RISK: Health, Safety & Environment (1990-2002)

Volume 1
Number 1 *RISK: Issues in Health & Safety*

Article 7

January 1990

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Joseph L. Lakshmanan

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Joseph L. Lakshmanan*

Introduction

While other papers in this issue discuss theoretical arguments favoring increased representation of the public in science-law decision-making procedures, this paper seeks to show that those arguments also have a basis in an actual regulatory setting. Thus, although this paper is based mainly on data from two surveys, it should be remembered that much that is said elsewhere in this volume is equally applicable here.[1]

The Food and Drug Administration (FDA) uses advisory committees as an integral part of its regulatory process. Because FDA views the work of its present committees as technical, most of them do not have voting nontechnical representation. Yet nonvoting consumer members are on many of FDA's committees.

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* Mr. Lakshmanan received his J.D. from Franklin Pierce Law Center where he was a Food and Drug Law Scholar. He is presently practicing with the firm of Heron, Burchette, Ruckert & Rothwell in Washington, DC.

1 Much of this paper appears in different contexts, but in similar forms, in two other papers. Lakshmanan, *FDA's Advisory Committees: Some Suggestions Based on Empirical Data*, 43 Food Drug Cosm. L.J. 877 (1988) (which details the results of the author's surveys while suggesting some process-oriented changes) [hereinafter *Advisory Committee Suggestions*]; Lakshmanan, *Nontechnical Representation on FDA Advisory Committees: Can There Be More?*, 44 Food Drug Cosm. L.J. 181 (1989) (which advances theoretical arguments for increased non-technical representation) [hereinafter *Nontechnical Representation*]. These two papers should be consulted by those who wish more complete discussions of and citations to much of the information presented here.

After putting the subject into perspective, the extent to which the public is currently represented on advisory committees in FDA will be explored. Then, data collected from two surveys of committee members will be discussed. Next, the legal implications of present and further representation will be discussed in light of the Federal Advisory Committee Act (FACA) powers FDA has. In particular, a Fourth Circuit case[2] will be discussed because it appears to set limits on how FDA may increase public input in its deliberative processes.

Advisory Committees — Background

Advisory committees are "a useful and beneficial means of furnishing expert advice, ideas, and *diverse opinions* to the federal government."[3] Legislation establishing advisory committees "shall ... require the membership of the advisory committee to be fairly balanced in terms of *the points of view represented* and the functions to be performed by the advisory committee."[4] Similarly, agency heads and others should follow this mandate for balance in creating advisory committees.[5] Despite these praiseworthy words, FACA does not mention representation by the public or consumers. Congress left most of the details, including committee membership, to the organization creating the committee.[6] Congress has occasionally set by statute the groups to be represented on certain committees. Only rarely has it mandated voting representation of the public or consumers on advisory

2 Pacific Legal Foundation v. Goyan, 664 F.2d 1221 (4th Cir. 1981).

3 Federal Advisory Committee Act, 5 U.S.C. app. 2, § 2 (emphasis added) [hereinafter: FACA § x]. For a more complete discussion and citation of the information presented in this section, *see generally Nontechnical Representation, supra* note 1, at 181-84.

4 FACA § 5(b)(2) (emphasis added).

5 FACA § 5(c).

6 FACA § 8.

committees.[7] More frequently, Congress has opted for an advisory committee that has no public members on it.[8]

Although Congress did not include mandatory voting representation by a public or consumer representative on all advisory committees, it did attempt to ensure that committee hearings and proceedings would be as open as possible to the public. All hearings are open, except under special circumstances; the minutes and reports of the committees are available for public inspection, with certain exceptions as well.[9] Similarly, the public is encouraged to participate in committee proceedings.[10] However, the standard mode of notifying the public of upcoming proceedings is publication in the Federal Register.[11]

A daunting array of factors tend to lead to few members of the public appearing at committee hearings. Few people know what the Federal Register is, much less read it regularly to discover which hearings are of interest to them. This is especially true when the cost and size of the Federal Register are taken into account.[12] Furthermore, since most hearings are in Washington, it can be extremely expensive and time-consuming for a private citizen to attend. A private citizen may feel that s/he does not understand the issue from the proposal published

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7 The medical devices act mandates advisory committees with two of nine members being voting public members. 21 U.S.C. § 360j(f)(3)(B); *see also* 21 U.S.C. § 360c(b)(2) (Nonvoting consumer and industry members mandated on classification panels).

8 *See e.g.* 21 U.S.C. § 42 (The Board of Tea Experts consists of seven experts in the field with no public representation).

9 FACA § 10.

10 FACA § 10(a)(3).

11 FACA § 10(a)(2).

12 The Federal Register costs $300 a year [*see* p.II of any issue of the Federal Register] and consists of approximately 50,000 pages a year. Volume 51 (the 1986 volume) contained 47,418 pages, excluding indices, finder's aids and similar sections — an extraordinary amount of paper for anyone, much less a layperson, to digest.

in the Federal Register because the proposal was written by and for those knowledgeable in the field. Finally, citizens may not feel that their views will be taken seriously because of their perceived lack of experience, credentials or education compared with other participants. Therefore, only highly organized consumer groups, if anyone, are likely to be on hand to represent the public. The same is true for people interested in committee minutes or reports — especially in terms of the time required for sifting through the voluminous material.

But even well organized consumer groups face problems under the present process. They are rarely as well financed or as cohesive as industrial trade organizations. Further, they do not have the manpower necessary to handle effectively many large research projects at once (a trade organization may be concerned with only a few issues at any one time; whereas, a consumer group may try to deal with issues affecting many trade groups because all of those issues affect its broader constituency).

Even if consumer groups did not suffer from these imperfections, they are rarely able to fully and accurately represent public concerns and values. Moreover, such organizations may feel compelled to take extreme, hard-line views in order to combat perceived or real industrial intransigence, not because such views are popular with the public.

FDA attempted to lessen the problems of underfunding and underrepresentation of the public at hearings by funding such representation. In *Goyan* v. *Pacific Legal Foundation*, this FDA program was found improper by the Fourth Circuit.[13] The court decided that FDA could not fund certain groups to even the imbalance in public representation ostensibly because Congress had not authorized FDA to do so.[14] As will be discussed later, it appears that the court

[13] 664 F.2d 1221 (4th Cir. 1981).

[14] *Id.* at 1224-1227.

was not responding to Pacific Legal Foundation's (PLF's) real complaint and therefore, missed an opportunity to address some very serious and valid concerns. Although reimbursing poorly-funded, but worthy, participants is an obvious way of getting more views, a congressional mandate is necessary before FDA can expend funds this way.[15] Even if such congressional action is forthcoming, this solution suffers from certain problems. Those funded would likely be consumers groups and not the public because consumer groups would be able to present the best and most complete applications for the scarce dollars available for such participation. Also, it is no more likely that the public will pay more attention to the Federal Register just because there exists the minute chance that they will be funded to present their views to an agency on an issue about which they are concerned.

FDA's Current Advisory Committee Program

FDA currently uses advisory committees extensively. The ramifications of classifying advisory committees[16] as "technical" or "policy" are not slight. The membership and duties of members changes drastically depending on this distinction. There are at least 38 standing advisory committees.[17] Of these, seventeen are technical

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15 *See id.* at 1227 ("We hold that whether there shall be reimbursement for public participation in agency proceedings is a decision for the Congress and not the FDA or this Court."). Congress granted explicitly the power to support public representation at hearings in at least three statutes: 1. The Magnusson-Moss Warranty-Federal Trade Improvement Act, 15 U.S.C. § 57a(h)(1); 2. The Toxic Substances Control Act, 15 U.S.C. § 2605(c)(4); and 3. The Foreign Relations Authorization Act, 22 U.S.C. § 2692. *See generally, Goyan*, 664 F.2d at 1225.

16 Although § 14.100 calls the advisory bodies "panels", "committees", and "boards", here the terms "advisory committee", "committee", and "panel" will be used interchangeably to refer to all such groups. For a more complete discussion and citation of the information presented in this section, *see generally Nontechnical Representation, supra* note 1, at 184-86.

17 21 C.F.R. § 14.100 [hereinafter, section citations will be to 21 C.F.R. unless

prescription-drugs-for-human-use committees, sixteen are technical devices committees, and the remaining five are also considered technical by FDA.

FDA specifically classifies advisory committees as technical or policy.[18] FDA treats all of its current committees as technical committees.[19] Any distinction between the technical and policy committees would be purely theoretical at this time since FDA has no policy committees. This distinction should not be one purely of semantics, but rather could be used to great advantage.[20] However, given the current FDA usage of the terms, this paper will treat the terms as ones of art with little real meaning given to the words.

Technical committees may have consumer or industry members on them but only the technical experts vote.[21] In technical committees, nonvoting members are meant to act as "liaisons" between their constituencies and the committee.[22] These members are "to represent" their class' interests at hearings,[23] but without "undue influence."[24]

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otherwise stated].

18 § 14.1(b)(2) ("An advisory committee may be a policy advisory committee or a technical advisory committee. A policy advisory committee advises on broad and general matters. A technical advisory committee advises on specific technical or scientific issues, which may relate to regulatory decisions before the FDA."); *see also* § 14.80.

19 The FDA's Office of Consumer Affairs, in its Directory of Consumer Representatives on FDA Advisory Committees [hereinafter "Directory"], implies that all current committees are technical by making no distinction between the two types. *See* the second page of the unpaginated document; *see also FDA Public Advisory Committees: A Handbook for Committee Members and Executive Secretaries* (1982) at p.7.

20 *See, e.g.*, PROCEEDINGS OF THE SCIENCE COURT COLLOQUIUM (1977).

21 §§ 14.80(b)(2), 14.84(b).

22 § 14.86(a).

23 § 14.86(c).

24 § 14.86(c)(6).

They are to review "all official committee minutes to assure their completeness and accuracy."[25] Further, they have educational and information disbursement functions as well as an obligation to bring information to the committee from members of their constituencies.[26] The use of nonvoting members on advisory committees is of major importance to the advisory committee program of FDA since all present committees are technical in nature and almost 90 percent have or would like to have nonvoting consumer representation on them.[27]

Voting members are, and nonvoting members "may" be, compensated and reimbursed for their services and expenses.[28] All members, however, appear to be paid while attending meetings of the full committee.[29] Similarly, all members appear to be paid while working on special, agency-directed projects.[30]

The Results of Two Surveys

Given FDA's current system, a question arises as to whether the committees would function better if nontechnical voting members were on each committee. The obvious group to be asked such a question would be the committee members themselves; yet, no one had done so until recently. To address this void, the author performed two surveys

25 § 14.86(c)(2).

26 § 14.86(c)(3).

27 Of the 36 advisory committees listed in the Directory, *supra* note 19, as wanting or requiring consumer members, only the Device Good Manufacturing Practice Advisory Committee is required by law to let its consumer and industry members vote. 21 U.S.C. § 360j(f)(3).

28 § 14.95(a).

29 § 14.95(b). This section does not distinguish between voting and nonvoting members as does § 14.95(a).

30 § 14.95(c). This section does distinguish between voting and nonvoting members as does § 14.95(a).

of advisory committee members.[31] Although the surveys did not focus on the need for or the desirability of increased nontechnical representation on the committees, that was at least one goal of the surveys.[32] The responses were quite frank and tend to bolster the idea that non-technical participation improves a committee's advice in two major ways.

First, all groups surveyed felt that nontechnically trained members did not hinder the process and should not be excluded.[33] Further, consumer members played other roles than merely reacting to industry members' positions.[34] Consumer members not only play a useful role on the committees even if they are not technically trained.[35] Thus,

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31 The surveys were conducted under a grant from the Food & Drug Law Institute. The results are reprinted in full in *Advisory Committee Suggestions*, *supra* note 1, at App. B.

32 For a complete discussion of the surveys the methods used in obtaining the survey results, *see Advisory Committee Suggestions*, *supra* note 1, at Apps. A & B. All data presented below is reprinted from App. B. The results are set forth as follows: **upper row** Class(number in that class); **lower row** Average ± Standard Deviation

Unless otherwise stated, all questions asked for a 1 to 5 response with a "1"= disagree strongly and "5" = agree strongly. The numbers preceding or following a question refer to all responses treated together. The data was also broken to reflect the views of specific sub-groups of committee members: T = Technical members; C = Consumer members; I = Industry members; G = Good Manufacturing Practices Advisory Committee; S = Science Advisory Board; Ch = Chairpeople; E = Executive secretaries; U = Unidentifiable.

33 2.0 ± 1.4 (61) 13. Nontechnically trained members hinder the process and should be excluded from committees.

T(22)	C(4)	I(6)	G(3)	S(1)	Ch(8)	E(2)	U(16)
2.1 ± 1.4	1.0 ± 0.0	2.5 ± 1.2	1.3± 0.6	1.0 —	1.9 ± 1.5	2.5± 2.1	1.9 ± 1.6

34 2.0 ± 1.1 (58) 11. Consumer members tend do little more than react to industry member's positions.

T(20)	C(3)	I(7)	G(3)	S(1)	Ch(7)	E(2)	U(16)
2.2 ± 1.3	1.0 ± 0.0	1.7 ± 1.0	1.3 ± 0.6	1.0 —	2.3 ± 1.4	1.0 ± 0.0	2.2 ± 0.9

35 4.0 ± 1.4 (43) b. They [consumer representatives] play a useful role.

when confronted with the issue squarely, even technical members are in favor of nontechnical representation.[36]

Second, because of the way most members view the concept of safety, the use of nontechnical members is also bolstered. All groups agree that they use the concept of safety often.[37] Yet, most groups do not feel that safety is a pure question of technical fact.[38] This may be because most groups agree that safety involves the "acceptable risk",[39]

T(12)	C(4)	I(11)	G(5)	S(1)	Ch(11)
4.0 ± 1.5	4.0 ± 2.0	3.6 ± 1.4	4.6 ± 0.9	5.0 —	4.0 ± 1.3

3.8 ± 1.4 (42) d. They have been helpful to my committee, even if they are not technically trained.

T(10)	C(4)	I(11)	G(5)	S(1)	Ch(11)
3.6 ± 1.6	3.8 ± 1.9	3.6 ± 1.3	4.6 ± 0.9	5.0 —	3.8 ± 1.3

2.8 ± 1.5 (42) f. Their contributions are related to their technical competence.

T(12)	C(4)	I(11)	G(4)	S(0)	Ch(11)
2.7 ± 1.4	3.5 ± 1.7	2.6 ± 1.6	3.5 ± 1.3	—	2.4 ± 1.6

[36] *But see* Brown & Richard, *Advisory Committees and the Drug Approval Process*, 2 J. Clin. Res. & Drug Dev. 15, 21 (1988) (presenting data to the contrary for drug committees).

[37] 4.5 ± 1.0 (67) 1. My committee often deals with the concept of "safety".

T(23)	C(4)	I(8)	G(3)	S(2)	Ch(8)	E(2)	U(19)
4.5 ± 1.0	4.0 ± 1.2	4.5 ± 0.8	4.7 ± 0.6	3.5 ± 2.1	4.9 ± 0.4	5.0 ± 0.0	4.5 ± 1.3

[38] 2.6 ± 1.2 (59) 5. Whether something is safe is pretty much a question of technical fact.

T(20)	C(3)	I(8)	G(3)	S(1)	Ch(7)	E(2)	U(16)
2.5 ± 0.9	2.0 ± 1.0	2.9 ± 1.5	2.0 ± 1.7	5.0 —	3.6 ± 1.0	1.0 ± 0.0	2.6 ± 1.2

2.6 ± 1.4 (66) 9. Whether something is safe is pretty much a question of technical fact.

T(30)	C(5)	I(11)	G(4)	S(1)	Ch(15)
2.4 ± 1.3	2.0 ± 1.0	2.4 ± 1.2	2.0 ± 1.4	5.0 —	3.3 ± 1.6

[39] 4.3 ± 1.1 (58) 6. When safety issues come up, I try to put myself in the shoes of the ultimate patient.

which is linked to the ultimate patient and that even technical people do not feel strongly that they are capable of putting themselves in the shoes of end-users.[40] Thus, nontechnical members play a useful role in providing some measure of acceptable risk and how not only the public but the user will view a product.[41]

The data detailed above suggest that FDA should increase its use of nontechnically trained members on advisory committees and give those members full voting status.[42] Its current technically trained advisory committee members do not seem to be against this change; indeed they

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T(19)	C(4)	I(7)	G(3)	S(0)	Ch(8)	E(2)	U(15)
4.3 ± 1.1	4.8 ± 0.5	4.9 ± 0.4	4.3 ± 0.6	—	4.4 ± 0.6	5.0 ± 0.0	3.7 ± 1.4

4.4 ± 1.0 (68) 10. When safety issues come up, I try to put myself in the shoes of the ultimate patient.

T(31)	C(5)	I(11)	G(5)	S(1)	Ch(15)
4.4 ± 0.9	5.0 ± 0.0	4.5 ± 0.8	3.8 ± 1.3	5.0 —	4.3 ± 1.3

[40] 3.4 ± 1.1 (58) 7. To the extent that technical or professional people attempt to put themselves in the shoes of the ultimate patient, they are successful.

T(19)	C(4)	I(7)	G(3)	S(0)	Ch(8)	E(2)	U(15)
3.6 ± 1.1	2.8 ± 1.3	3.3 ± 1.0	2.7 ± 0.6	—	3.9 ± 0.8	5.0 ± 0.0	3.1 ± 1.0

3.6 ± 1.2 (63) 11. To the extent that technical or professional people attempt to put themselves in the shoes of the ultimate patient, they are successful.

T(29)	C(4)	I(11)	G(4)	S(1)	Ch(14)
3.8 ± 1.1	2.5 ± 1.3	3.4 ± 1.2	2.2 ± 0.5	5.0 —	4.1 ± 1.2

[41] It should be noted that consumer representatives for the most part do not vote on committees, and this seems to have an influence on whether their views are reflected in the advice given to FDA.

3.3 ± 1.5 (61) 3. Whether a member can vote on all committee business has a great influence on whether their views are reflected in committee advice to FDA.

T(23)	C(3)	I(8)	G(1)	S(1)	Ch(8)	E(2)	U(16)
3.6 ± 1.5	4.0 ± 1.0	2.7 ± 1.8	4.0 —	5.0 —	2.4 ± 0.	3.0 ± 2.8	3.4 ± 1.5

[42] Of course, FDA may be limited in its ability to do so when Congress has mandated nonvoting nontechnical members. *See, e.g.*, 21 U.S.C. § 360c(b)(2).

seem to favor it. The question remains as to whether this change is possible, especially in light of *Goyan*.

Advisory Committees & *Goyan*

The Pacific Legal Foundation (PLF) brought suit to enjoin FDA from expending funds to increase participation at FDA hearings by compensating certain participants.[43] The legal theory advanced by PLF (and adopted by the majority) was that FDA did not have the authority to appropriate funds for this purpose without specific prior congressional approval.[44]

Although PLF's legal theory may have been FDA's lack of authority from Congress, its complaint shows that other concerns may have been the motivating force. The concerns seem to have been that PLF would be forced to expend more time and money due to: 1. delayed proceedings; 2. elongated proceedings; 3. the wide variety of new views that would have to be supported or contradicted; and 4. whether the "public" would be truly represented by applicants for reimbursement.[45]

Although these concerns are valid, the Fourth Circuit did not deal with them. PLF's true concerns could have been addressed by the Court requiring FDA to further constraint the program via rule-making.[46] Through this process, FDA could have dealt with the problem of delay and the need to expedite hearings, while retaining broader representative participation. Unfortunately, there is nothing that can be done about increased participation creating increased ideas. As Judge Bownes has observed elsewhere in this issue, democracy is not

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43 *Goyan*, 664 F.2d at 1222. For a complete discussion and citation of the information presented in this section, *see generally Nontechnical Representation*, *supra* note 1, at 189-92.

44 *Id.* at 1223.

45 *Id.* at 1224.

46 5 U.S.C. §§ 553, 557 provide for such rulemaking.

very "efficient," but it is what we have chosen.

The majority in *Goyan* was concerned with negative statutory enactment.[47] The majority might have been right in this instance, where Congress rejected a number of bills that would have granted the power to reimburse certain participants to all agencies.[48] The dissent, however, could not accept this proposition as applied specifically to FDA because "[t]he mandate of FDA to protect the public health is not shared by all agencies."[49] Indeed, given FDA's mandate, the dissent felt that the power to reimburse was plainly implied.[50] Rather than using FDA's highly technical deliberations as a reason for discouraging outside participation, the dissent noted that "[t]he scientific nature and overweening importance of the subject matter with which FDA deals leave no doubt that it may often benefit from outside assistance."[51] The dissent realized that this "outside assistance" would bring many salutary effects.[52] Where the majority refuses to address PLF's real concerns, the dissent accepts PLF's concerns and answers them by saying that longer, slower hearings with more participation "may, accordingly, equip an agency to determine which course is in the 'public interest.'"[53] Thus, in this situation, where we must choose between faster, less reliable proceedings and slower, more representative proceedings, the dissent (and the author) would choose the latter — while the majority refuses to address the basic question.

FDA's regulations were broad enough to include that process.[54]

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47 *Goyan*, 664 F.2d at 1225-1227.

48 *Id.* at 1225 n.12.

49 *Id.* at 1229 (Judge Murnaghan dissenting).

50 *Id.*

51 *Id.*

52 *Id.* at 1228.

53 *Id.*

Similarly, the Court's holding was broad enough to include the advisory committee process.[55] There are, however, ways to argue that *Goyan* does not affect FDA's current advisory committee scheme of funding consumer and industry participation.

The strongest argument is that Congress has mandated diverse representation on advisory committees. Congress has also mandated, on some committees, the membership of "consumer" and "industry" representatives, who do not vote, on committees. Furthermore, it allows all members (including presumably these nonvoting representatives) to be compensated. Finally, Congress has expressly called for this compensation to be included in the agency's budget. Therefore, the court's authority concerns in *Goyan* have been, at least implicitly addressed by Congress.

As discussed above, nonvoting members are not the same as paid public participants at agency proceedings. They do not represent any specific group or organization. They are supposed to act as liaisons to their classes, locate suitable presenters from their class, and serve as checks on the honesty of the system. They are not supposed to present information. The differences between committee members and advocates are both obvious and legion.

Finally, where *Goyan* relies on Congress' refusal to enact an extension of the power to reimburse participants by FDA and all other agencies, FACA has no such "clear" negative mandate. Indeed, recently

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54 "The expressed purpose of the program is '... to determine whether the process of administrative decision-making will be enhanced by reimbursing participants whose participation in agency proceedings contributes or can reasonably be expected to contribute to a full and fair determination of the issue, but who would otherwise be unable to participate effectively.'" *Id.* at 1222 (quoting 44 Fed. Reg. 59,174 (1979); footnote omitted).

55 The court held "that whether there shall be reimbursement for public participation in agency proceedings is a decision for the Congress and not for the FDA or this Court." *Id.* at 1227.

the General Services Administration adopted rules that leave the compensation of committee members up to the agency.[56]

It does not appear that FDA's use of nonvoting members has ever been the subject of a legal dispute. This may be because the concerns that worried PLF in *Goyan* are not present in the advisory committee program: proceedings are not delayed; additional information is not presented; and they add rather detract from balance.

Summary

FDA's extensive advisory committee process provides an excellent model for testing whether increased nontechnical representation on committees will enhance the process. Two surveys of committee members indicate in two fundamental ways that increased nontechnical representation would enhance the process.

First, the members are in favor increased consumer representation as a direct matter. Second, increased nontechnical representation is warranted because decisions of safety are not purely technical decisions, but rather involve end-user contemplation.

Despite surface similarities, *Goyan* is not applicable to the advisory committee process, especially if FDA were to increase the number of consumer representatives on its advisory committees and give them full voting status.

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56 *See* 41 C.F.R. §§ 101-6.1003, -6.1033(a) (1988). While § 1033(a) calls for uniform compensation, to be set by the agency, for all committee members, § 1003 defines "committee members" as only those who have full rights, including the right to vote.