Transcript of FDA Media Briefing on New Policies for Managing FDA Advisory Committees

FTS-HHS FDA

Moderator: Christopher DiFrancesco
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Coordinator: Good morning and thank you for waiting.

All participants will be able to listen only until the question and answer portion of the call. At that time, to ask a question, please press star 1. Please state your name and affiliation.

This conference is being recorded. If you have any objections, you may disconnect at this time.

I would like to introduce your speaker for today's call, Mr. Christopher DiFrancesco.

Sir, you may begin.

Christopher DiFrancesco: Thanks very much, Grace.

Again, this is Chris DiFrancesco with the Food and Drug Administration's Office of Public Affairs, and this is an FDA teleconference for credentialed media to discuss this morning's announcement of new policies for managing the FDA's advisory committees.

With me today are Dr. Randall Lutter, Deputy Commissioner for Policy, Bill McConagha, Assistant Commissioner for Accountability and Integrity, Jill Hartzler Warner, a Senior Policy Advisor and Counselor, and Dr. Michael Ortwerth, Director of the Advisory Committee Oversight and Management staff.

Dr. Lutter will make a few brief remarks and then we move into a question and answer segment where all of our experts will be able to answer your questions about the announcement.

Reporters will be in listen-only mode until we open up for questions.

The news release announcing the new policies has been sent to reporters on our media list, as well as posted to the FDA's Web site at www.fda.gov.

Thank you and I'll now turn the call over to Dr. Lutter.

Randall Lutter: Thank you very much, Chris.

The FDA's Advisory Committee provides important expert scientific and technical advice in public to FDA and important regulatory decisions. The advisors are experts recognized for their scientific and professional credentials.

So, for example, let's say we were deciding whether to approve how to label a new drug for diabetes. We want to get expert opinion from clinicians and statisticians about the efficacy and safety data, as well as specific labeling language.

We'll convene a meeting of Endocrinologic and Metabolic Drugs Advisory Committee to help us make those decisions.

While FDA will make the final decision, advisory committee meetings assure that we're getting the best available expert advice on important decisions that affect the health and safety of the public.

As part of FDA's mission to protect and promote public health, we continually improve the way we make regulatory decisions and communicate them to the public.

Today, we're announcing a package of improvements to FDA advisory committees and these are designed to enhance decision making, increased transparency and strengthen public confidence and trust.

The first announcements are new policies on how we will address potential conflicts of interest, financial ties that advisors may have to certain companies.

First, we are finalizing guidance that puts a general cap of $50,000, as the maximum amount of personal financial interest an advisor or his spouse and minor children may have in all companies affected by a particular meeting.

Over $50,000, the advisor will not be allowed to serve on that meeting; if less than $50,000, we'll grant a waiver provided we determine the waiver is necessary to afford advisory committee essential expertise.

These policies go well beyond the legal requirements enacted recently by Congress.

Second, the guidance has four scenarios where the conflict is significant and we will not issue a waiver even if the potential conflict is below $50,000. For example, if the advisor is a principal investigator of a clinical trial of a product about which the committee will be providing advice, the investigator will not be allowed to participate in that meeting.

Third, we're finalizing guidance that will insure that when FDA grants such a waiver, the circumstances of that waiver will be made clear and transparent to the public. All waivers and advisors' disclosures with potentially conflicting interests will be posted at the FDA Web site.

New templates for waivers and financial interest disclosure will make them clear and more consistent. These changes will make facts in the decision-making process surrounding the decision to waiver clear to the public.

The next several points also involve transparency enhancing communication with the public. We are finalizing guidance that establishes our policy to post all meeting briefing material on our Web site no later than eight hours after the meeting.

We are simplifying our Web site, making it easier to access news on advisory committee meeting dates, agendas, financial disclosures and briefing materials.

So, for example, you'll find briefing materials in two clicks from FDA's advisory committee Web site, as opposed to the eight clicks that you used to need.

Now, we'll also provide opportunities for consumers to provide feedback on our advisory committee and the advisory committee Web site and we'll post summaries of that feedback.

Further, we're improving the way advisory committees vote, by finalizing today, guidance to implement simultaneous voting; all committee members voting at the same time to avoid any perception that they may influence each other's vote.

And finally, we're proposing guidance on when to convene advisory committee meetings. In some instances, FDA is required by law to refer and issue to an advisory committee. In others, it has discretion to consider whether to refer a matter to an advisory committee.

The guidance proposes the FDA consider three factors when deciding whether to voluntarily refer a matter to an advisory committee. It proposes that when one of these factors is met, FDA should refer the matter to an advisory committee. Conversely, if none of the factors is met, FDA shouldn't refer the matter.

The guidance also proposes that for all first of a kind or first in class products for human use, FDA either refer the product to an advisory committee or provide an action letter for that meeting, a summary of the reasons why it did not refer the product to an advisory committee before approval.

These improvements that I've discussed will help insure that FDA is getting the highest quality scientific advice while, at the same time, preserving public confidence and trust in our regulatory decisions.

Christopher DiFrancesco: Dr. Lutter, thanks very much.

Grace, we'll now open it up for questions, please.

Coordinator: Thank you. At this time, if you would like to ask a question, please press star 1. I will announce you by your first and last name. Please state your affiliation before asking your question.

Once again, to ask a question, please press star 1.

One moment for our first question.

Jennifer Smith, you may ask your question.

Jennifer Smith: Hello?

Coordinator: Jennifer Smith, you may ask your question.

Jennifer Smith: Can you hear me here?

Sorry about that. I was on a headset. I was trying to figure it out. Okay.

First of all, my first question that I have is a follow-up was, I guess that when it comes to the first four guidances have been finalized. Are there any significant differences or any changes between the draft and the final? I'll start off there. And has FDA already been doing - been using these guidelines informally? And if so, how is that going or is that putting extra stress on FDA to do that?

Dr. Lutter: Now, that's a very big question. So maybe what we can do is respond to it in parts.

Jennifer Smith: Okay.

Dr. Lutter: Since there's four guidances, I think maybe, Jill, you can handle the one on waiver of conflicts of interest and also on the disclosures. And Bill, you can do the two others?

Jill Hartzler Warner: That's great. Thank you, Randy.

This is Jill Hartzler Warner. As to your first question about changes...

Jennifer Smith: Right.

Jill Hartzler Warner...from the draft status to the final guidance that we're announcing today. The guidance on when to grant a waiver and eligibility for participation in FDA advisory committee meetings...

Jennifer Smith: Okay.

Jill Hartzler Warner...did incorporate all changes from the draft items. We made these change in response to numerous public comments that we received and also in order to establish compliance with the new legislative provisions that were announced in 2007 that added the new laws to the way we look at conflicts of interest.

Jennifer Smith: You mean for FDAAA?

Jill Hartzler Warner: That's correct.

Jennifer Smith: Okay.

Jill Hartzler Warner: That's correct. So, as Randy mentioned, we are putting a cap of $50,000 on personal financial interests.

Jennifer Smith: Okay.

Jill Hartzler Warner: The financial interests that are imputed to the advisory committee member, such as the financial interests of a university that employs a member, are not subject to the $50,000 maximum.

Jennifer Smith: Okay, I just want to make sure I understand that. So

((Crosstalk))

Jennifer Smith: ...imputed to...okay.

Jill Hartzler Warner: So, a number of other changes actually, we are now going to apply this test of making sure that the advisor has essential expertise for the advisory committee before we would consider granting a waiver. So, we're going to apply that to all waivers and so that's the change from the draft as well.

Jennifer Smith: Okay. I'm sorry. So beforehand with their draft guidance tied to universities, those were included under the $50,000 cap.

Jill Hartzler Warner: That's right. We had made a very broad brush cap . But as the public comments pointed out, it's a very different situation when a university, you know, receives a grant that is not directly tied to that advisory committee member.

Jennifer Smith: I see what you're saying. Okay.

Jill Hartzler Warner: And there were a number of other changes as well, but those were the major differences from the draft, as well as some other differences to the...

Jennifer Smith: Okay.

((Crosstalk))

Jill Hartzler Warner...the legislative changes.

Jennifer Smith: The second one, I'm sorry, I didn't quite understand - I didn't quite understand what you were saying about a pretty big change to - I just didn't get what that was.

Jill Hartzler Warner: Okay. Under, we have a number of laws that we have to administer and there are some waivers that require us to do sort of a balancing test as to whether the financial interest that poses a potential conflict is outweighed by the need for that, that employee to participate.

Jennifer Smith: Right. Okay.

Jill Hartzler Warner: But, we're actually going to apply a more strict test. And now...

Jennifer Smith: Okay.

((Crosstalk))

Jill Hartzler Warner...we say, if this employee, is this advisor needed? Is the expertise so essential that we need him on our advisory committee...?

Jennifer Smith: Okay.

Jill Hartzler Warner...in order to provide that committee with essential expertise?

Jennifer Smith: Okay, okay.

Jill Hartzler Warner: That's the strict standard that we're going to apply to every waiver now.

Jennifer Smith: To every waiver, okay. Okay. All right. Will apply that waiver - okay.

So you think this is an example here too and that this is a conflict of waiver and a disclosure guidance document?

Jill Hartzler Warner: The disclosure guidance documents, as we're finalizing it today, it does not make major changes to the draft.

Jennifer Smith: Okay.

Jill Hartzler Warner: That's fairly similar to the draft.

Jennifer Smith: Okay.

Jill Hartzler Warner: And, I believe, Bill, will address the other two guidances that we're finalizing today.

Bill McConagha: Yeah, hi, this is Bill McConagha, Assistant Commissioner for Accountability and Integrity.

Jennifer Smith: Oh, right. Hi, Bill.

Bill McConagha: With respect to the voting guidance and the - and the disclosure of the briefing material guidance, they are substantively very similar to the draft. We did make some changes in language based on the comments which we carefully reviewed for both of them.

Also, with respect to the briefing materials, there - it was suggested in the comments that the timelines that we had offered in the appendices were - were not entirely clear and might confuse some - some readers so we made an effort to make each of those appendices more thorough and easier to understand as a standalone appendix.

Jennifer Smith: Okay.

Bill McConagha: And so, I think you'll see that what we really tried to do in both documents was improved clarity.

Jennifer Smith: Okay. Okay. Fantastic. Okay.

And then I was asking as to, has the FDA been using these, you know, these guidelines informally? And I was wondering how that's going for FDA in a sense is that, I mean, is there kind of more effort on FDA's part to try to apply this criteria and is it causing more work on FDA's part, like having to, you know, maybe to file four inquiries for a member with no financial interests? I mean, yes, financial interests as opposed to one inquiry? You know, I'm trying to see how this is going for the FDA.

Randall Lutter: Let me - this is Randall Lutter.

Jennifer Smith: Okay.

Randall Lutter: With respect to the conflicts of interest criteria, we have not taken steps to implement the new criteria that we put out for public comment in - in earlier last year.

Jennifer Smith: Okay.

Randall Lutter: That was submitted only for public comment and...

Jennifer Smith: Okay

Randall Lutter: ...and now that we're finalizing it, we will, after an implementation period that allows us to - time to insure that we apply this to the committees for which conflicts of interest decisions have not already been made, meaning the committees that are not holding meetings next week.

Jennifer Smith: Okay.

Randall Lutter: After that implementation period, we will, henceforth, go forward with the new criteria that Jill Warner has described.

With respect to the other guidances, I think Jill and Bill can talk to you about the status of those.

Jennifer Smith: I'm sorry, what was the implementation period, Randall? Like how long will that be about?

Randall Lutter: It takes - it takes us a matter of some weeks...

Jennifer Smith: Okay.

Randall Lutter: ...to review waivers and the potential conflicts of interest and make decisions about whether or not waivers are granted...

Jennifer Smith: Okay.

((Crosstalk))

Randall Lutter: ...to grant them and that implementation period is 120 days.

Jennifer Smith: Okay.

Randall Lutter: So 120 days from today will be - and henceforth, we will follow all meetings after that date will follow the new criteria for granting waivers of conflicts of interest.

Jennifer Smith: Great. Thank you.

Bill McConagha: Just to be clear on that. The criteria for the waivers has an implementation date of 120 days.

The other three guidances, which are being finalized today, are effective immediately.

Jennifer Smith: Oh, so somebody said (unintelligible) to differentiate that. (Unintelligible) it's the conflicts of interest - that's a specific name for that guidance, that's 120 days. But the other three guidances, that is effective immediately.

Bill McConagha: And, again, the reason is, as Dr. Lutter just described was that the conflict of waiver issue, the analyses that go into those decisions occur over a period of time and so what we wanted to make sure was that this guidance didn't

somehow impact decisions that have already been made or currently in process. The idea was to give us a period of time to start fresh with decisions that we'll just begin to work on in the days to come.

Jennifer Smith: Okay. Great, thank you.

Christopher DiFrancesco: Jennifer, thanks for your questions.

Grace, could we move to the next question please.

Coordinator: Sue Sutter, you may ask your questions.

Sue Sutter: Hi, Sue Sutter with "Scrip World Pharmaceutical News" -- sort of a two-part question.

In the original draft guidance on waivers, I believe it said that there were conflicts of less than $50,000 that person could be allowed to participate in the meeting but could not vote. Now has that changed from the original proposal?

And also, do you anticipate more difficulty in recruiting members for advisory committees as a result of these - finalizing these new procedures? I know the agency had to cancel a two-day meeting recently with the peripheral nervous system drugs because it was having trouble finding members.

Jill Hartzler Warner: This is Jill Hartzler Warner. Thank you for your question.

We certainly, just to take your last question first, your last comment. We certainly see recruitment of those advisors with minimal or no conflicts as a very important, primary goal. And we have, in fact, stepped up recruitment to

a significant degree. Just to throw some numbers at you, we've contacted in the past year, almost 280 professional organizations to recruit new members.

We've published six Federal Register notices, calling for nominations of new members. We've emailed almost 400 communications seeking new nominees to individuals and groups. And we've attended professional meetings.

We've gotten many, many CVs submitted through our Web site portal for nomination - 350 at this point.

So we're very, very much looking at recruitment of advisory committee members as a way to meet our goals to actually reduce the numbers of waivers that we grant.

In terms of the guidance on eligibility for participation in advisory committee meetings and conflicts of interest, we did make a number of changes from the draft guidance. There are really four major, major differences and some other differences as well.

As you mentioned, on voting, we have decide to not restrict all waivers to non-voting. Waivers may be voting or non-voting at the discretion of the agency. This is consistent with the FD Triple A (FDAAA) amendments that were mentioned earlier.

We have in the guidance actually enumerated certain circumstances where the conflict of interest we believe is significant. And so even if under $50,000 we would not issue a waiver. We have incorporated a cap on the number of waivers that we will grant. And that's in accordance with the Food and Drug Amendments Act.

These are the major differences in addition to the ones that we talked about earlier. The $50,000 cap on personal financial issues and that cap that expert has to be very essential to the needs of the committee in order to receive a waiver.

So I hope that helps you with your question.

Sue Sutter: Okay. Can you tell me why you eliminated the requirement that they not be allowed to vote? Was there a lot of push back on that?

Jill Hartzler Warner: We had a significant - a very, very large number of public comments and there were some concerns about voting.

We also looked very carefully at the intersection of the new laws that's in the Food and Drug Amendments Act with the other provisions - the criminal provisions that we have to apply that are applicable to all government advisory committee meetings.

And there was a change in the law and the voting became not so much an issue of trying to - to get these laws to sort of mesh with each other and harmonize. And so we did decide that we could leave that to FDA discretion. If the conflict is one that we feel there should be limitations on the advisor's participation; we can issue a non-voting waiver.

We can also decide not to allow that person to participate except as a speaker and in that way limit the participation of that advisor.

So there are numerous things that we can use to limit participation where needed.

Sue Sutter: Okay. Thank you.

Jill Hartzler Warner: Thank you.

Christopher DiFrancesco: Thanks, Sue. Grace, can we have the next question, please?

Coordinator: Jessica Bylander, you may ask your question.

Jessica Bylander: Hi, I'm Jessica Bylander with "The Gray Sheet." You've sort of pressed on this, but in the device field especially, there may be few experts on a given device and they're frequently involved in the study. Does the policy allow for that to be sure there is an expert on a particular device?

Jill Hartzler Warner: I'm sorry. Can you repeat that question?

Jessica Bylander: Sure. You kind of talk about it in the last question as well but, specifically, in the device field, there may be few people who are experts on a given device and they may be frequently - are involved in the study. Do these policies allow for that or, is there - how are you going to insure that there is some expert on a given device?

Jill Hartzler Warner: This is Jill Hartzler Warner again.

You bring up an important issue and that's how do we reconcile, you know, through these strict standards with also getting the experts that we need.

We feel that we've struck that balance by looking really at expertise and we may be talking about expertise and not in just a particular device, but in a broad sense, clinical expertise, statistical expertise.

Whatever expertise that is needed on that committee to - in order to convene a full and balanced committee, that's what we're going to be looking at under that test for essential expertise.

We do feel that this balance will give us the expertise we need while also establishing, but also maintaining the public trust and confidence in our procedures.

Jessica Bylander: And with the recruitment you mentioned, I guess, is that going as well on both sides of the drug and device field? Or how's the response from different device recruitment been going?

Jill Hartzler Warner: That's correct. Our recruitment is really for across the board. All of our advisory committee meetings and advisory committees, we have, as you know, all the centers as well as advisory committees in the Office of the Commissioner and we're recruiting in all of those areas.

Jessica Bylander: Successfully, so far.?

Michael Ortwerth: Hi, this is Michael Ortwerth. Yes, we are getting responses from all centers in terms of input for vacancies on our committees.

As the point you want to mention, the CVs that are submitted to the agency, 350 in the past 12 months, those are coming in for all of our different centers and CDRH as well.

So, we're getting a lot of information and we are keeping contact with a number of organizations in the device area, professional organizations to make sure that we have our finger on what the interests of the CDRH community is.

Jessica Bylander: Okay, thank you.

Christopher DiFrancesco: Thanks, Jessica. Grace, could we have the next question please.

Coordinator: Jared Favole you may ask your question.

Jared: Hi, this is Jared Favole of Dow Jones. Thank you for taking my questions.

I just have two. One is, is there a current cap for conflict of - for, I guess, personal financial interest, is there a current cap already in place? What is that cap? And then, why was $50,000 chosen as the number?

Jill Hartzler Warner: Thank you for your question. This is Jill Hartzler Warner.

FDA decided to put a limit of $50,000 on personal financial interest with this policy that we're finalizing today. There is no previous cap and it is not required by the existing law. So we're going actually beyond the existing law to put this limitation on.

We're adopting the $50,000 limit after carefully considering all the public comments we received on this limit last year. And we analyzed its implications in light of our need for experts and for public trust in our advisory committee processes.

Jared: Okay, and just a follow-up to make sure I'm clear on this. So this is only personal financial, I guess, investments. We're not talking about, you said, I think you brought up affiliations to a university or grants or anything like that does not play a part into this $50,000 cap. Correct?

Jill Hartzler Warner: That's correct.

Jared: So, it'd be like if somebody has $50,000 worth of shares or their, I guess, spouse does - that's the type of stuff we're talking about. Correct?

Jill Hartzler Warner: I'm sorry do I understand that you were giving me an example of stock ownership?

Jared: Yes, something like that, even if it's the spouse I think you said it applies to the family. Right?

Jill Hartzler Warner: That's right. That would be considered a personal financial interest, even if it's the spouse or the minor children.

Jared: And then, out of curiosity, how do you, I guess, get that information from someone? Do they have to, you know, I guess, give that out voluntarily to be a part of an advisory committee?

Jill Hartzler Warner: Yes, there are legal requirements where a financial - where a financial disclosure is required to the agency, a very full financial disclosure that the potential advisory committee member makes. And we carefully scrutinize those documents.

Jared: Okay, thank you very much.

Christopher DiFrancesco: Thanks, Jared. Grace, can we have the next question, please?

Coordinator: (Elizabeth Crawford), you may ask your question.

(Elizabeth Crawford): Hi, this is (Elizabeth Crawford). I'm with the (TNC). Thanks for taking my question.

I understand that some of the committees are already implementing some of these procedures such as the simultaneous voting. I'm curious which elements of these items are completely new change from this point forward.

Bill McConagha: Hi, this is Bill McConagha once again, with the Office of Accountability and Integrity.

It is true that say with respect to the voting guidance, there - the agency has, on some level, tried to adopt some of these ideas as best practices. But, let me be clear that they the way the agency implements guidances, we call our good guidance practice, which is set forth in our regulations.

And the idea is these are all new policies, inasmuch, as we have now formalized the expectation that all FDA employees will adhere to these as a function of good guidance practice at the agency. And, while in the case of the simultaneous voting, it is true that some of the ideas that are included and these guidances have kind of informally been practiced for a short time. What we have today is a kind of new formalized expectation of all FDA employees to adhere to these guidances and the concepts they set forth moving forward.

(Elizabeth Crawford): Okay, thank you.

Christopher DiFrancesco: Thank you, (Elizabeth). Grace, can we have the next question.

Coordinator: (Mark McCarty), you may ask your question.

(Mark McCarty): Hi, I'm (Mark McCarty) from "Medical Device Daily," and thanks for answering my question.

One quick question and it's kind of a two-parter. Is there a minimum number of voting members? I don't' know if it's determined as an absolute number or as a percentage of the desired number of appointed members. And, if you don't have a quorum, do you reschedule the advisory committee hearing or how do you handle that?

Michael Ortwerth: Hello, this is Michael Ortwerth, Advisory Committee Oversight. In terms of a quorum, generally according to the Charter, a quorum is considered as one person greater than half of the standard membership of the committee.

Now, with that said, we also have the ability to augment our committees with special government employee experts, should there not be a pro forma of members - standing members on the committee. So we really don't have an issue or have not had an issue before not having a quorum for a meeting.

(Mark McCarty): Okay.

Christopher DiFrancesco: Thanks very much, (Mark). And thank you everyone.

That's all the time we have scheduled for this briefing but we can respond to additional questions offline,

If you have additional questions, please email me at christopher.difrancesco@fda.hhs.gov. That contact information is on our Web site. And again, the guidance documents and a fact sheet summarizing all five guidance documents is available on the Web site.

This concludes the briefing. Thanks to Randy, Bill, Jill and Michael for your time and thanks to everyone for participating.

Man: Thank you.

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