

Federal Advisory Committee Act Regulations
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DR. McCABE: We now want to talk about the relevant rules of conduct, and we will have presentations from Valerie Hurt from the Office of the General Counsel, Public Health Division, DHHS, on Federal Advisory Committee Act regulation, and also from Holli Beckerman-Jaffe from the Office of the General Counsel, Ethics Division, DHHS, on ethics in government regulations.

MS. HURT: Thank you, Dr. McCabe.

I'm an attorney at the Department of Health and Human Service's General Counsel's Office. I work in the NIH branch. I've been asked to speak to you briefly about the Federal Advisory Committee Act. A lot of you are familiar with it. You've served on federal advisory committees before, so this is really a quick overview.

As Dr. Zerhouni explained, Secretary Thompson convened this committee to seek advice from all of you concerning genetics, health, and society. The purpose of the Federal Advisory Committee Act is to ensure that when the government asks for advice from experts like yourselves, the public has the opportunity to participate. All of FACA's rules stem basically from that concept.

You are an advisory committee; we know that. You come under (C), established or utilized by one of the agencies. There are a few exceptions. I'm not going to go over them.

As I mentioned, Congress enacted the Federal Advisory Committee Act because it believed that it was important for the government to seek advice from outside experts such as yourselves, but it wanted to ensure that when the government did that, there would be uniform standards and practices for obtaining advice and that the public would be kept informed and have the opportunity to participate.

There are a number of laws that govern what you do. I'm not going to go through them. The number-one law is obviously FACA. If you have any questions, you can ask Sarah. I mentioned the primary requirements are that advisory committees should meet in the open. That's why you're all here. That's why the opportunity for people to view it on the Web is available.

The idea is that the government wants to ensure the public has the opportunity to know what you're doing and to participate. Notice of your meetings has to be published in the Federal Register 15 days ahead of when you meet, at least. The reports that you prepare, transcripts of your meetings, minutes, working papers, basically all the information that you receive should be made available to the public as well, and the public has the opportunity to review that material. There are a couple of exceptions having to do with trade secrets, et cetera, but I'm not going to go through that right now.

These are some of the more mundane aspects of the law, but they'll explain a little bit, for those of you who are less familiar with how it works, why certain activities have to happen. A federal official has to be here, minutes have to be kept, financial records must be kept, all federal advisory committees must be chartered -- you have your charter -- and the membership must be balanced in terms of points of view. Again, that's explained. Congress wanted to ensure that both the public would be informed and it would do what it could do to ensure that the government got good advice.

There are some activities that you may do which may not necessarily be subject to the open meeting requirements, and that's working group activities into relatively narrow contexts. Again, remember the idea was that the public should have the opportunity to know what you're doing and participate. However, the law recognizes that for certain activities, it maybe makes more sense and the interest in ensuring public participation isn't perhaps as strong, and those activities are preparatory work, which means doing an investigation, gathering information, conducting research, maybe drafting some position papers, provided that that drafting, investigation, et cetera, isn't passed on to the advisory committee in a sort of pro forma fashion. If a working group develops a paper or an idea, that really has to be the kind of thing that the committee then deliberates upon fully.

Similarly, administrative work. To the extent that some of your members are going to learn about administrative activities related to what you're doing, that doesn't need to necessarily proceed in the open because the judgment has been made that those kinds of activities aren't the kinds of things that need to necessarily occupy the whole committee and the public access.

Sarah is your designated federal officer. Sarah has a bunch of jobs. She approves or calls the meetings. She approves the agenda. She attends the meetings. She adjourns the meetings. She chairs the meetings when directed by the agency head. I doubt that Dr. McCabe will let that happen. She ensures that the minutes are kept. Also, if you have questions, at least initially about how your operations proceed and what you can do and what you can't, Sarah is here to answer those questions.

As you know, you all serve by appointment and you vote, and you have the full right to participate in the activities of the committee. You're compensated for your time and site visits, et cetera. As I mentioned, if you have questions, refer them to Sarah. Although Holli is going to speak at length to you about this, the other thing to sort of keep in mind is that if you have a conflict of interest or you're concerned about a conflict of interest, you need to be sensitive to that and raise it. You are, when you are here, serving as a special government employee and subject to all the restrictions and obligations of that role.

So as I mentioned, the key point to keep in mind is that the Federal Advisory Committee Act regulates the way you do business, and its primary purpose is to ensure that the public has a meaningful way to participate in what you do.

That's it.

DR. McCABE: Thank you very much.