)	.42* (87)	.55* (88)	.61* (88)	—	
8. Number of meetings participated in as member	7.8[a]	8.0	.00 (91)	–.27* (91)	–.11 (90)	.23* (90)	.31* (90)	.23* (89)	.29* (89)	—
9. FDA has recused member from service at least once due to conflict of interest	1.9	.36	–.00 (91)	.19 (91)	.14 (90)	.00 (90)	–.12 (90)	–.06 (89)	.05 (89)	–.23* (92)

Note: For variables 1 to 7, scale values range from 1 to 7 with higher means indicating more positive responses. For variable 9, 1 = yes, 2 = no. Pairwise deletion of missing values; number of cases used in analysis shown in parentheses.

[a] The mode was 1; the median was 6.

* $p < 0.05$.

Several correlations were significant at $p < 0.05$. Namely, perceived impartiality of the process was positively correlated with the perceived fairness of the conflict-of-interest procedures to committee members and to the public ($r = 0.38$ and $r = 0.63$, respectively). In addition, members who perceived the process as impartial also were more satisfied with their participation ($r = 0.29$), considered it more worth their time ($r = 0.29$), and believed their participation more useful to the FDA ($r = 0.27$). Believing the conflict-of-interest procedures fair to the public was strongly correlated with believing the procedures fair to committee members ($r = 0.63$). Members who believed their participation impacted FDA policy making and was worth their time were also more satisfied with their experiences ($r = 0.44$ and $r = 0.76$, respectively). Members who believed their participation was useful to the FDA were also more likely to believe their participation impacted FDA policy making ($r = 0.42$), were more satisfied ($r = 0.55$), and more likely to believe their participation was worth their time ($r = 0.61$). Finally, members who had participated in more meetings were more likely to believe their participation impacted FDA policy making ($r = 0.23$), be satisfied with their participation ($r = 0.31$), and consider their efforts worthwhile and useful to the FDA ($r = 0.23$ and $r = 0.29$, respectively); however, they were *less likely* to consider the conflict-of-interest procedures as fair to committee members ($r = -0.27$).

To assess the importance of each independent variable on satisfaction, we performed a standard regression analysis (Tabachnick and Fidell, 1996). In addition to examining the relative influence of perceived meeting neutrality, committee impact, procedural fairness to public, procedural fairness to committee member, and meeting usefulness, we also included the number of meetings a member had participated in and whether the member was ever recused from service for control purposes. Owing to the high correlation between members' satisfaction with participation and believing their participation worthwhile (both variables also shared the same mean and standard deviation), we excluded the latter variable from the equation. All variables were entered simultaneously with pairwise replacement of missing values. The regression equation produced a multiple correlation coefficient of $R = 0.66$ ($R^2 = 0.43$, adjusted $R^2 = 0.38$), $SEE = 0.75$, $F(7, 82) = 8.19$, $p < 0.001$. The variables having a significant impact on committee members' satisfaction with their participation were committee impact ($ß = 0.24$, $p < 0.05$) and meeting usefulness ($ß = 0.39$, $p < 0.001$). Collinearity diagnostics showed no multicollinearity among variables. Table 3 presents the results of the analysis.

To review, the first three hypotheses related to procedural justice and member satisfaction with committee participation. Hypothesis 1a predicted that perceptions of fairness of the conflict-of-interest procedures to the public would positively influence satisfaction with participation, Hypothesis 1b predicted that perceptions of fairness of the conflict-of-interest procedures to the committee member would positively influence satisfaction with participation, and Hypothesis 2 predicted that perceived committee impartiality would positively influence satisfaction with participation. The results did not show significant correlations among perceptions of fairness to the member or public and member satisfaction. Thus, hypotheses 1a and 1b were not supported. In comparison, committee impartiality was significantly correlated with satisfaction; however, it did not remain significant after controlling for the influence of other variables in the regression analysis, suggesting only partial support for Hypothesis 2. Hypothesis 3 predicted that perceiving a greater impact from participation would positively influence satisfaction, and the results from the correlations and regression analysis supported this hypothesis. Finally, Hypothesis 4 predicted that when members viewed their participation as more useful to the FDA, they would also be more satisfied with their participation. Both the results from the correlation and regression analysis supported this hypothesis.

Table 3. Regression analysis for variables predicting satisfaction with advisory committee participation ($n = 82$)

Variables	*B*	SE B	*Beta*
Meeting neutrality	.11	.11	.12
Conflict-of-interest procedural fairness to members	.13	.10	.16
Conflict-of-interest procedural fairness to public	–.04	.11	–.05
Committee impact on FDA policy	.19	.08	.24*
Committee usefulness to FDA	.38	.10	.39**
Number of meetings	.02	.01	.14
Recusal from meetings	–.31	.23	–.12
Constant	2.16	.79	
Adjusted R^2 = .38			
SEE = .75			
F (7) = 8.19**			

Note: All variables entered simultaneously. Pairwise replacement of missing values.
* $p < 0.05$, ** $p < 0.001$.

Qualitative responses

We concentrated on the written comments to answer the research question, which focused on how committee members perceived and understood the challenges associated with managing real or potential conflicts of interest among advisory committee members. In doing so, we first looked for patterns in the responses (Miles and Huberman, 1994). Some of these patterns related to the questions we asked, but other patterns emerged as well. Our intent was to let the comments "tell a story" in relation to our research question, so we looked for possible connections among responses to reveal underlying themes. Below, these recurring themes are woven together under prose-like headings and supplemented by illustrative quotes chosen to represent frequently expressed viewpoints in the members' own words.

The committee is impartial . . . the written comments suggested that members believe the advisory committee process is as impartial as it can be given certain factors. As one committee member stated, "It's done very well in an atmosphere where potential for bias is great." Some of the challenges mentioned were legal and political influences on the advisory committee process. One committee member cited an example when a panel's recommendations were "overridden by staffers—when 'pressure' was applied." Another committee member offered this summary:

> The regulatory process is obviously social and political, in addition to being intellectual and scientific. The agency is very much aware of this, and works quite hard to balance the process—getting buy-in (from the medical, research, and general community); listening to industry while maintaining a proper distance (they're perhaps less successful on this score), and living with political pressures from inside the beltway.

. . . because the screening process works. A review of the comments suggests that members attributed the perceived impartiality of the advisory committee process to their perceptions that the conflict-of-interest screening process works. Many committee members provided favorable comments on the conflict-of-interest screening process, describing it as

"exhaustive," "fair," and "well managed, thoughtful, [and] intelligent." Some members seemed to indicate that, at times, the screening process is more than what is called for, or "scrupulous to a fault," in the words of one committee member.

The members are well-qualified and objective. With regard to expertise, committee members offered comments regarding the well-roundedness of committee makeup and the objectivity of committee members. One member wrote, "There seems to be a good distribution of experience and representation from a good distribution of stakeholders and experts. I especially appreciate the representation position for industry." Another member mentioned the balanced representation of committee membership, including "clinicians, clinical researchers, adult and pediatric representatives, statisticians, consumer [representatives] and industry [representatives]. In addition, we bring in outside experts to add additional expertise." Another member commented,

> I have been impressed by the expertise of invited consultants brought in to give input on scientific issues. The fact that they can vote reinforces and strengthens their input and position. I think we could use a full time community representative on the committee. Otherwise, I've been very impressed with the process.

Committee members also pointed to the independence and objectivity of the panel. As one member wrote, "The panel, being mainly academics, is composed of those used to examining critically issues, processes, etc.—the main panel function. The screening process is exhaustive enough to 'weed out' those biased individuals" (underlining in original).

Members also mentioned the willingness of committee members to listen to other viewpoints. As one member commented, "The members of the committee mostly do their homework, and are generally quite thoughtful in their comments, pretty open and honest in their opinions and votes. They're usually willing to listen, base their final decisions on the evidence."

The FDA benefits from this objectivity . . . according to their comments, committee members believe that the FDA benefits from the perceived impartiality of its advisory committee process. Members called their work "an important public service," and a "tremendous opportunity for gathering new information." One committee member stated that the "deliberation" and "free exchange" were very important. This member continued, "Many of the subjects discussed are new concepts and need a lot of thought and discussion." Other comments clustered around the "real world" expertise that science advisors offer. One member wrote, "Outside experts provide a practical 'real world' reality check on clinical applicability of policies and add importantly to the fund of scientific expertise." Another concurred, "I believe the discussion is useful to FDA staff and that the committee brings a 'real-world' and diverse perspective not otherwise heard."

. . . as does the wider public. Members' comments also suggested that members believed their activities carried benefits beyond the FDA to the wider public. They used this to justify the stringent conflict-of-interest procedures. For example, one member wrote that committee work was "vitally important for the national health," and therefore required "a standard of rigor and impartiality that serves as an additional safe guard." Another member pointed out the benefit of giving a voice to individuals and groups impacted by the decisions:

> These are important policy discussions and have far reaching impacts on the services being provided. The importance of participation is to influence the decisions and provide a voice . . . for the community for which these decisions have major impacts.

But the screening process can be burdensome . . . several committee members' comments suggested that some members perceived the conflict-of-interest screening process as burdensome or the public disclosure "uncomfortable." As one member wrote, "I resent having to divulge [dollar] amounts received for consulting/speaking." Another member expressed similar sentiments: "Private information must be disclosed to [the] public, but it's uncomfortable." Another commented that the FDA "goes overboard to eliminate <u>any perception</u> of conflict of interest—not only by vetting members in detail before the meeting, but also by reading the results in the record" (underlining in original). Other members commented that the extent of disclosure could dampen enthusiasm to serve on an advisory committee. One committee member stated a concern that:

> making financial disclosures public opens committee members to potential (inappropriate) attack within their own institutions by envious professional colleagues. This is a political problem that may cause some potentially excellent candidates to avoid service on the committee.

. . . and even appear arbitrary at times. Some committee members perceived the conflict-of-interest procedures as arbitrary or unscientific, perhaps because the conflict-of-interest procedures were merely guidelines, not absolutes. One member commented that the "arbitrary nature of determination of who may not participate removes real experts from the discussions," while another member stated, "At times, [the] decision to exclude a member has seemed unnecessary if full disclosure had been done." With their comments, some committee members suggested that the conflict-of-interest procedures, perhaps owing to their somewhat arbitrary nature, have allowed some conflicted members to "slip through the cracks" to participate in advisory committee meetings. As one member put it, "The panel, by the design of the panel meeting process itself, can often get skewed in a certain direction."

A committee that is too impartial could ultimately hurt the public. Members' comments suggested that, in trying to close those cracks in the process, the FDA can sometimes be overzealous in its attempt to reconcile the need for expertise in view of real or potential conflicts. Or, and this may speak to the shared pool dilemma, unconflicted experts could not be found, and so the FDA brought in people to participate who lacked the specific knowledge and expertise about the subject at hand. Members' comments suggested that they viewed this scenario as problematic because the FDA risked basing a decision on advice and recommendations from people who, although they may be otherwise well credentialed, were unqualified to weigh in on that subject. As one committee member wrote:

> I believe the emphasis on conflict of interest has resulted in a too impartial committee. As a result the expertise is limited because of a lack of knowledge about the field. This can result in decisions that adversely impact the operations of the field . . .

Another member expressed similar views, "The FDA prefers ignorance to perceived conflicts. Several members know little about the issues because they are so far removed . . .". The consequences are far-reaching, according to another member's comments:

> I think the public loses when "experts" can't give their expertise because of perceived "conflicts," which may not be (and usually aren't) real. I have been at meetings where the real expert/most knowledgeable person was not allowed to vote due to this. This is then *unfair* to the public, ultimately (emphasis in original).

6. Discussion

This article sought to describe the shared pool dilemma of scientific advisory committees and then examine it from the perspective of science policy advisors who have participated in one or more FDA advisory committee meetings. Overall, the numerical data suggested that these science advisors were generally very positive about their experiences on advisory committees and considered their participation meaningful, satisfying, worth their time, and useful to the FDA. They also viewed the conflict-of-interest procedures as fair to the public and to committee members, and they considered the meeting process impartial.

The theory of procedural justice provided a framework within which to examine more closely science advisors' attitudes toward the FDA's conflict-of-interest procedures. Because procedural justice research suggests that individuals will be more satisfied with the process when they view the procedures as just, we hypothesized that when members viewed the conflict-of-interest procedures as fair to committee members and to the public, they would be more satisfied with their participation. The results showed no significant correlations among these variables. Perceived impartiality of the meeting process was significantly correlated with satisfaction, but it was not a significant predictor of satisfaction in the regression analysis.

Because of the strength of previous research demonstrating a relationship among these variables (e.g., Colquitt, 2001; Thibaut and Walker, 1975; Tyler et al., 1996), we are reluctant to claim that no relationship exists but prefer to explore alternative explanations. Among possible explanations for the lack of significant results are that the single items we used to measure the variables were insufficient to capture the complexity of the concepts. In addition, our sample could have been too small to capture accurately relationships among variables. It is also possible that committee members viewed the conflict-of-interest procedures as just one of many procedures related to advisory committee meetings, with the likelihood being that there are many other procedures unrelated to conflicts of interest (e.g., agenda items, speaking turns, meeting logistics, and so forth). Furthermore, the question on satisfaction asked whether members were satisfied with their participation on advisory committees, not whether they were satisfied specifically with conflict-of-interest procedures, although the written comments provided some feedback in this regard.

In considering the results, it is therefore important to review some limitations. From the study's inception, we viewed it as an exploratory first step. In designing our study, we considered conducting personal interviews with committee members attending the meetings; however, the extremely tight schedules of committee members at the meetings prohibited conducting these interviews on site. To capitalize on the salience of the issue in members' minds (which an interview scheduled at a later date could not count on) and potentially obtain the broadest participation from a variety of committee members, we opted for a survey at the meetings. Our initial intent was to request only written comments on the questions; ultimately, we included scales with the questions to further reduce respondent burden, i.e., respondents could choose only to provide numerical data and reduce their effort considerably. To ensure adequate response rates from committee members, already viewed as pressed for time, we deliberately limited our survey to nine questions. Certainly, the reliance on scales to collect data poses limitations on the richness of data collected, which we tried to offset by soliciting written comments. In addition, limiting the questions to only nine items restricted our ability to construct more robust scales using multiple items. Future research would do well to expand the questionnaire, using well-developed measurements, and seek a larger sample.

The results supported Hypothesis 3, which predicted that when members viewed their

efforts as impacting FDA policy making, they would be more satisfied with their participation. Similarly, Hypothesis 4, which predicted that when individuals viewed their efforts as more useful to the FDA, they would be more satisfied with their participation, was also supported. These findings reinforce previous research in group decision making, on which these hypotheses were formulated, while underscoring the importance of outcome variables in participant satisfaction (Chess and Purcell, 1999). Outcome variables, as opposed to process variables, relate to whether participants' input impacted decisions or made a difference. In this case, members were most satisfied when they believed that the FDA appreciated their efforts and that their efforts made a difference. Given that science advisors obtain little financial compensation for serving on committees, it is quite understandable that they would appreciate knowing that their time was "well spent."

The qualitative data provided additional insight into members' responses to the questions, including their satisfaction with the procedures. More specifically, as reflected in the numerical data, members' comments suggested a strong belief that the committee process was impartial. Their written comments appeared to link this impartiality to the effectiveness of the conflict-of-interest process, which results in well-rounded, diverse viewpoints on the committees and objective members. They believed that the FDA and, in turn, the public benefit from this impartiality because it ostensibly increases the value of the committees' recommendations, the committees' credibility, and the credibility of the FDA and its decisions.

A recurring theme in members' comments, which was not apparent from the numerical data, was the burden of the conflict-of-interest procedures (e.g., lots of paperwork, loss of privacy, and repetitiveness). The quantitative data did show, however, that the more meetings members had participated in, the less likely they were to view the conflict-of-interest procedures as fair to committee members. This is an example where the qualitative data complemented the quantitative data. Two related themes in the written comments pointed to potential flaws in the procedures' effectiveness: (a) the process may sometimes be arbitrary (exclusions or waivers were not warranted, sometimes decisions were judgment calls, and the like) and (b) biased members sometimes slip through loopholes in the process. Some members' comments suggested that, perhaps worse than having conflicted members participate in committee meetings was having members participate who were unqualified to advise on the meeting's subject. This likely happens because of the FDA's quest to find disinterested experts to serve as members, considered a difficult task, and/or perhaps from the FDA's zeal to mend loopholes in the process.

When interpreting the data, however, it is important to consider the potential of sample bias. This was not a statistical sample, and the results should not be generalized to all advisory committee members at the FDA or other federal agencies. In addition, it is possible that committee members used their responses to this questionnaire to substantiate or justify their commitment to the advisory committee process. Essentially, to rationalize their time and effort given to the process, committee members could have been overly positive about their experiences and the neutrality of the process, thereby offering a biased perspective. A related possibility is that only members having strong opinions (positive or negative) about their experiences on advisory committees responded to this questionnaire; the quantitative results were indeed skewed toward favorable assessments of the advisory committee process. Nevertheless, respondents were markedly candid in their qualitative assessments, offering praise as well as criticism. As noted above, questionnaire responses were anonymous, so we presented comments without information identifying whether the respondent was a research scientist, clinician, consumer or patient advocate, or industry representative.

In retrospect, having this information may have provided additional insight into respondents' comments. Given the strong patterns or themes we found, however, that the results were biased by one particular individual or perspective seems unlikely.

7. Conclusions

As government dependence on scientific advisory committees likely increases, presumably so will the need for science advisors. Among factors potentially muddying the pool is the increased availability of, and dependence on, industry funds for scientific research. Perhaps more than ever before, many potential members for scientific advisory committees are disqualified from participating due to their relationship—or their institution's relationship—with industry. This will result in increased challenges for government agencies seeking to staff their committees.

This study examined one US agency's quest to recruit science advisors for its advisory committees who are free from real or potential conflicts of interest. According to a sample of science advisors serving on FDA advisory committees, the FDA receives high marks for perceived committee impartiality, fairness of conflict-of-interest procedures to the public, and fairness of conflict-of-interest procedures to committee members themselves. Moreover, the results indicate a deep, personal investment of many of these advisors into their role as committee experts. In addition to feeling satisfied with their participation, these advisors believed their efforts valuable to the FDA and to a wider stakeholder audience, and they believed that their efforts were impacting FDA policy making. This connection to a higher purpose or altruism could, in fact, play a role in lessening the influence of real or potential conflicts of interest. Tyler (2003) recently found that when individuals' ethical motivations were activated, they were less motivated by self-interest and more by principles of fairness and justice. Thus, to the extent that science advisors feel compelled to serve a greater public good, they may be less motivated to act in a biased or self-interested manner. This would serve to decrease the moral, if not technical, problem of conflict of interest (Davis, 2001).

Certainly, there are some cracks in the system, as there will most likely be in any system seeking to regulate human behavior. According to the science advisors, sometimes people have served on committees when they should not have, due to their having either a conflict of interest or, alternatively, inadequate expertise or experience with the topic. Resonating with the shared pool dilemma, it seemed that these challenges represent two sides of the same coin, so to speak. That is, advisors either have (a) the requisite practical experience and knowledge and are thus often conflicted because of some prior relationship with industry, or (b) the theoretical knowledge and expertise yet no practical or professional experience. Interestingly, it seemed that advisors were more disturbed by the latter type of advisor serving on committees.

Another aspect of the shared pool dilemma is the laborious review process to which members must submit before serving on committees. Many members lamented the burden of the lengthy review process and the amount of information they were compelled to provide. The degree to which the process decreases members' willingness to serve could exacerbate the shared pool dilemma. Finding ways to streamline this process may offer one solution for federal agencies seeking to recruit science advisors, yet streamlining in itself brings to bear substantial political and ethical implications, which could lessen the possibility of its occurrence.

Two other solutions to the shared pool dilemma speak more directly to its assumptions. The first entails expanding a more traditional conceptualization of expertise to include

scientists and/or other individuals who may lack conventional credentials, e.g., personal or professional experience with the product or long, established careers, but who nonetheless can offer intelligent, critical, and perhaps fresh perspectives as science advisors. In some sense, the FDA is already doing this when populating some of its advisory committees. Some wariness accompanies this solution, however, as indicated by respondents' comments suggesting that an overly impartial committee may ultimately be a public disservice. Working to balance membership by including scientists having traditional expertise yet potentially also some conflicts as non-voting members may provide one compromise.

A second solution to the dilemma addresses the public's willingness to accept some conflict of interest among science advisors in exchange for access to what some may consider the best expertise (e.g., the more traditional credentials noted above). Realistically, as industry funding for scientific research increases, few alternatives may exist to relying on some science advisors who have some financial ties to industry. In these cases, public disclosure is key so that people can evaluate the scientist's advice in light of the conflict. Medical journals have adopted such an approach when publishing studies whose authors have received industry funds for their work (International Committee of Medical Journal Editors, 1993). For advisory committees, this approach would require a commitment from the agency to ensure that real or potential conflicts among science advisors are publicly disclosed and that the conflicts' latent impacts on outcomes are somehow neutralized, such as by limiting voting privileges. Some agencies, such as the FDA, already have adopted such disclosure, and preliminary evidence has suggested that for members of the public who attended FDA advisory committee meetings, tolerance for conflicts of interest among science advisors was significantly correlated with knowledge of the conflict-of-interest procedures and trust in the authorities in charge of those procedures, i.e., the FDA (McComas et al., 2004). Thus, in addition to having conflict-of-interest procedures in place to screen for conflicts and ensure that conflicts are publicly disclosed, members of the public must know about these procedures and trust that those in charge will apply them fairly and scrupulously.

In sum, this article offered a closer look into a dilemma that will continue to affect government agencies seeking impartial expertise on science policy decisions. To the extent that it has shed some light on potential challenges and barriers government agencies must overcome, it has served a pragmatic purpose and achieved some applicability. Despite the limited support for our hypotheses, we also believe that the procedural justice framework holds considerable promise for examining conflict-of-interest procedures, and future research should endeavor to explore this possibility further.

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Note

1 In addition to scientific or *expert* advisory committees, the federal government relies on policy-level and site- or region-specific. Policy-level committees are typically comprised of stakeholder interest groups; whereas

members of site- or region-specific committees typically come from local communities (Beierle and Long, 1999).

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