

1 of their own research?

2 CHAIRMAN FISCHHOFF: I think that  
3 you need the in-house people in order to do  
4 the outreach to bring in the other expertise.

5 So that was my intent. I don't think it says  
6 that.

7 MEMBER KHANNA: I think that's open  
8 interpretation because of the word "execute."

9 So I think you're covered.

10 CHAIRMAN FISCHHOFF: Okay. So let  
11 me read it again.

12 "The Committee applauds FDA's  
13 commitment to creating the in-house scientific  
14 workforce needed to execute its strategic  
15 communication plan. The Committee recommends  
16 that FDA develop an organizational structure  
17 that ensures that individuals with the needed  
18 expertise are recruited, retained and  
19 effectively integrated with its operations."

20 I think that would be wording that  
21 would include rotators and post-docs and  
22 fellowships and other kinds of things, because

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1 your workforce doesn't all have to be, you  
2 know, from the government employees.

3 MEMBER KHANNA: So you read  
4 "needed," but you still have "necessary"  
5 there. Did you want to change "necessary" to  
6 "needed?"

7 CHAIRMAN FISCHHOFF: "Needed," is I  
8 think -- we're saving a syllable. Yes.

9 MEMBER BRUHN: But then you have  
10 "needed" twice. I thought "necessary" was  
11 nice.

12 CHAIRMAN FISCHHOFF: Okay.

13 MEMBER KHANNA: It's a tough crowd,  
14 Baruch.

15 CHAIRMAN FISCHHOFF: Okay. Any  
16 further suggestions?

17 Those who favor this  
18 recommendation?

19 Those who are opposed?

20 Those who abstain?

21 Either you're getting tired or you  
22 favored, opposed and abstained. No, your hand

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1 came down slowly.

2 You have not traditionally been a  
3 fence sitter.

4 MEMBER KHANNA: Whichever slot you  
5 need filled.

6 CHAIRMAN FISCHHOFF: Okay.

7 MEMBER KHANNA: That's where I  
8 voted.

9 CHAIRMAN FISCHHOFF: No, no, no,  
10 no. Strike that from the record.

11 Okay. All right. The next one.  
12 "The Committee applauds FDA's commitment to  
13 producing an evaluating its communications to  
14 a scientific standard. The Committee  
15 recommends that as part of its continuing  
16 efforts FDA develop a work flow system for  
17 ensuring that communication needs are  
18 integrated into its operation so that its  
19 scientific create, summarize, and deliver the  
20 information that its communication researchers  
21 identify as needed in time to allow proper  
22 evaluation."

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1 Ma'am?

2 DR. OSTROVE: Can I ask a  
3 clarification?

4 CHAIRMAN FISCHHOFF: Yes.

5 DR. OSTROVE: Because we have in  
6 the same sentence "its scientific staff  
7 create, summarize, and deliver the information  
8 that is communications" -- never mind. I take  
9 it --

10 CHAIRMAN FISCHHOFF: Yes, I mean,  
11 would "technical staff" -- what I mean is the  
12 people who do --

13 DR. OSTROVE: Right.

14 CHAIRMAN FISCHHOFF: You know, the  
15 subject matter experts.

16 DR. OSTROVE: Right.

17 CHAIRMAN FISCHHOFF: So "scientific  
18 staff" is bad --

19 DR. OSTROVE: It kind of then  
20 implies --

21 CHAIRMAN FISCHHOFF: -- because it  
22 suggests that we're not scientists.

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1 DR. OSTROVE: Right.

2 CHAIRMAN FISCHHOFF: On the other  
3 hand, if we call them technical staff that  
4 puts them -- that might be viewed as putting  
5 them down, but maybe they'll understand what  
6 technical staff is. Maybe that's a better  
7 word. "Subject matter?"

8 DR. OSTROVE: "Subject matter  
9 experts" or -- that's a tough one.

10 CHAIRMAN FISCHHOFF: "Subject  
11 matter" might actually be --

12 MEMBER GOLDSTEIN: "Professional?"

13 CHAIRMAN FISCHHOFF: "Substantive"  
14 is one of my favorites. "Subject matter."  
15 Maybe that's better.

16 No? Okay. Little clumsy, but  
17 that's probably better descriptive.

18 DR. OSTROVE: Yes, because the  
19 problem comes into you see "scientific" and  
20 then you see "communications" and so it  
21 implies that the communications are not  
22 scientific.

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1 CHAIRMAN FISCHHOFF: Right. And  
2 make this "subject matter."

3 MEMBER KHANNA: Now you're implying  
4 that the subject matter be scientific experts.

5 CHAIRMAN FISCHHOFF: I'll read it  
6 from the top and we can entertain changes.

7 "The Committee applauds FDA's  
8 commitment to producing an evaluating its  
9 communications to a scientific standard. The  
10 Committee recommends that as a part of its  
11 continuing efforts FDA develop a work flow  
12 system for ensuring that communication needs  
13 are integrated into its operations so that its  
14 subject matter experts create, summarize, and  
15 deliver the information that its communication  
16 scientists identify as needed in time to allow  
17 proper evaluation."

18 So we could take out "as part of  
19 its continuing efforts." But I didn't want  
20 say this was the only thing that they went  
21 through. That would save us six words.

22 MEMBER MAYER: I don't think that's

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1 the problem. I think you just need to break  
2 it into two sentences.

3 CHAIRMAN FISCHHOFF: Okay. Okay.

4 MEMBER PETERS: May I ask a  
5 question first?

6 CHAIRMAN FISCHHOFF: This gets us  
7 to a Flesch index of eight years of graduate  
8 school with that simplification.

9 MEMBER PETERS: A quick question,  
10 if I may? Are the communication scientists  
11 always the ones who are identifying the needed  
12 information? Don't the subject matter experts  
13 do that as well to some extent? So the  
14 amendment would really just be "and deliver  
15 the needed information in time to allow proper  
16 evaluation."

17 CHAIRMAN FISCHHOFF: Well, so what  
18 I wanted to capture here was the backflow that  
19 the communication people will say people want  
20 to know about how this works with real people.  
21 People want to know how this drug will work.  
22 You know, if people don't always take their

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1 drugs or may be taking other drugs, who  
2 sometimes don't refrigerate things the way  
3 they want. So I actually want the  
4 communication scientists essentially to  
5 identify the topics. That's what I was  
6 thinking. They ought to have a hand in  
7 identifying the topics. They identify the  
8 variables and then the subject matter experts  
9 provide the estimates. So that's why I wanted  
10 to have them in that role.

11 MEMBER KHANNA: But, I mean,  
12 Ellen's point is valid that it shouldn't be  
13 exclusive. Would it work if you put the word  
14 "help" before "identify?"

15 MEMBER BRUHN: I have a suggestion  
16 for this. I thought we liked having them work  
17 together. Wasn't that suggested as one of the  
18 models? Instead of having a line item, then  
19 it goes back and forth. It's they're working  
20 together. So might that be modified to "its  
21 subject matter and communication scientists,"  
22 so they're both together?

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1                   CHAIRMAN      FISCHHOFF:            Yes,  
2            excellent.

3                   MEMBER BRUHN:    Then you get rid of  
4            the rest of the line.

5                   CHAIRMAN FISCHHOFF:    Yes, I know.  
6            Why is there a little green line under  
7            "scientist?"

8                   MEMBER KHANNA:    To play with your  
9            mind.

10                  CHAIRMAN FISCHHOFF:    Are we going  
11            to take on Microsoft Word? Can I put that to  
12            a vote?

13                  Let me read it from the top so we  
14            get a feel for it and then we -- oh, Mike. Go  
15            ahead.

16                  MEMBER GOLDSTEIN:    In order to get  
17            the iterative piece, we can use "refine" after  
18            "deliver." So "work together to create,  
19            summarize, deliver, and refine," or "revise"  
20            or something like that.

21                  CHAIRMAN FISCHHOFF:    Say what you  
22            mean by "refine."

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1                   MEMBER GOLDSTEIN: As you said, to  
2 use the information that comes from the  
3 studies to refine and improve the  
4 communication messages.

5                   CHAIRMAN FISCHHOFF: Okay.

6                   MEMBER GOLDSTEIN: It's a cyclical  
7 process.

8                   CHAIRMAN FISCHHOFF: Yes, but just  
9 as a biostatistician on a review team would  
10 say, you know, we have to take this additional  
11 slice of the data in order to get a good  
12 picture of the physiological responses.  
13 Somebody might say, you know, we really got to  
14 disaggregate this for men and women because  
15 they want to know different things about this.  
16 So that would be a refinement that would come  
17 from somebody who's representing the public.

18                   MEMBER MAYER: "Refine" should  
19 precede "deliver."

20                   CHAIRMAN FISCHHOFF: Yes. That's  
21 right. Yes. Yes. Absolutely. Yes. Okay.  
22 Absolutely. Yes. Excellent.

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1 I'll read it again. Okay.

2 "The Committee applauds FDA's  
3 commitment to producing and evaluating its  
4 communications to a scientific standard. The  
5 Committee recommends that as part of its  
6 continuing efforts FDA develop a work flow  
7 system for ensuring that communication needs  
8 are integrated into its operations. The  
9 system will ensure that its subject matter  
10 experts and communication scientists work  
11 together to create, summarize, refine, and  
12 deliver needed information in time to allow  
13 proper evaluation."

14 Okay? Those in favor?

15 Those opposed?

16 And those abstaining?

17 Okay. Thank you.

18 Next one. "The Committee  
19 recognizes that current interpretations of the  
20 Paperwork Reduction Act hamper FDA's ability  
21 to evaluate its communications to a scientific  
22 standard in a timely fashion and with

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1 adequately diverse samples. The Committee  
2 recommends that FDA: (A) identify the public  
3 welfare implications of not testing its  
4 communications; and (B) submit a proposal to  
5 the Office of Management and Budget for an  
6 evaluation protocol that balances the public  
7 welfare concerns of FDA's mandate and of the  
8 Paperwork Reduction Act."

9 John?

10 MEMBER PALING: I'll take your  
11 guidance on this. I totally approve of the  
12 wording and the message so much so that I  
13 question is it valuable putting this as Number  
14 2 in this list?

15 CHAIRMAN FISCHHOFF: Yes, that's an  
16 interesting question and let's address it at  
17 the end.

18 "Hampers," I would say is a  
19 stronger word than "limits." When I was  
20 typing it, "limits" was an alternative and I  
21 used "hampers," but that was a word choice  
22 that I made.

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1 Musa?

2 MEMBER MAYER: I'm just afraid that  
3 the effectiveness of the final sentence is  
4 diminished because it's so long and complex.  
5 I'm wondering if it couldn't be also broken up  
6 so that (A) and (B) -- "The Committee  
7 recommends two points," or something like  
8 that. First --

9 CHAIRMAN FISCHHOFF: Okay. Yes.

10 MEMBER MAYER: -- that, second  
11 that, you know? Yes, two, T-W-O.

12 Might be stronger to say "first"  
13 and "second" rather than "A" and "B."

14 CHAIRMAN FISCHHOFF: Okay.

15 MEMBER MAYER: Read it.

16 CHAIRMAN FISCHHOFF: Okay. Let's  
17 try it from the top. "The Committee  
18 recognizes that current interpretations of the  
19 Paperwork Reduction Act hamper FDA's ability  
20 evaluate its communications to a scientific  
21 standard in a timely fashion and with  
22 adequately diverse samples. The Committee

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1 makes two recommendations to address this  
2 problem. First, FDA should identify the  
3 public welfare implications of not testing its  
4 communications. Second, FDA should submit a  
5 proposal to the Office of Management and  
6 Budget for an evaluation protocol that  
7 balances the public welfare needs of FDA's  
8 mandate and of the Paperwork Reduction Act."

9 I think I'll make this a  
10 "communication evaluation protocol."

11 MEMBER PETERS: You also said the  
12 word "needs," but you have written down there  
13 the word "concerns." And I think "needs" is  
14 actually better.

15 CHAIRMAN FISCHHOFF: Which line?

16 MEMBER PETERS: The very last  
17 sentence, the second-to-last line. "The  
18 public welfare needs."

19 CHAIRMAN FISCHHOFF: Oh, okay.  
20 Yes. Yes, that was a weak word. Yes, that's  
21 better.

22 Mike?

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1                   MEMBER GOLDSTEIN:    Do we want to  
2                   add the term "representative" to "diverse" in  
3                   the first sentence?   "Adequately diverse and  
4                   representative samples," or is it unnecessary?

5                   CHAIRMAN FISCHHOFF:   I think that's  
6                   unnecessary and it will kind of get us from  
7                   the six to the seventh year graduate school  
8                   reading level.   Yes.

9                   Does somebody know,   it's the  
10                  Paperwork Reduction Act of 1980?  Or was there  
11                  a revision?   Anybody know what year it is?  
12                  Nevermind.   Okay.

13                  MEMBER ANDREWS:   It says 1990.

14                  DR. OSTROVE:    It's 1990.

15                  CHAIRMAN FISCHHOFF:   Okay.  I think  
16                  we ought to show them we know our stuff.

17                  MEMBER MAYER:    One more little  
18                  point, but the way you've got it, the very  
19                  last phrase, "the Paperwork Reduction Act"  
20                  seems to be modified by "public welfare."  
21                  Wait a minute.

22                  CHAIRMAN FISCHHOFF:   Yes, that was

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1 meant to be "the public welfare needs of."  
2 Each of them has public welfare needs.

3 MEMBER MAYER: Oh, okay.

4 CHAIRMAN FISCHHOFF: That's what I  
5 was trying to capture.

6 MEMBER MAYER: So what would be the  
7 public welfare need of not doing research?

8 CHAIRMAN FISCHHOFF: That we not  
9 --

10 MEMBER MAYER: Of having this  
11 cumbersome process to -- I can't get my mind  
12 around how the public is --

13 CHAIRMAN FISCHHOFF: Yes. Well, I  
14 think you're probably in good company.

15 MEMBER MAYER: -- actually served  
16 by that.

17 DR. OSTROVE: No, it's undue burden  
18 on the public of excessive requests or demands  
19 for information from the public that may be  
20 duplicative or overly burdensome. So, you  
21 know, if there are a lot of different  
22 agencies, for instance, all collecting

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1 information, then there may be duplication of  
2 effort and I think the concern is to avoid the  
3 public being unduly burdened by duplicative  
4 and unnecessary also, by duplicative and  
5 unnecessary requests for information.

6 CHAIRMAN FISCHHOFF: Yes. And I  
7 actually think, you know, were this to be  
8 executed, I think the execution would likely  
9 show economies of scale that you -- or is it  
10 scope? Maybe economies of scope that if FDA  
11 did this in a concentrated way, there would be  
12 basic templates for how to communicate.  
13 They'd be adapted for classes of products.  
14 And there would be some work done to show how  
15 this would be done most efficiently, which  
16 would then address these legitimate concerns  
17 of not burdening the public. And whatever  
18 they were, you know, however they are balanced  
19 against the public welfare concerns of  
20 ensuring that people use regulated products  
21 appropriately you'd still want to minimize  
22 those by an efficient plan.

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1                   MEMBER MAYER: Okay. I understand.  
2            Would it be better to say instead of "and of"  
3            versus "those of?" I mean, maybe it's just  
4            me, but was the end of that sentence  
5            completely clear to everybody but me? I mean,  
6            what I'm suggesting is a little more wordy,  
7            but it makes it really explicit.

8                   CHAIRMAN FISCHHOFF: I didn't want  
9            to put in "versus" because that implies an  
10           opposition. I would like to afford both them  
11           -- they're both laws and they're both --  
12           afford them their legitimacy. Maybe --

13                   MEMBER MAYER: Fair enough.

14                   CHAIRMAN FISCHHOFF: Okay. Let me  
15            read it again. "The Committee recognizes that  
16            current interpretations of the Paperwork  
17            Reduction Act of 1990 hamper FDA's ability to  
18            evaluate its communications to a scientific  
19            standard in a timely fashion and with  
20            adequately diverse samples. The Committee  
21            makes two recommendations to address this  
22            problem. First, FDA should identify the

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1 public welfare implications of not testing its  
2 communications. Second, FDA should submit a  
3 proposal to the Office of Management and  
4 Budget for a communication evaluation protocol  
5 that balances the public welfare needs of  
6 FDA's mandate and those of the Paperwork  
7 Reduction Act."

8 MEMBER MAYER: How about "with  
9 those?"

10 MEMBER WOLF: I think we've got to  
11 really limit the words here. I'm not really  
12 sure I see -- I don't know. I'm voting that  
13 it's okay.

14 CHAIRMAN FISCHHOFF: Okay.

15 MEMBER BRUHN: I like "with."

16 CHAIRMAN FISCHHOFF: Like "with?"  
17 "With?"

18 MEMBER BRUHN: Yes.

19 CHAIRMAN FISCHHOFF: Okay.

20 MEMBER WOLF: We're not terribly  
21 concerned with who's reading this, right?

22 CHAIRMAN FISCHHOFF: What?

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1                   MEMBER   WOLF:           Not    terribly  
2   concerned with who's reading this, right?

3                   CHAIRMAN FISCHHOFF:   Okay.   So it's  
4   as I read it the last time with an "and"  
5   substituted with a "with."   So now it's been  
6   said for the record.

7                   Okay.   Any other suggested changes?

8                   Those who are in favor of this  
9   recommendation?

10                  Those opposed?

11                  Any abstentions?

12                  Okay.   Thank you.

13                  Okay.           So now which one is  
14   operative here?   There's two versions of the  
15   final conclusion.

16                  MEMBER BRUHN:   I thought the bottom  
17   was the most --

18                  CHAIRMAN FISCHHOFF:   Was the bottom  
19   the operative one?

20                  MEMBER BRUHN:   I think the bottom  
21   is the most recent one.

22                  CHAIRMAN FISCHHOFF:   Okay.

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1                   MEMBER PALING: Yes, and before you  
2 do it, can I just -- I'll say my last comment.

3           I like the penultimate one and I would  
4 suggest to satisfy my colleagues who have for  
5 good reasons difficulties with the word  
6 "publicize" we might add "and promote  
7 awareness of." And this would do the internal  
8 communications as well as the external.

9                   CHAIRMAN FISCHHOFF: Okay. I think  
10 "publicize" was problematic, but I think  
11 "promote awareness" is more neutral than  
12 "publicize." So if you will, maybe I'll just  
13 replace "publicize" with "promote awareness."

14                  MEMBER PALING: If it takes that to  
15 get it passed, yes. It's not my personal  
16 wish, but I will bow as usual to the group.

17                  CHAIRMAN FISCHHOFF: Okay. So  
18 since we have two somewhat thinkings there,  
19 let's take this chance to -- let me just pull  
20 these up to -- let's just look at those. And  
21 then a member of the audience has passed up a  
22 suggestion that's related to this. So let me

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1 just read this aloud, and there's a somewhat  
2 different set of words. So this was a  
3 proposed rewrite of this and I thank whoever  
4 sent this up for their penpersonship.

5 "The Committee recommends that FDA  
6 use the strategic communication initiative as  
7 an opportunity to underscore, or communicate,  
8 or reaffirm FDA's renewed commitment in  
9 leadership in fulfilling its mandate, or  
10 mission to help the public to make informed  
11 choices regarding the products that FDA  
12 regulates."

13 Maybe I'll type this up and then  
14 we'll have a third suggestion.

15 MEMBER BRUHN: I think that sounds  
16 very nice. Yes, type it up.

17 CHAIRMAN FISCHHOFF: Okay. There  
18 are two places where there alternative word  
19 choices. Something in the wording kind of  
20 gets back to John's original suggestion.

21 MEMBER PALING: I think it's so  
22 good, Mr. Chairman, that I would not only

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1 compliment the author, but also declare that  
2 it is so good that person should be sitting on  
3 this Committee in place of me. And that as of  
4 the meeting after next that opportunity will  
5 be available.

6 CHAIRMAN FISCHHOFF: Well, the  
7 question is, are you hiring?

8 Okay. So I'll read aloud, so we  
9 have it for the record, the suggestion from  
10 the audience. Although the wording came from  
11 the audience, this formally would be the  
12 Committee's recommendation.

13 "The Committee recommends that FDA  
14 use the strategic communication initiative as  
15 an opportunity to underscore, or communicate,  
16 or reaffirm FDA's renewed" -- that was with a  
17 caret, so I wasn't sure whether that was -- we  
18 could have that in or not -- "commitment in  
19 leadership in fulfilling its mandate, or  
20 mission to help the public make informed  
21 choices regarding the products that FDA  
22 regulates."

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1           Okay. So we need to make some word  
2 choices and then we can change anything or go  
3 back to the other ones.

4           Christine?

5           MEMBER BRUHN: I really like using  
6 "reaffirm." You then do not need the word  
7 "renewed." And for consistency would suggest  
8 "mission" be chosen. And the reason I like  
9 "reaffirm," it reminds us all that FDA has  
10 been striving to do this all along. And I  
11 think it's a very proactive positive  
12 statement.

13           CHAIRMAN FISCHHOFF:           Okay.  
14 AnnaMaria?

15           MEMBER DeSALVA: I want to suggest  
16 that we strike the "leadership" reference,  
17 which may sound strange, but you know good  
18 public affairs and public relations practice  
19 is to have your stakeholders experience you as  
20 leading and as doing important things that are  
21 making a difference and not for you to tell  
22 them that that's what you're doing.

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1 CHAIRMAN FISCHHOFF: Okay. Yes.  
2 You demonstrate leadership through your  
3 commitment interest.

4 MEMBER DeSALVA: Exactly.

5 CHAIRMAN FISCHHOFF: Okay. Good.  
6 That will save four syllables as well.

7 Yes, Musa?

8 MEMBER MAYER: I think that's  
9 right, too. Because I think John's original  
10 use of that had to do with a wish that the  
11 leadership of the FDA would take an active  
12 role, right? And that is understood here now,  
13 so we don't really need to say that, I think.

14 MEMBER PALING: Yes, I'm very  
15 comfortable with that.

16 CHAIRMAN FISCHHOFF: So I will  
17 strike the two previous drafts and we'll do a  
18 reading of the --

19 MEMBER DeSALVA: Sorry.

20 CHAIRMAN FISCHHOFF: Okay.

21 MEMBER DeSALVA: I'm really sorry.  
22 I don't mean to make people crazy about this.

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1 I still think -- okay.

2 CHAIRMAN FISCHHOFF: No, no, no.  
3 We got -- no, please.

4 MEMBER DeSALVA: I think the ideas  
5 are very related, but I do think they're  
6 distinct. Although the changes -- I'm sorry.  
7 I just need to think about this for a second.

8 CHAIRMAN FISCHHOFF: Sure.

9 MEMBER DeSALVA: To me there are  
10 still two different things. One is an  
11 expression of commitment, you know, a  
12 communication of commitment and demonstration  
13 of commitment. The other is as part of the  
14 plan choosing to engage and inform  
15 stakeholders so that the changes are clear,  
16 people understand how to participate in risk  
17 communication coming from the Agency and that  
18 they achieve full benefit. So there is an  
19 engagement and education component assuming  
20 that some of FDA's practices and products  
21 change as a result of the strategic plan. So I  
22 mean I don't want to make your crazy about it.

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1 It's just --

2 CHAIRMAN FISCHHOFF: Yes. So we  
3 want to get --

4 MEMBER MAYER: I think that what  
5 you're suggesting is actually in one of the  
6 earlier paragraphs.

7 MEMBER DeSALVA: Okay.

8 MEMBER MAYER: But maybe we should  
9 look.

10 CHAIRMAN FISCHHOFF: So there's  
11 sort of two things. We psychologists think in  
12 terms of dual process models, so there's a  
13 symbolic statement that we're committed, we're  
14 taking this on, you know, where the details  
15 don't matter. And then there's this question  
16 of saying, well, we need to promote awareness  
17 of the details so that you know what we're  
18 doing and we take full awareness of it. So I  
19 think that was the part that wasn't captured  
20 by just, you know, having FDA sort of  
21 publicize what it's doing. So I don't know if  
22 this is the right wording, but here's an

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1 attempt to get them both in.

2 "The Committee recommends that FDA  
3 use the strategic communication initiative as  
4 an opportunity to reaffirm FDA's commitment."

5 "To," yes. "To fulfilling its  
6 mission to help the public make informed  
7 choices regarding the products that it  
8 regulates. By promoting awareness of the  
9 initiative FDA" --

10 MEMBER MAYER: I think you need  
11 "FDA" there rather than "it."

12 CHAIRMAN FISCHHOFF: Yes.

13 MEMBER MAYER: Because otherwise it  
14 will modify "public."

15 CHAIRMAN FISCHHOFF: Yes. Okay.  
16 From the top. "The Committee recommends that  
17 FDA use the strategic communication initiative  
18 as an opportunity to reaffirm FDA's commitment  
19 to fulfilling its mission to help the public  
20 make informed choices regarding the products  
21 that FDA regulates. By promoting awareness of  
22 the initiative, FDA will ensure that full

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1 benefit is derived from its efforts."

2 There were a couple of extra words  
3 in the first sentence.

4 MEMBER MAYER: You could make the  
5 final sentence a little simpler by just saying  
6 "promoting awareness of the initiative will  
7 ensure that full benefit is derived from these  
8 efforts." You don't really need "its."

9 CHAIRMAN FISCHHOFF: Yes.

10 MEMBER GOLDSTEIN: And if we wanted  
11 to get the stakeholders back in there, if we  
12 thought it was important, it could go in that  
13 last sentence. "Promoting awareness of the  
14 initiative among all stakeholders will ensure  
15 that full benefit is derived."

16 MEMBER MAYER: And stakeholders is  
17 sort of jargon.

18 CHAIRMAN FISCHHOFF: Yes, I agree.

19 Does anybody have a suggestion for  
20 taking out a word or two, kind of a last  
21 editorial gasp in the first sentence?

22 DR. OSTROVE: Well, you know, you

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1 can always say "FDA-regulated products" rather  
2 than "the products that FDA regulates."

3 CHAIRMAN FISCHHOFF: Oh.

4 DR. OSTROVE: I mean, it's just a  
5 short cut that some of us use sometimes.

6 CHAIRMAN FISCHHOFF: Yes. Is there  
7 a government style manual on whether it's "FDA  
8 or" "the FDA?"

9 DR. OSTROVE: Actually, in writing  
10 for the web, we have a style guide in writing  
11 for the web and it instructs specifically that  
12 you do not use "the FDA." You use "FDA."

13 CHAIRMAN FISCHHOFF: Oh.

14 DR. OSTROVE: In terms of writing  
15 for the web, at least.

16 CHAIRMAN FISCHHOFF: Okay.

17 DR. OSTROVE: So there is a style  
18 guide that addresses some of these issues.

19 CHAIRMAN FISCHHOFF: Okay. Yes,  
20 EPA has the same thing.

21 Okay. So I'm going to strike the  
22 other two?

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1                   MEMBER KHANNA:     Yes, strike the  
2 other two.

3                   CHAIRMAN FISCHHOFF:   Okay.

4                   MEMBER KHANNA:     And then I have  
5 another suggestion.

6                   When I originally suggested the  
7 word "use," I was using it as an opportunity  
8 to strike the words "as an opportunity."

9                   CHAIRMAN FISCHHOFF:   Oh, okay.

10                  MEMBER KHANNA:     So, "recommend the"  
11 -- no, no, no. Stop, stop, stop. "That FDA  
12 use the strategic communication initiative to  
13 reaffirm."

14                  CHAIRMAN FISCHHOFF:   Oh. All  
15 right. All right. Boy, that was what I was  
16 -- there was something in there that we could  
17 do. Okay. So I'll read it again.

18                  "The Committee recommends that FDA  
19 use the strategic communication initiative to  
20 reaffirm FDA's commitment to fulfilling its  
21 mission to help the public make informed  
22 choices regarding" -- no. No, we can -- yes,

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1 yes, yes, yes.

2 MEMBER MAYER: Can we take out  
3 "fulfilling?"

4 CHAIRMAN FISCHHOFF: Yes.

5 MEMBER MAYER: "To its mission."

6 CHAIRMAN FISCHHOFF: How about  
7 that?

8 MEMBER MAYER: "To help," even  
9 better.

10 CHAIRMAN FISCHHOFF: Yes. From the  
11 top. "The Committee recommends that FDA use  
12 the strategic communication initiative to  
13 reaffirm" -- could be now "its" -- "The  
14 Committee recommends that FDA use the  
15 strategic communication initiative to reaffirm  
16 its commitment to help the public make  
17 informed choices regarding FDA-regulated  
18 products. Promoting awareness of the  
19 initiative will ensure that full benefit is  
20 derived from these efforts."

21 And who says that groups can't  
22 write?

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1                   Those     in     favor     of     the  
2     recommendation?

3                   Those opposed?

4                   Any abstentions?

5                   Thank you.

6                   Now let's think about the ordering.

7     So let me make a suggestion about the  
8     ordering.     It seems like the first one;  
9     remember back at the first one in the earlier  
10    part of this meeting, that it talks about the  
11    plan will lead to developing the capacity and  
12    then I suggest this question about -- the  
13    third recommendation, which addresses capacity  
14    would kind of logically flow from that.    Okay?

15                  And then I think the next one is to  
16    say -- so it's going to build up internally  
17    and then it's going to partner with other  
18    people to make the system work.    Feels like  
19    that seems to come next.    So that's kind of  
20    the resource- based.    Then there's a  
21    suggestion about internal organization to see  
22    that the communication is part of the

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1 organization. And then we have these two  
2 things.

3 So I think the Paperwork Reduction  
4 Act is of a different type than the other.  
5 And my inclination would be to flip these last  
6 two and say this is about the initiative and  
7 then we got this other issue, you know, that  
8 hampers us. My guess is that there will be,  
9 you know, people in the system who think that  
10 it's out of line for us to address the OMB  
11 issue and people who will really welcome our  
12 doing it. And, I don't know, my feeling is  
13 that that belongs -- the last, even though we  
14 view it as a -- I mean, unless there's some  
15 other work-around that comes from implementing  
16 the rest of the plan, you know, the OMB thing  
17 is going to severely limit FDA's ability to do  
18 it. But it seems like it needs to work out --  
19 you know, get the pieces in order and kind of  
20 work this other problem in parallel, unless  
21 there's some sort of other miracle that comes  
22 up.

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1                   So that would be my suggested --  
2                   develop the plan, tell people about it and  
3                   work this really important technical problem.

4                   MEMBER ANDREWS: You might get some  
5                   recency effects. The last thing.

6                   CHAIRMAN FISCHHOFF: Okay. I'm  
7                   happy with that. Okay.

8                   MEMBER ANDREWS: The last point.

9                   CHAIRMAN FISCHHOFF: Yes. Yes.  
10                  Well, also because it's of a different kind  
11                  that we'll also get kind of a saliency effect.

12                  Okay. Any other comments?  
13                  Questions? Oh, John?

14                  MEMBER PALING: Thank you, Ellen.  
15                  Can we take five minutes and ask questions of  
16                  any of the speakers that presented earlier, if  
17                  we limit it to that?

18                  CHAIRMAN FISCHHOFF: No, because we  
19                  don't have a public hearing thing.

20                  MEMBER PALING: That's fine.

21                  CHAIRMAN FISCHHOFF: Two years and  
22                  you still can't read my mind. What I was

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1 going to do is thank at least one of our  
2 members who's a founding member. One of the  
3 founding members of the Committee is Ellen  
4 Peters who this will be her last meeting. And  
5 I just wanted to thank Ellen for her  
6 incredible service, and thank you.

7 MEMBER PETERS: Thank you very  
8 much. This has been such a privilege to get  
9 to be part of this group, to get to know the  
10 FDA better and the incredible people who work  
11 here. So thank you very much. I can't make  
12 the August meeting.

13 CHAIRMAN FISCHHOFF: Can we come to  
14 Barcelona with you?

15 MEMBER PETERS: You are all invited  
16 to Barcelona. It's supposed to be a lovely  
17 city. Otherwise, I'll send pictures.

18 CHAIRMAN FISCHHOFF: Okay. And if  
19 we have nothing else, then let me just thank  
20 the audience and whoever gave us that  
21 anonymous suggestion, buy yourself a drink and  
22 let me thank you all. And we'll see everybody

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1 in August.

2 Thank you. And let me particularly  
3 thank the staff, Lee and Nancy, for incredible  
4 service, as well as Karen. Is Karen here?  
5 Karen gets us here and there.

6 Okay.

7 (Whereupon, the meeting was  
8 adjourned at 12:40 p.m.)  
9

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