SUMMARY REPORT

CONFLICTS OF INTEREST AND FDA ADVISORY COMMITTEE MEETINGS

A STUDY OF PUBLIC ATTITUDES AND OPINIONS

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This document summarizes the findings of a study of attitudes and opinions of a sampling of people who attended FDA advisory committee meetings in the spring of 2003 and advisory committee members who participated in those meetings. The study's intent was to examine the perceived fairness and credibility of FDA advisory committee meetings related to FDA's management of real or potential conflicts of interest among advisory committee members. We also wanted to gain insight into knowledge about the FDA's conflict of interest procedures among audience members, as well as what audience members considered most important about advisory committee meetings. Finally, we measured audience and advisory committee member satisfaction with the FDA, its advisory committee meetings, and its conflict of interest procedures.

We took great efforts to ensure that the study was conducted in an unbiased manner and have tried to present the summary report as objectively as possible. The funding was provided by the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a University of Maryland/FDA collaborative research institute; however, the results should not be construed as representing the viewpoints of JIFSAN, FDA, or Cornell University. Questions about this report or the research should be directed to Katherine McComas, Dept. of Communication, 313 Kennedy Hall, Cornell University, Ithaca, New York, 14853; phone 607-255-06508; email kam19@cornell.edu.

HOW THE STUDY WAS CONDUCTED

PART I. AUDIENCE MEMBER SURVEY

From March to July 2003, we distributed questionnaires on audience members' chairs at 11 FDA advisory committee meetings held in the Washington D.C. metropolitan area. Meetings were selected to represent the four largest FDA centers: 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). Each questionnaire contained a letter describing the research and soliciting participation and a business reply envelope. We encouraged participants to complete the questionnaire before leaving the meeting and drop it in the box marked "FDA Survey" at the meeting registration table; however, we also told them they could return the questionnaire at a later time in the business reply envelope. Responses were anonymous.

Of the questionnaires distributed, 273 were returned and included in the data analysis. To estimate response rates, we counted the number of non-FDA individuals sitting in the audience at several points during each meeting. (FDA employees typically wore official name tags and sat in a separate section.) We used the highest estimate of attendance to provide a conservative estimate of response rates. Table 1 lists the meetings used in this study, as well as the estimated response rates for audience members per meeting. Our intent was not to draw comparisons among meetings but to examine relationships among variables; therefore, having a statistically representative sample of

responses from any particular meeting was unnecessary. *Still, given the non-random sampling procedures and the likelihood of self-selection bias in responding to the questionnaire, it is important to underscore that our data should not be generalized to all individuals who attend FDA advisory committee meetings.*

TABLE 1. MEETINGS AND ESTIMATED RESPONSE RATES FOR AUDIENCE MEMBERS

MEETING	DATE(S)	ATTENDANCE	RESPONSES	RESPONSE RATES
Oncologic Drugs (CDER)	March 12-13	170	61	36%
Blood Products (CBER)	March 13-14	200	36	18%
Dietary Supplements (CFSAN)	March 25	27	14	52%
Circulatory System Devices (CDRH)	April 10	100	21	21%
National Mammography Quality Assurance (CDRH)	April 28	26	15	58%
Antiviral Drugs (CDER)	May 13-14	180	35	19%
Dental Products (CDRH)	May 22	17	4	24%
Cardio-Renal Drugs (CDER)	May 29-30	250	30	12%
Nonprescription Drugs (CDER)	June 12	25	8	32%
Endocrinologic and Metabolic Drugs (CDER)	July 9	175	22	13%
Transmissible Spongiform Encephalopathy (CBER)	July 17-18	150	27	18%
Overall Response Rate for Data Collection		1,320	273	21%
Average Response Rate for 11 Meetings				28%

RESULTS

The first set of questions focused on audience members' knowledge of the FDA's conflict of interest procedures, attitudes about the fairness of FDA advisory committee meetings, tolerance toward real or potential conflicts of interest among advisory committee members, satisfaction with the FDA and its advisory committee process, and attitudes about disclosing committee members' real or potential conflicts of interest. Data were collected using 1 to 7 scales, from "strongly disagree" to "strongly agree." Tables 2 through 6 provide a percentage breakdown of responses to the questions.

TABLE 2. AUDIENCE KNOWLEDGE

STATEMENT	AGREE	IN-THE-MIDDLE	DISAGREE
• I am familiar with the FDA's procedures for reviewing conflicts of interest of advisory committee members.	44.8%	16.9%	38.3%
• I consider myself knowledgeable about how the FDA monitors conflicts of interest among its advisory committee members.	33.8%	20.6%	45.3%

TABLE 3. AUDIENCE OPINIONS REGARDING THE FAIRNESS OF FDA ADVISORY COMMITTEE MEETINGS

STATEMENT	AGREE	IN-THE-MIDDLE	DISAGREE
• The meetings are fair to all those involved.	61.3%	17.3%	19%
• The meetings do not favor certain people or organizations above others.	44.2%	23.9%	29%
• The meetings try to bring the issue into the open so that they can be solved.	80.6%	8.8%	9.5%
• The committees work hard to get the information needed to make good decisions or recommendations.	77.2%	12.1%	17.4%
• The FDA tries hard to monitor conflicts of interest of its advisory committee members.	60.3%	23.5%	11.7%
• I trust the FDA to monitor conflicts of interest among its advisory committee members.	70.6%	16.9%	11.5%
• The FDA's procedures for reviewing potential conflicts of interest of its advisory committee members are fair.	51.6%	30.5%	9.3%
• The FDA advisory committee meeting process shows concern for my rights.	64.3%	21.7%	11.4%

TABLE 4. AUDIENCE TOLERANCE FOR CONFLICTS OF INTEREST AMONG FDA ADVISORY COMMITTEE MEMBERS

STATEMENT	AGREE	IN-THE-MIDDLE	DISAGREE
• The FDA should <u>not</u> allow members with conflicts of interest to participate in any capacity at advisory committee meetings.	16.2%	8.8%	75.1%
• You cannot trust an advisory committee's decision if any of its members have conflicts of interest.	7.3%	4.8%	86.8%
• When committee members have conflicts of interest, they will always decide in favor of their interest.	17.7%	14%	66.5%
• In order to have access to the best expertise in the field, you have to accept that advisory committee members may have some conflicts of interest.	87.6%	5.1%	7.3%
• In this day and age, you have to expect some conflicts of interest among advisory committee members.	81.3%	7.4%	11.4%
• I am not really concerned about advisory committee members' conflicts of interest.	20.2%	10.3%	69.4%
• It is unreasonable to expect that advisory committee members won't have some conflicts of interest.	83.5%	5.1%	10.2%

TABLE 5. AUDIENCE SATISFACTION

STATEMENT	AGREE	IN-THE-MIDDLE	DISAGREE
• In general, I am satisfied with the FDA's procedures for reviewing potential conflicts of interest of advisory committee members.	58.5%	26.5%	10.6%
• In general, I am satisfied with the FDA's advisory committee meetings.	67.7%	18.8%	12.2%
• All in all, I am satisfied with the FDA's performance as a regulatory agency.	67%	16.2%	15.5%
• In general, I am willing to accept recommendations made by FDA advisory committees.	72.4%	16.5%	9.3%
• I would be willing to attend future advisory committee meetings.	96%	2.2%	0.4%

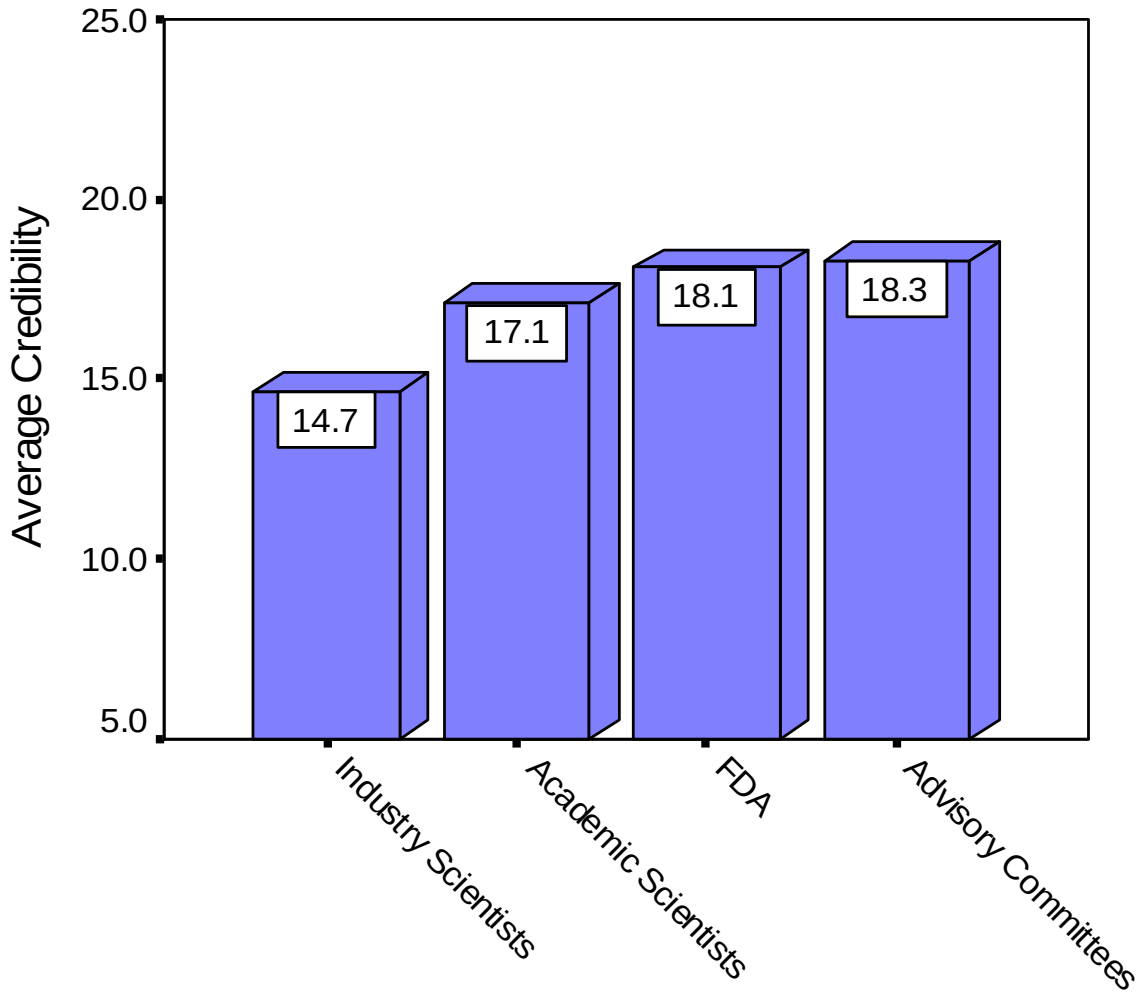
TABLE 6. AUDIENCE OPINIONS REGARDING THE FAIRNESS OF DISCLOSING CONFLICTS OF INTEREST AMONG ADVISORY COMMITTEE MEMBERS

STATEMENT	AGREE	IN-THE-MIDDLE	DISAGREE
• I believe it is fair to disclose whether advisory committee members have conflicts of interest at advisory committee meetings.	96.3%	1.5%	2.2%
• Learning about committee members' conflicts of interest affects how credible I view the advisory committee meeting process.	65.1%	11%	23.9%
• I think the advisory committee process is more credible when the FDA discloses committee members' conflicts of interest at the meetings.	89.3%	6.6%	4%
• It is important that there be full disclosure at the meetings of committee members' conflicts of interest	86.1%	7%	5.5%

CREDIBILITY OF INFORMATION SOURCES

We also asked audience members to rate the credibility of scientific information coming from four different sources: the FDA, industry scientists, academic scientists, and advisory committees. Figure 1 displays a chart showing the average credibility score each source received. The scale ranged from 5 to 25, with higher scores indicating higher credibility.

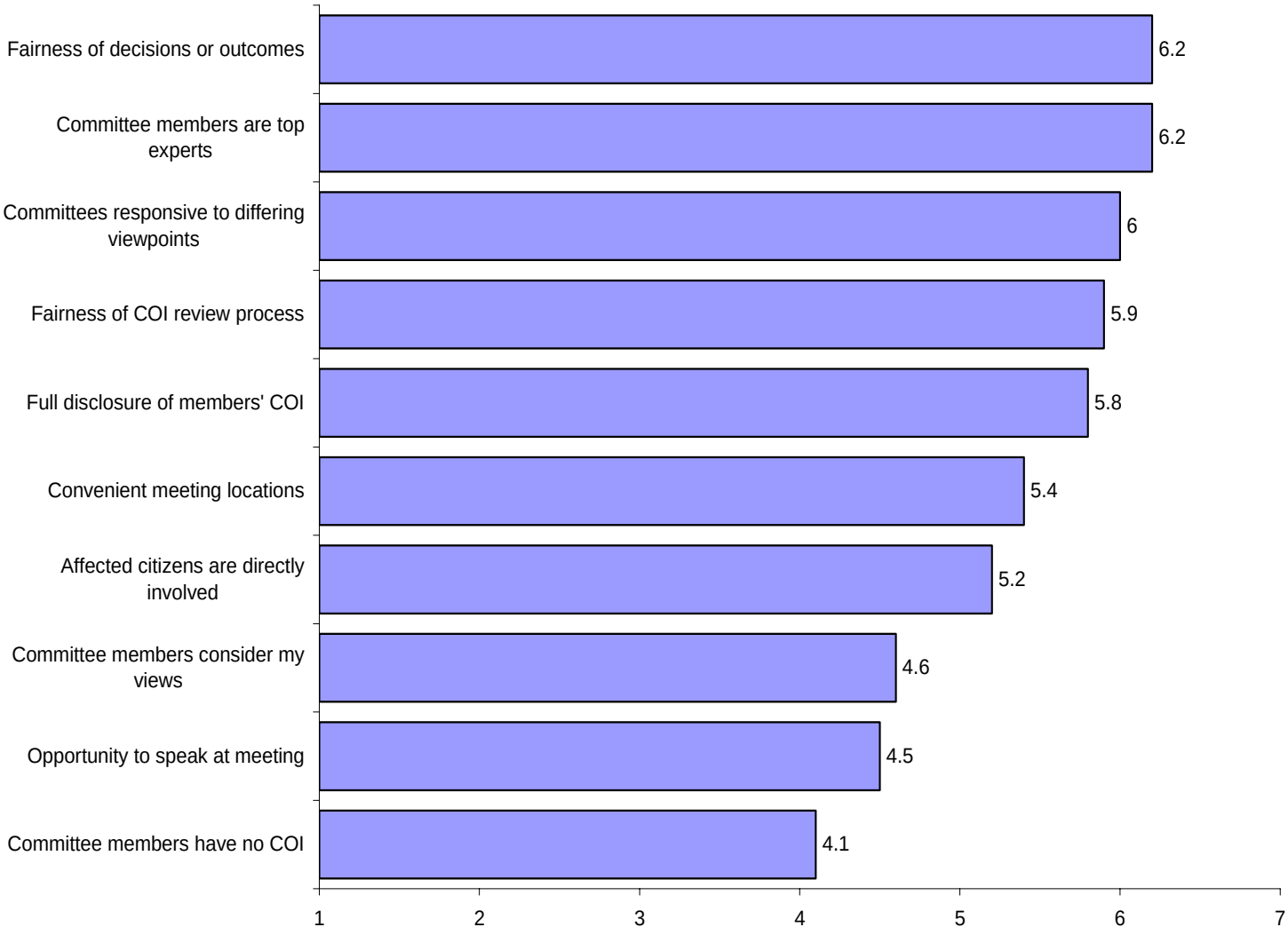
FIGURE 1. AUDIENCE OPINIONS REGARDING THE CREDIBILITY OF DIFFERENT INFORMATION SOURCES



IMPORTANT ASPECTS OF ADVISORY COMMITTEE MEETINGS

We also invited audience members to tell us, on a scale of 1 to 7, what was important to them at advisory committee meetings. Figure 2 displays a chart illustrating their mean responses, with higher scores indicating greater importance. It is important to note that these aspects may not represent all of the aspects of advisory committee meetings that audience members consider important; however, below are the relative rankings of the list we provided to respondents.

FIGURE 2. AUDIENCE OPINIONS REGARDING THE IMPORTANCE OF DIFFERENT ASPECTS OF ADVISORY COMMITTEE MEETINGS



Note: "COI" is "conflict(s) of interest"

WHO RESPONDED? AUDIENCE MEMBER CHARACTERISTICS

Finally, we asked some questions to let us know something about the audience members who responded to our survey. The results showed:

- 60% were male; 37% were female (3% declined to answer)
- 85% had some level of graduate study (e.g., master's degree, M.D., J.D., or Ph.D.)
- 42% estimated that they had attended between 1 to 5 advisory committee meetings, 20% said 6 to 10 meetings, 13% said 11 to 20, another 13% said 21 to 50, and 5% said over 50 meetings
- 82% were paid by an employer or organization to attend the meeting

PART II. ADVISORY COMMITTEE MEMBER SURVEY

At each of the 11 meetings, the advisory committee executive secretaries permitted us to distribute questionnaires at the advisory committee member's seat. Each questionnaire included a letter describing the research and soliciting participation, as well as a business reply envelope. As with audience members, advisory committee members were encouraged to complete questionnaires before leaving the meeting and drop them in the "FDA Survey" box; however, they were also told they could return the questionnaire at a later time in the business reply envelope. Responses were anonymous.

Of questionnaires distributed, 92 were completed and returned. Table 7 lists the estimated response rates for advisory committee members per meeting. *As with the audience data, given the non-random sampling procedures and the likelihood of self-selection bias in responding to the questionnaire, our data should not be generalized to all FDA advisory committee members.*

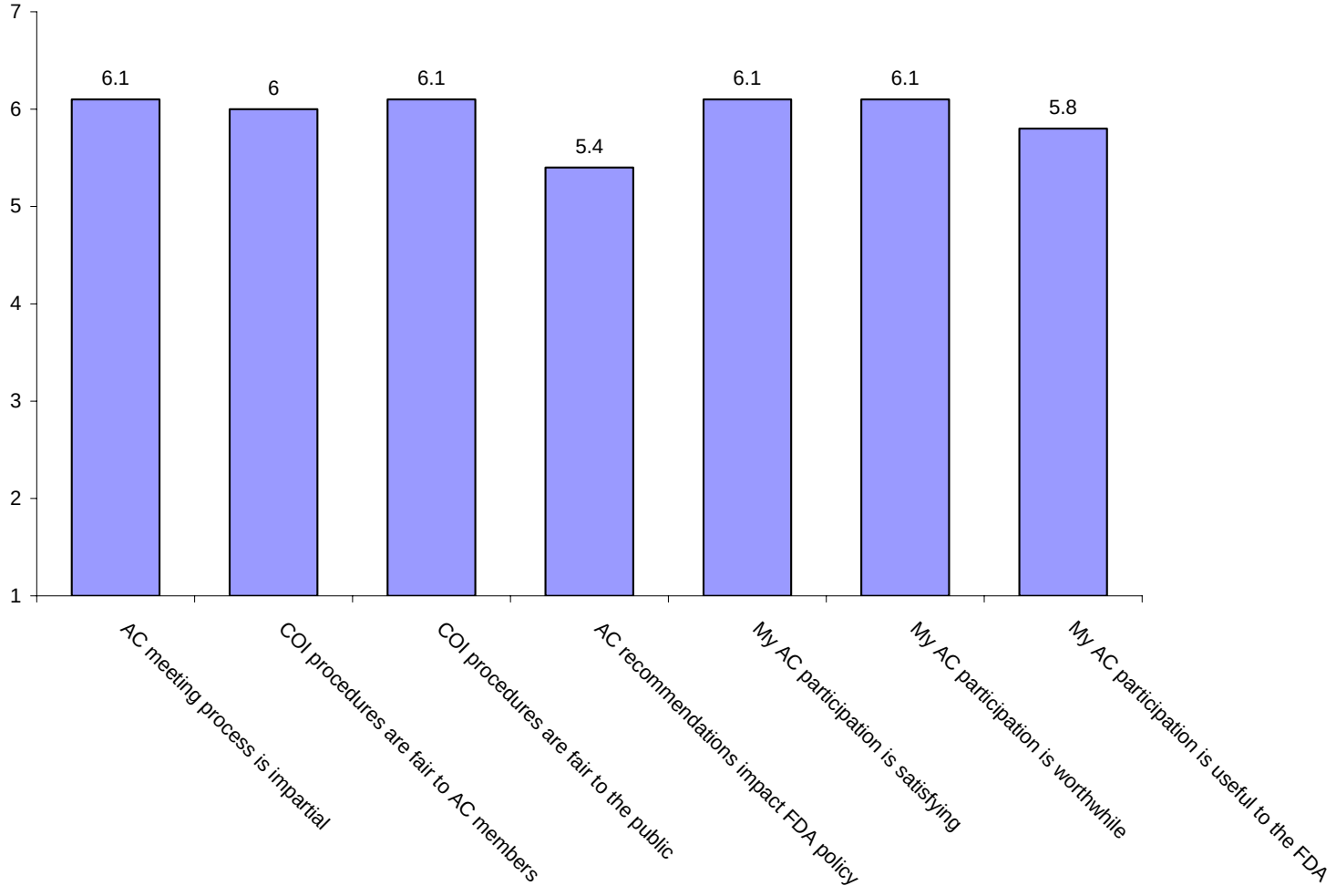
TABLE 7. MEETINGS AND ESTIMATED RESPONSE RATES FOR AC MEMBERS

MEETING	DATE(S)	MEMBERS	RESPONSES	RESPONSE RATES
Oncologic Drugs (CDER)	March 12 to13	16	11	69%
Blood Products (CBER)	March 13 to 14	12	11	92%
Dietary Supplements (CFSAN)	March 25	8	4	50%
Circulatory System Devices (CDRH)	April 10	12	7	58%
National Mammography Quality Assurance (CDRH)	April 28	13	8	62%
Antiviral Drugs (CDER)	May 13to 14	17	9	53%
Dental Products (CDRH)	May 22	8	8	100%
Cardio-Renal Drugs (CDER)	May 29to 30	14	8	57%
Nonprescription Drugs (CDER)	June 12	10	8	80%
Endocrinologic and Metabolic Drugs (CDER)	July 9	14	6	43%
Transmissible Spongiform Encephalopathy (CBER)	July 17 to 18	15	12	80%
Overall Response Rate for Data Collection		139	92	66%
Average Response Rate for 11 Meetings				68%

RESULTS

The questionnaire for advisory committee members was shorter in length than the one distributed to audience members; however, the questions also related to the perceived impartiality of the advisory committee process and the fairness of FDA's conflict of interest procedures. Figure 3 provides the mean scores of responses to the seven primary questions. These questions were coded on a "strongly disagree" to "strongly agree" scale of 1 to 7, with higher scores indicating greater agreement.

FIGURE 3. ADVISORY COMMITTEE MEMBER OPINIONS REGARDING ADVISORY COMMITTEE MEETINGS AND CONFLICT OF INTEREST PROCEDURES



WHO RESPONDED? ADVISORY COMMITTEE MEMBER CHARACTERSTICS

Finally, we asked some questions to let us know something about the advisory committee members who responded to our survey. The results showed:

- This was the first advisory committee meeting for 13% of respondents; 33% had participated in 2 to 5 meetings, 35% had participated in 6 to 10 meetings, and 20% had participated in more than 10 meetings
- 15% had been recused by the FDA from serving at a particular advisory committee meeting due to conflict of interest. Of those who had been recused, 71% had been recused once, 21% had been recused twice, and the remaining 8% more than twice.
- 11% had recused themselves from serving at a particular advisory committee meeting due to a conflict of interest. Among those who had recused themselves, 90% had only done it once.
- The FDA had limited the participation of 11% of the respondents during a particular advisory committee meeting. For 75% of those whose participation had been limited, this occurred only one time; it had occurred twice for 25% of the respondents.

SUMMARY

This report has provided a general overview of the survey results. For those interested in additional theoretical and methodological detail, the following publications and conference papers are available from Katherine McComas upon request:

- McComas, K., Tuite, L., & Sherman, L. (2004, August). Conflicted Scientists: The "Shared Pool" Dilemma of Scientific Advisory Committees. Paper presented at the *2004 Association for Education in Journalism and Mass Communication Annual Convention*, Toronto, ON.
- McComas, K., Waks, L., Simone, L., and Sherman, L. (2004, May). Predicting Satisfaction and Outcome Acceptance with Decision-Making Processes: The Role of Procedural Justice. *Paper presented at the International Communication Association Annual Meeting*, New Orleans, LA.
- McComas, K.A., & Simone, L. (2003). Media Coverage of Conflicts of Interest in Science. *Science Communication, 24,* 395-419.
- Simone, L., & McComas, K.A. (2003, August). Perceptions of Media Coverage of Conflicts of Interest within the U.S. Food and Drug Administration's Advisory Committees. *Paper presented at the Association for Education in Journalism and Mass Communication Annual Convention*, Kansas City, MO.

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