

1 FEMALE VOICE: Yes.

2 MALE VOICE: So you take two
3 thyroid pills?

4 FEMALE VOICE: No, I take one. I'm
5 more like got it messed up when I got
6 refilled.

7 FEMALE VOICE: And then are these
8 stickers helpful?

9 FEMALE VOICE: No. Don't even look
10 at them.

11 FEMALE VOICE: Don't even look at
12 them.

13 MALE VOICE: What do you take that
14 medicine for?

15 FEMALE VOICE: I don't know what
16 it's for. He just puts me on stuff and I just
17 take it."

18 (End of video transcription.)

19 DR. DAVIS: So the point is you
20 know these people. They're your patients.
21 They're your relatives. They're your
22 neighbors. They're us and that's where we are

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1 with this information.

2 DR. FISCHHOFF: Thanks. So --

3 MS. HENDERSON: Can I just say
4 that's why we've invited you here.

5 DR. FISCHHOFF: So let me give you
6 a forecast of what's happening. We will start
7 again at 12:30 and at that time we'll have an
8 opportunity to speak with our guest speakers,
9 some Q and A with the speakers who were here
10 this morning.

11 We will also ask the panel to look
12 at the five questions, one of them multi-part,
13 that we had to, as our charge for this meeting
14 and would like to get some -- if there are
15 issues that haven't gotten on the table I will
16 try with Lee's help to synthesize what we've
17 said and to answers to those questions. But
18 if there are things that you feel haven't been
19 said, let's spend some time doing that or if
20 you think have been said and haven't been
21 heard -- and then as we did at our last
22 meeting, I've drafted some recommendations for

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1 us to consider.

2 So this is kind of a higher-risk
3 operation, either I got it right or I got it
4 wrong. We won't have that much time to talk
5 about it, but last time it worked relatively
6 well.

7 I will put up those draft
8 recommendations when we come back at 12:30 so
9 that people can have a chance to study them.
10 I decided to break them -- there's ten of them
11 because I tried to break them into bite-size
12 bits and we could see no double-barrel loaded
13 questions, so we could see whether we agreed
14 or disagreed with them.

15 I think when we saw from Dr.
16 Shuren's presentation, people are listening to
17 our recommendations and they have some weight
18 that just the answers to questions don't have,
19 although you'll see there's a great deal of
20 overlap between them. In some sense, they are
21 the answers to questions in recommendation
22 form and they also force us to be succinct.

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1 So that's our program and then we have a hard
2 stop at 2 o'clock which will be harder than
3 our stop at 11:30. So thank you all and we'll
4 see you back real soon.

5 (Whereupon, the above-entitled
6 matter went off the record at 11:39 a.m. and
7 resumed at 12:35 p.m.)

8
9

10
11

12 A F T E R N O O N S E S S I O N

13 12:35 P.M.

14 DR. FISCHHOFF: Okay, I'm happy to
15 have everybody back. As promised, our
16 procedure for what we're going to be doing for
17 the remaining hour and 27 minutes is that we
18 will first have an opportunity to have
19 questions and answers from our three morning
20 speakers who are still in the room.

21 After that, we will -- I would like
22 to solicit final comments from Committee

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1 members regarding the answers to the questions
2 that the staff posed us, again in the spirit
3 of if it was said there's every chance that I
4 took it down, but if you think I might not
5 have taken it down or it occurred to you over
6 night, then let me know and if you can make
7 those comments keyed to the question, then I
8 can kind of type them into my notes and then
9 make connected text out of it later on. And
10 then I'd like to speak about the
11 -- and I'd like us to consider a set of
12 recommendations.

13 For the recommendations, again what
14 I said just before the break, I tried to
15 capture what was the spirit of the -- what had
16 come out of our deliberations in terms of the
17 issues that were addressed and the questions.

18 And the questions, in some sense, I always
19 teach our students, if you have conclusions
20 that are just on the facts, and then you have
21 recommendations that follow from them.

22 The recommendations are policy and

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1 -- but the questions are, some of them are
2 kind of a mixture of conclusions -- they
3 require a mixture of conclusions and
4 recommendations. But I believe that these
5 recommendations you may not agree with what
6 they say, but I think they're on the topic of
7 the questions.

8 And so I'd like you to look at
9 them. I don't have tremendous pride of
10 authorship in anything. Lee will put them up
11 so they'll be up here for half an hour. What
12 I propose and when we get to that you can
13 suggest something else, is that we first have
14 -- so we'll have perhaps an hour to talk about
15 the recommendations, that we first have a
16 general discussion about whether the thrust of
17 the recommendations is right or the strategy
18 is right, if there are particular issues that
19 come up.

20 And then I suggest we go -- and if
21 we're, you know, if we're going down the wrong
22 path, then we'll come up with Plan B. If we

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1 seem to be in the general vicinity, then I
2 suppose that we will go through the
3 recommendations, take a test vote on each in
4 turn without any discussion. Then -- remember
5 we're voting simultaneously, so there's no log
6 rolling, social pressure, anything. If we
7 have a recommendation where it looks like --
8 and if a recommendation turns out to be
9 unanimous, then we should just move on to the
10 next one.

11 If there's a disagreement, then we
12 should have a discussion about whether the
13 disagreements are matters of principle or
14 matters of wording and I'll try to figure out
15 from the sense of the discussion whether we
16 could land this one with discussion under the
17 time that's constrained.

18 The way I think about this and you
19 could disagree with any of this is these are
20 just advisory recommendations. We have -- so
21 we should be somewhat more tolerant of gist,
22 than if this was going to become law. So if

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1 you've got a better gist than -- when we get
2 to a topic, then I'd be perfectly happy. I'm
3 a very fast typer, we can type -- replace my
4 gist with your gist. So that's what we'll try
5 to do and then finish at 2.

6 Okay, so let me welcome questions
7 for our speakers from this morning. Let's
8 start with AnnaMaria, then Sid, and then
9 Craig.

10 MS. DeSALVA: Thank you. That was
11 a wonderful presentation on the drug facts
12 box. And I just had a couple of clarifying
13 questions. And the first one is about the
14 people who participated in the study and
15 because I was surprised in a good way to find
16 out that the table was such an effective means
17 of communication, I couldn't help but wonder
18 if there might have been a selection bias of
19 any sort.

20 So there were 274 participants in
21 that study and in reading your paper I saw --
22 thank you -- I happened to see that some of

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1 them were -- you had recruited them from two
2 Dartmouth programs and then one from a VA
3 program. And I was just wondering if you
4 think there may be any type of selection bias
5 that maybe would mean that these people had a
6 higher degree of literacy or numeracy. And
7 I'm sorry if I missed that in your
8 presentation.

9 DR. WOLOSHIN: There are actually
10 two studies, actually, there are three
11 studies. And the one you're referring to
12 there were participants were selected from two
13 populations. One was sort of the -- it's
14 called the Dartmouth Community Medical School.

15 It's like retirees and sort of high socio-
16 economic status group. But we sort of think
17 of them as worded well. Then the other group
18 was patients and family members in the waiting
19 room in our VA hospital which is sort of the
20 other end of the socio-economic spectrum.

21 But in the main paper, the
22 randomized trials that Lisa talked about this

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1 morning, the ones published in The Annals just
2 the other day, those patients were selected at
3 random from a nationally representative sample
4 frame.

5 MS. DeSALVA: Okay.

6 DR. WOLOSHIN: So in that case I
7 would say there's no selection bias.

8 MS. DeSALVA: Okay, thanks for
9 clarifying that. And my train of thought was,
10 I couldn't help but anticipate the downstream
11 effect of adding this box to direct-to-
12 consumer advertising which I think we all
13 agree is really very compelling.

14 I know that some companies are
15 really trying very hard to communicate more
16 effectively and communicate risk and benefit
17 in a much more balanced way, much, much more
18 effectively. And I'm quite sure that there
19 are programs in development to further support
20 consumers and patients in interpreting
21 relative risk and relevant benefit information
22 that will be sponsored very likely by the

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1 companies.

2 And so in thinking about what a
3 second step may be, as people become exposed
4 in direct-to-consumer advertising not only to
5 the proposition of the benefit, but also to
6 the facts about the benefit-risk profile in
7 some respects they will be in a position to
8 make certain judgments or to begin the process
9 of making judgments about whether or not the
10 treatment option is appealing to them.

11 And I think that's a very good
12 thing, but I think it's a little bit
13 concerning because the -- that discussion
14 needs to be held with a learned intermediary
15 and needs to be ideally held with a physician
16 and there may be times when the relative
17 benefit and the relative risk aren't so
18 obvious and where it's open to interpretation
19 and open to professional interpretation in
20 terms of whether or not the patient, which
21 should be appropriately treated.

22 And so I'm sure it would be within

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1 your recommendation that there be some further
2 evaluation of what the downstream effect will
3 be in terms of people's actual choices and
4 their health-seeking behavior following
5 exposure to all that information.

6 I think that direct-to-consumer
7 advertising is an incomplete communication and
8 it needs to be more complete. And I think
9 that's the premise, but then all of a sudden
10 we're moving way upstream, a lot of
11 information that a consumer that hasn't even
12 been diagnosed yet may or may not be able to
13 adequately interpret based on whatever their
14 own needs are.

15 DR. WOLOSHIN: So first, the box
16 isn't meant to replace learned intermediary.

17 MS. DeSALVA: Of course.

18 DR. WOLOSHIN: Would a doctor count
19 as a learned -- yes. So any doctor who can be
20 replaced by the box should be.

21 MS. DeSALVA: No, and that's not my
22 point. I'm just saying that it moves further

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1 upstream --

2 DR. WOLOSHIN: I understand what
3 you're saying. And so the other thing is our
4 sort of fantasy of how the box is used,
5 whether it's replacing a brief summary or some
6 other method of using it is I mean ideally
7 it's to encourage shared decisionmaking so let
8 the patient and the doctor make the decision.

9 This information may be surprising, it's not
10 easily available to doctors either.

11 And so this is a way of bringing
12 the information to the fore when it's needed.

13 But it's also useful before the visit and one
14 of the concerns we had in the study that was
15 the reason we chose the outcome measure for
16 the second study was we were concerned that
17 small, but important benefits might be
18 dismissed out of hand by patients.

19 We're very pleased to see in the
20 second randomized trial that in fact the small
21 mortality benefit of the statin for secondary
22 prevention, that three quarters of the

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1 patients even though it corrected a big
2 overestimation of benefit on their part, they
3 were still interested in the drug.

4 MS. DeSALVA: Absolutely, no, and I
5 completely agree. Your own observations were
6 that this has been looked at, I believe with
7 four advertisements in terms of your
8 presentation and all I'm anticipating is that
9 if you start to apply this method much more
10 broadly with many more different types of
11 products that it may actually have an effect
12 in terms of how people process their options
13 and what types of help they seek and that
14 could be very positive in most cases. And it
15 could be less positive in other cases.

16 All I'm saying is it would be
17 helpful to know and the reason why is because
18 I think the industry is -- everything is kind
19 of on the table. Everyone is trying to
20 understand how to do this better and I think
21 that would be a very valuable input for some
22 of that decisionmaking going forward. That's

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1 all.

2 DR. SCHWARTZ: Right, and I think
3 we agree with you. I think the other hope is
4 by presenting people with standard information
5 over time they'll become better. I think with
6 the nutrition facts box, there has been a
7 learning curve and the more that you see
8 information in a consistent format, then
9 people start to develop a context or sort of
10 the ability to make judgments better. And
11 maybe it will generate some more sort of basic
12 education about helping people to understand
13 more about risk.

14 DR. WOLFE: I was listening to one
15 of the presentations this morning,
16 AdvanceMarketWoRx, was the name of it, with
17 the very eye catching ads and ways of reaching
18 people. The question has to do with
19 advertising, the role of these boxes in
20 advertising. We followed pretty closely FDA's
21 really increasingly poor performance in terms
22 of monitoring drug advertisers. There's been

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1 an 85 percent decrease in enforcement actions
2 against illegal drug ads from 1998 through
3 now.

4 So if anything, I don't think the
5 ads overall are any better. They're just not
6 being enforced. And so the unbalance of
7 benefits and risks and so forth in the ads are
8 daunting and the benefit-risk balance box has
9 the opportunity to try and correct some of
10 this balance, some of the fair balance is one
11 of the tests for stopping an ad. The ads are
12 supposed to be derived from labeling.

13 So the question is have you had any
14 discussion with the FDA? You mentioned the
15 brief summary about one other use or one use
16 of the benefit-risk box as part of
17 advertising. If they're going to do a brief
18 summary, do they have to have a benefit-risk
19 and you don't need to go into detail. Just
20 have you had any discussion with the FDA about
21 the use of your exciting project and research
22 in advertising?

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1 DR. WOLOSHIN: That was the
2 original idea.

3 DR. WOLFE: I remembered. We
4 talked about --

5 DR. WOLOSHIN: Let's replace it and
6 as we mentioned, the idea of moving it
7 upstream in the decision process came up and
8 we think that's good because that's the ideal
9 place to produce them, but yes, we still think
10 replacing the -- that's still in our minds a
11 great thing to replace the summary.

12 DR. WOLFE: So you moved it
13 upstream and the idea of it being part of the
14 approval process is great, but then since it
15 is the FDA-approved labeling itself that is
16 the standard against which ads are judged,
17 this would seem to be one way of making the
18 ads a little fairer.

19 DR. FISCHHOFF: Let's go to Debbie
20 and then Craig, Ellen, and John.

21 MS. HENDERSON: I just wanted to
22 add one piece of information for you guys to

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1 please consider in your thinking about
2 especially this particular issue. I was
3 spurred to think of it by something AnnaMaria
4 said is that as most of you around the table
5 know when we do clinical trials, the risk-
6 benefit evaluation that is done in the course
7 of a clinical trial is really on a population
8 basis.

9 And so the data that are generated
10 from that have to do with the population of
11 patients who were studied. The risk-benefit
12 decision that a physician makes with his
13 patient takes into account a lot of other
14 things and as you all know, the risk or
15 benefit for a specific patient is not
16 necessarily exactly what was seen in the
17 clinical trial and that is why are in great
18 measure prescription drugs is because we
19 believe they require the intervention of a
20 learned intermediary.

21 So just to consider in your
22 thinking as you go forward the difficulty I

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1 think of interpreting that information without
2 the help of your physician.

3 DR. FISCHHOFF: Craig, Ellen, and
4 then John.

5 DR. ANDREWS: I want to thank
6 Steven and Lisa for staying. I was really
7 excited to see stimuli data up there, moving
8 forward. So I certainly was in heaven looking
9 at it.

10 I had a couple of questions. I
11 wanted to echo what AnnaMaria was saying about
12 the population. I believe when I took a look
13 at it it was 70 percent college-educated
14 population. I was looking at the table. And
15 I kept thinking what Terry just shows as far
16 as certainly low literacy folks, so I think
17 absolutely we need to kind of move into these
18 other populations.

19 And from our research on nutrition
20 facts panels and nutrition claims, we have
21 some research showing the quadratic effects
22 where it's only those people at the highest

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1 levels of nutrition knowledge, highest levels
2 of motivation that it's really helping as far
3 as comprehension, etcetera. So I'm very
4 concerned about that.

5 And I guess my second issue I
6 wanted to raise is whether or not you took a
7 look at the OTC drug facts standards that kind
8 of work that. I know this is an evolutionary
9 process, but there were some other things I
10 saw on that particular facts panel on
11 contraindications, directions for use, how to
12 use. Obviously, that would add to additional
13 information on a panel, so I just wanted your
14 thoughts on it and thank you very much for
15 getting involved in this research.

16 DR. SCHWARTZ: Thank you. In terms
17 of the first question about it not working for
18 everybody, that's true. It doesn't work for
19 everybody, but clearly for most people in the
20 randomized trial where it's a random sample of
21 the representative population, not a self-
22 selected population, it works, the box works.

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1 So even though people with less formal
2 educational with a high school, less than a
3 high school education, had a lower level of
4 comprehension, the box still results in a big
5 absolute increase among people at the lowest
6 level of education.

7 So that's reassuring in terms of
8 the fact that even -- I know it's not an exact
9 measure of health literacy, but it's certainly
10 a reasonable proxy and so there is evidence
11 that for some people who are at the lower
12 ends, it does work and I think it's further
13 work to figure out how to make it work for
14 these other subsets.

15 But I guess the question is
16 compared to the current situation what we have
17 is a vast improvement over the status quo
18 which will work for most people. It certainly
19 won't work for everyone. But also, part of
20 doing this would help to create more
21 consciousness about understanding risks and
22 make it part of the things that we talk about.

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1 And that may in and of itself -- and you can
2 imagine a public health campaign around
3 understanding your risk and there could be
4 depths of explaining this information when you
5 rolled out, if the drug facts box were
6 adopted.

7 I forgot the second question now.

8 DR. ANDREWS: The second question
9 was about the OTC.

10 DR. SCHWARTZ: OTC, yes.

11 DR. ANDREWS: Right, because it's
12 somewhat different. We have additional pieces
13 of information that would be very important
14 that would add to what you have.

15 DR. SCHWARTZ: Right, well, we
16 struggled in trying to make it a one-page
17 document and to us what's really fundamentally
18 different about the box is the data table.
19 It's about laying out what are the good things
20 that you can expect to happen and what are the
21 bad things that might happen. And that's
22 where we spend most of the space.

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1 And there are, in terms of
2 contraindications and in our work with the FDA
3 reviewers, we have -- and to figure out how to
4 put contraindications that's in the box and
5 how to put black box warnings into the box.
6 You know, so there are more elements than what
7 we've showed you here. But the OTC label does
8 not include any data on efficacy and side
9 effects. It includes a lot of qualitative
10 headers, but not what we're proposing.

11 DR. ANDREWS: Thank you. An
12 interesting mix of obviously numerical
13 efficacy with some of the other standards. So
14 thank you.

15 DR. FISCHHOFF: Ellen and then
16 John.

17 DR. PETERS: I actually had a
18 question for David Moxley who I think is still
19 here. Yes. Sort of -- you're very much
20 working at sort of the other end of the
21 spectrum in many ways, not necessarily in
22 terms of these people's native ability, but

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1 certainly from your very vivid descriptions of
2 the various stressors that they have in their
3 lives and the lack of resources.

4 And so my question revolves around
5 how do we help such populations, given what we
6 do as a Committee? With the drug facts box we
7 can perhaps help comprehension of numbers, but
8 we also want to be able to go beyond
9 comprehension of numbers. I often argue that
10 you have to not know just what the numbers
11 are, but you have to understand the meaning of
12 the numbers so that they can be used instead
13 of other information that might impact the
14 actions that they're taking. And that may
15 involve interpretive help, for example, from
16 an information provider.

17 I mean do you think that helping
18 comprehension of numbers or helping the people
19 understand the meaning of the numbers might
20 actually, even in the kinds of populations
21 that you deal with, motivate better use of
22 medications or do you think that there's

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1 something different from us that you think we
2 should be looking at that we're really not
3 considering yet?

4 DR. MOXLEY: Well, I like the idea
5 of planning a context in which the
6 communication occurs and of course that's not
7 based on a paradigm of mass communication or
8 mass dissemination of like CMI. But there are
9 a lot of -- there are contexts, you know,
10 where there is health information and that is
11 often mediated by their faith-based social
12 service organizations like Catholic Charities
13 or Jewish Family Services or Lutheran Social
14 Services where people invariably sort of show
15 up in the system and there just needs to be a
16 couple of screens asked and if people are --
17 if there's, let's say, a broad dissemination
18 of this kind of information it's really -- I
19 could just see this in the hands of a case
20 manager who is able to interpret it herself or
21 himself who actually may be part of the
22 population, who have moved out of the

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1 population and it would just, I think, create
2 a very engaging kind of conversation about --
3 and all you need to do is ask some trigger
4 questions like, you know, are you dealing with
5 arthritis and are you, you know, using
6 medication for arthritis? And do you know
7 about this particular medication or an
8 antidepressant or -- it doesn't really take
9 that much time.

10 I think a communication program
11 that would be directed to caregivers whether
12 that's -- and I'm not thinking really even
13 like family members. I'm thinking more like
14 social service personnel. I think ministers -
15 - I was part of this great effort to create a
16 handbook for church leaders in every area of
17 human need. We worked on it over the holiday
18 and we just finished it. Oxford University
19 Press will publish it I think next year. And
20 it's all directed to what church leaders need
21 to know in order to engage their congregations
22 in healthful communication. And we all know

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1 that's real critical and we all know that that
2 taps into the health literacy or the health
3 sophistication of care givers and those kinds
4 of exchanges is not direct to the consumer.
5 It's oftentimes mediated.

6 Apart from the actual logistics of
7 being able to manage your own medication, the
8 information may actually stimulate some other
9 advocacy efforts to help people store their
10 medication, to handle it kind of differently,
11 to be more vigilant in communicating with the
12 dispenser. I just think it's -- I like this
13 idea of raising the -- I was talking to
14 Michael about you know you pick Cocoa
15 Krispies, my favorite cereal, and I always
16 look at the nutrition facts as I read them off
17 to my daughter and say don't eat these.

18 So I do think -- I think -- and
19 then this other idea of the kind of symbols
20 people respond to. I think I was talking to
21 someone about putting a symbol of a sandwich
22 on one of these indicators, but if you don't

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1 have the sandwich, if you don't have access to
2 that that's just a real tragedy. But that's a
3 different part of the system that FDA doesn't
4 have -- while I think FDA is responsible for
5 fresh sandwiches, right?

6 I think a campaign that would focus
7 on these intermediaries and there -- and we
8 know who they are. We know who they are and
9 they're not so hard to get to with economical
10 communication about what case managers can do
11 to communicate around medication safety or
12 risk information or benefits or all of it to
13 the people they care about.

14 DR. FISCHHOFF: So my formulation
15 of listening was that these people have health
16 sophistication, they just don't have some kind
17 of presence of mind and capability to deal
18 with. That personal contact can take
19 advantage, if properly informed.

20 DR. MOXLEY: It's really, if you
21 think about it, it's just really gross fatigue
22 and under what conditions can you handle

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1 complex information under substantial fatigue
2 or demoralization and then someone, you know,
3 you fit into some kind of solution plan which
4 is what a case manager may be doing with a
5 person and they'll just need to say you know,
6 address this kind of stuff. And it could even
7 be handled probably with accreditation like
8 the Council on Accreditation and
9 Rehabilitation Facilities, you know could be
10 approached to nest health provision
11 information in their accreditation criteria
12 and they're so consumer driven they would
13 probably take that as a serious opportunity.

14 DR. FISCHHOFF: You can't make them
15 doctors, but you could make them interpreters
16 of succinct communication about specific --

17 DR. MOXLEY: You're not talking
18 outside of the box, right? You're staying
19 within the box and it's a good guide and I
20 think the useability -- I don't want to be a
21 proponent, but the useability of it just
22 struck me as being real clean as opposed to

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1 the other things we looked at over the course
2 of the last couple of days.

3 But you know broadly defined, you
4 know defining health provider broadly is a big
5 issue.

6 DR. FISCHHOFF: Thank you.

7 DR. MOXLEY: I was going to put
8 this in my pocket.

9 DR. FISCHHOFF: So let's have a
10 quick comment from John and then from Mona and
11 then we'll move to the recommendations.

12 John.

13 DR. PALING: I'm highly supportive
14 of the drug box and compliment you. If
15 there's a chance at this meeting for me to add
16 my voice to a recommendation the FDA open
17 further development of what I see as the most
18 advanced and potentially progressive
19 communication took for drugs, I'd be happy to
20 do it.

21 I'd like to draw a general point
22 and that is that once you hear these

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1 presentations, yours too, but others this
2 morning too, what becomes clear is that to
3 have the vision as to what might be done
4 differently from what is going on at present
5 is a huge first step because when you begin to
6 aim in one direction, even if you don't hit it
7 immediately, you're moving in the right
8 direction, ignoring all the rest. So I think
9 we can all draw that encouragement from that.

10 I would like to give you my vision
11 for a way that not just your communication
12 tool, but all those we've had discussed this
13 last day and a half might be improved. You
14 might have picked up the fact from the
15 gentleman at Leeds that when they put their
16 information material together, they also are
17 trying to do a version in Braille. Now I'm
18 not saying that's unimportant.

19 Numerically, it's not very great in
20 proportion to the total population, but here
21 and Mr. Chairman, I'm going to give my remarks
22 to this last paragraph that we've been asked

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1 to address. How to help effective
2 communication with patients, different
3 literacy levels, and primary language skills
4 other than English. To my mind is someone who
5 for over two and a half decades was involved
6 in visual communications, there is a prime
7 opportunity to get the equivalent of the
8 recycling icon for each of the various
9 categories down the side of your document.

10 And I'm thinking of simple things
11 like pills and the medicine with a question
12 mark for what is it? A smiley face for what
13 it purports to do. A negative face or a
14 marginally negative face for what the risks
15 are. And then the old sign like the anti-
16 smoking sign through it for on no account do
17 this.

18 My vision is simple, as for you,
19 I'm sure we could criticize whatever the
20 specifics are and how well they test out, but
21 to agree it would be a worthwhile thing in the
22 same way as the Braille variant of the

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1 European project would add significantly to
2 people who are underserved and no one should
3 feel that that would be a not less than
4 commendable initiative.

5 Now I have a suggestion for my wife
6 as to how we can do that. That's my code for
7 saying I think this is a very good idea. Why
8 not get my friends from the FDA to get them
9 out of their budget, five grand or ten grand,
10 and invite all the students in graphic arts
11 colleges to put together their own suggestions
12 for what these seven symbols should look like.

13 You will be astonished at the quality and the
14 variety. A subordinate value will be that a
15 whole lot of publicity comes from your
16 efforts.

17 A whole lot of younger people from
18 the new generations will begin to talk about
19 the very thing that we're struggling to find
20 reach for. So that in my summary is my vision
21 to do something which would be, in my mind
22 down the line an improvement to your forms and

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1 every other sort of risk communication tool
2 that does not at present contain some visual
3 reinforcement.

4 DR. FISCHHOFF: Thank you. I guess
5 Mona has yielded.

6 Bruce, did you want to say
7 something?

8 DR. BURLINGTON: Yes, I did. I
9 wondered if you had any information or have
10 done any research on the effect size and
11 what's more of interest to the consumer and
12 more important to them? Is it the effect net
13 of the placebo effect or is it the gross
14 effect including the placebo effect that is
15 more predictive of what may happen to them or
16 do they need both. And if they need both, how
17 are they going to understand what that means
18 for them?

19 DR. SCHWARTZ: Well, we haven't
20 directly tested that in a study, but I will
21 tell you in other studies that we've done the
22 two absolute risks side by side and the way

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1 that we've done them are the best understood.

2 So if you do comprehension tests that if
3 people understand those two numbers, we know
4 that in looking at the work and understanding
5 different presentations like a relative
6 change, that's much more confusing to people
7 than the absolute numbers.

8 We do a lot of teaching. I mean I
9 don't have -- we haven't done a standard
10 format comparison, but we've done a lot of
11 qualitative work with people. And they really
12 understand those numbers. It's sort of like
13 you know, this is the sales price and the
14 regular price, you know? And they can get
15 that, but what happens if I do this? What
16 happens if I don't do this?

17 We do have one study that we did
18 early on which was studying how women
19 understood the benefit of mammography
20 presented in different formats. And four
21 different formats and the best understood was
22 the one that we have in our box.

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1 And the worst was the difference. If you just
2 give them a subtraction, the subtraction alone
3 without providing the two risks, because
4 people were confused whether you were
5 subtracting or dividing.

6 DR. FISCHHOFF: Musa?

7 MS. MAYER: I've been a fan of the
8 drug facts box ever since I came across it
9 some years ago and I'm just delighted that
10 you've gathered so much good research to
11 support it. And I for one am eager and ready
12 to see it go into practice.

13 I did note, however, in your
14 presentation that you were recommending it
15 perhaps on the basis of your study to apply to
16 new drugs coming on the market. And I think
17 that despite the logistic problems that would
18 be involved, I think that's a problematic
19 recommendation simply because why should we
20 see new drugs realistically, but not be able
21 to see the thousands upon thousands of on
22 patent and generic drugs currently on the

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1 market in the confused way that we see them
2 now. I think there has to be one standard,
3 even though I realize that presents an
4 enormous amount of work for FDA should they
5 take this on.

6 DR. WOLOSHIN: You have to start
7 somewhere and the reason we suggested the new
8 drugs is just because this idea of the
9 reviewers building the box in real time as
10 they review the drug and when they're
11 analyzing the data. But of course, you're
12 right. It would be great to have it, but I
13 think that practically speaking I think that's
14 very difficult.

15 DR. LESAR: I had to ask this
16 question without Dr. Raynor being on the
17 satellite, but in his -- what struck me about
18 his discussion was that through requirements
19 for 90 percent success rate as it were for
20 their information documents, in order to be
21 placed on the market in the EU, I wonder if
22 you could comment on that degree of success

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1 and are you familiar with that testing
2 processing and why was it -- how can it be so
3 high with even more complex information than
4 you're presenting in the box? Apparently, it
5 was within those documents and I was just
6 struck by the difference in the apparent
7 consistency with which they must be able to do
8 that in order to have the drugs on the market.

9 DR. SCHWARTZ: Well, I mean -- I
10 guess first of all, we're not very familiar
11 with their standards. Today, we're hearing
12 about it, but I mean some of it is also
13 depending on how hard you make the
14 comprehension task. You can make an easy test
15 and you can make a hard test. I guess we were
16 trying to make the hardest test we could think
17 of to see how that worked. It's much easier,
18 you know if you want a test, like in our very
19 first study which we didn't present data from,
20 we just asked people to find information, like
21 can you read a cell, can you find and navigate
22 and read a cell. And we can get 95 percent.

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1 That's pretty easy, the navigation issue.

2 What's much harder is taking that
3 information and applying it and making a
4 judgment about it. That's a lot harder. So I
5 think it's hard to know what the 90 percent
6 means because it's so important to know how
7 easy or hard the test is to know what that 90
8 percent really means.

9 DR. WOLOSHIN: Or sometimes the
10 measure is the consumer's rating of how
11 helpful the information was. And that's very
12 problematic because they may feel it helped,
13 but it in fact may not help.

14 DR. LESAR: Just one follow-up.
15 You would agree that these materials can be
16 scientifically tested on a fairly consistent
17 basis and at some -- have some relative way of
18 gauging effectiveness on a fairly consistent
19 manner. That is this could be applied
20 systematically to patient materials. I think
21 that's what I'm really trying to say and can
22 and should be applied.

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1 DR. WOLOSHIN: Yes.

2 DR. SCHWARTZ: Yes.

3 DR. FISCHHOFF: Thank you. So
4 let's move now to the recommendations. So my
5 proposed process, if somebody dislikes the
6 process, then I'll open -- you can describe
7 that as well, I'd like to have kind of an open
8 discussion about strategy, the specific
9 proposals and then break that at 1:30, 1:30
10 kind of go through the list, taking
11 simultaneous votes on things that are there
12 and then see what the opportunities we have
13 for consensus and we'll stop at 2 as far as we
14 can go.

15 Musa?

16 MS. MAYER: Can I make a request if
17 this can be done without taking this offscreen
18 to break this into two and make the font
19 larger? I can't read that and reading this
20 one is going to make it impossible for me to -
21 -

22 DR. FISCHHOFF: Let me -- we were

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1 fussing with it, with -- let me suggest the
2 following. Let's have a general discussion on
3 this and when we do the sort of actual voting,
4 then I'll isolate the additional things --

5 DR. ZWANZIGER: Can I just print
6 out copies of this?

7 DR. FISCHHOFF: Apparently we don't
8 have the capability.

9 If it's just one page it seems like
10 the pharmaceutical industry could print that
11 out.

12 MS. MAYER: If it were just larger
13 on the screen. I can't read it as it is.

14 DR. FISCHHOFF: It would really be
15 kind of a shame not to do this because of --
16 some people have had a chance to look, so let
17 me fuss with this.

18 DR. OSTROVE: In the meantime I can
19 say something if that's okay.

20 DR. FISCHHOFF: Lee, why don't you
21 manage the list. Let's do this. Lee, why --
22 let me fuss with the fonts. Let Lee call on

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1 people, talk about whatever you want. If
2 people haven't been able to read anything,
3 I'll make it possible in a minute.

4 DR. ZWANZIGER: Can I just ask
5 Ellen to call on people?

6 DR. PETERS: I think Nancy wanted
7 to --

8 DR. OSTROVE: Yes, it's on. Am I
9 not loud enough? Oh, come on. I'm always
10 loud.

11 All right, actually, it came to the
12 third one that Baruch is working on right now.

13 It seems as if -- this is kind of -- we're
14 not trying to tell you to go one way or
15 another or to not consider something or not
16 say something. But when it comes to like
17 numbers two and three, it seems like there's
18 overlap. When you get to see them again,
19 there may be some overlap there and we had
20 some questions about specifically number three
21 in relation to number two.

22 Number two says that the standard

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1 document, a standard document should include
2 quantitative summaries of risks and benefits,
3 along with use and precaution information.
4 And number three, gets into specifics about
5 whether you're recommending or these would
6 recommend that FDA should adopt/consider which
7 are different, I think are significantly
8 different, use of the drug facts box which
9 again is a quantitative -- is a tabular
10 description of the quantitative information
11 about risks and benefits. So there seems to
12 be -- one is more general and the other one is
13 a lot more specific.

14 I guess one of the things that we
15 would want you to just keep in the back of
16 your mind about making specific, a specific
17 recommendation is simply that as I think I
18 alluded to yesterday, there are a lot of other
19 considerations that go into making -- go into
20 our evaluating different policy options and
21 there are a lot of those that would be
22 relevant to choosing a specific format. And I

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1 think that we definitely want to hear from you
2 about the kind of -- these general issues of
3 the communication of qualitative and
4 quantitative information and perhaps what
5 you're thinking about is a tabular form as
6 opposed to the specific one that we're talking
7 about here, but perhaps you're thinking about
8 this specific one here.

9 Again, the purpose here is not
10 necessarily to encourage you to go one way or
11 another, but just to keep in the back of your
12 mind that whatever you do recommend is one
13 factor that we take into account when kind of
14 deciding where to go, what road to go down to
15 just -- does that make any sense to any of
16 you?

17 DR. FISCHHOFF: So let me suggest
18 the spirit in which this was offered. I said
19 everything is up for grabs. I think under the
20 time constraints I figured we were better off
21 with a concrete proposal. So it's been my
22 feeling sort of all along, you know, that we

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1 should be generally informed, but we shouldn't
2 need to master -- we shouldn't even try to
3 master the laws, the internal procedures and
4 so on. We should tell you what the science
5 says relative to this situation.

6 When I formulated this, I thought
7 that having quantitative risks and benefits
8 which was a recommendation we made at our last
9 meeting as well, that was part of it, but that
10 the drug box was a particular instantiation of
11 that. As a tabular framework, it has the
12 additional information that's in most of the
13 guidelines of usage and precautions and so on.

14 So this was intended as a specific
15 recommendation. And we can vote yes or not.
16 So that's what this is intended to say.

17 You'll see now that you can see it,
18 there's a couple of places where there's
19 alternative wording in gray. I wasn't -- I
20 wanted to put up that. I didn't have strong
21 feelings. My thoughts -- it says should,
22 shall. I think we're should people, not shall

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1 people because we can't mandate anything.

2 I thought that here adopt is
3 probably the right word rather than mandate
4 because again, that's stronger language than
5 otherwise, but I wanted to at least get that
6 out there for discussion. And if somebody has
7 on the strength of the language, maybe there's
8 a strategic thing and we could resolve that in
9 the discussions that people have.

10 So Sid?

11 DR. WOLFE: I just wanted to
12 comment what Nancy was saying. Yesterday, we
13 were told we want some concrete things, right?

14 And today, we are attempting to give with the
15 excellent quarterbacking of Baruch some
16 concrete things.

17 And we all, of course, realize that
18 this is an Advisory Committee to FDA and that
19 FDA sometimes, more often than not, follows
20 the advice, but there are other considerations
21 and I don't think we will feel insulted if we
22 used should adopt the drug box for instance,

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1 and you decide to adopt three quarters of the
2 drug box, whatever.

3 I think it is nice that you're
4 saying and we know that, that there are other
5 positive considerations, but I don't think
6 that that should diminish the concreteness of
7 what we're saying. I appreciate the language
8 or the wording that Baruch has used as he has
9 summed up all this stuff that's happened in
10 the last couple of days. So at least we can
11 give you that we agree with the ten
12 recommendations or however many there are and
13 that's what you asked for yesterday, concrete
14 recommendations.

15 DR. FISCHHOFF: Okay, Mike?

16 DR. GOLDSTEIN: I just want to make
17 a general plea and that is that we consider
18 and come to some consensus about what we think
19 are the appropriate outcomes that we think are
20 important for FDA to be tracking when they
21 assess the quality of communications. And
22 that's my recommendation. So I would argue as

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1 a -- my recommendation for that that we go
2 beyond just readability and usefulness, to
3 include comprehension and we can define that
4 in various ways and also include the quality
5 of the decisionmaking, so the outcome, similar
6 to what the research that we heard about was
7 presented about the drug box, that we look at
8 the quality of decisions. We look at
9 the confidence that patients have, the
10 information they need in order to make
11 decision, that we actually look at some other
12 outcomes potentially like use of the medicine
13 appropriately, like following up with the
14 recommendations when there is a dangerous
15 adverse event that occurs, how they handle it.

16 So that we look beyond just the usefulness of
17 the material, the readability of the material,
18 to comprehension and action as an outcome.

19 DR. FISCHHOFF: I'm just fiddling
20 here. If I didn't have to use a PC I'd be in
21 better shape.

22 Next. Keep talking while I'm

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1 fiddling.

2 DR. ANDREWS: I just want to ask
3 some points of clarification. I don't know if
4 this is the right time. And I realize there's
5 a broad tent here, as what Nancy was saying.
6 But when we hear multiple communication tools
7 versus single tools on essential gradients,
8 basically, I'm assuming that does not rule out
9 a two-levels process that John was talking
10 about earlier yesterday. Anyway, maybe that's
11 open for debate. That's my first --

12 MS. HENDERSON: That's certainly
13 correct from our point of view. Absolutely,
14 does not rule out something that would be two
15 tiered.

16 DR. ANDREWS: And second, when you
17 referred to the drug box, that's just in
18 general. There are many different drug boxes,
19 including the one presented today, the OTC one
20 and others, in general, or more specifically.

21 MS. HENDERSON: That was not one of
22 our questions, so from our point of view it

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1 would be useful if you're going to talk about
2 a specific product or a specific concept to be
3 clear what you're recommending to us and the
4 question as stated says that we recommend the
5 use of the drug box as a standard format. It
6 would be useful to us if we knew what you were
7 recommending that is a standard format for
8 what? Would that be -- the context, my
9 understanding, the context in which it was
10 developed was for direct-to-consumer
11 advertising.

12 It would just be useful, as you
13 make a recommendation, that we knew what you
14 were recommending as the standard format for
15 whether that was for CMI or DTC or for both,
16 whatever it is you would be recommending box
17 format for. We really came to this meeting
18 looking at CMI. This was not to discuss how
19 DTC advertising is done, although they are
20 obviously overlapping in length. So just some
21 specificity for us in what exactly it is
22 you're recommending.

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1 DR. ANDREWS: Right, and what I was
2 referring to is different variations or
3 modifications of that box. Again, there are
4 many different forms, other sort of tweaking,
5 I think on it. Certainly, we get the CMI, PPI
6 problem.

7 MS. HENDERSON: Right, just to be
8 clear about what you're recommending, if
9 you're recommending the specific drug box that
10 we heard about, you know in the presentation
11 you need to be clear to us that that's exactly
12 what you'd like to see as opposed to we like
13 the drug box format and we think FDA ought to
14 consider that or use it, whatever your
15 recommendation may end up to be.

16 DR. PETERS: I think it was John,
17 Christine, and then Terry.

18 DR. PALING: I had a simple point
19 that the end of the first phrase which you
20 have to have your mind very clear and adaptive
21 to be able to read, we have the words
22 particularly focused on patients. It was

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1 about getting a uniform document. I would
2 just like to give it a focal point that the
3 primacy of it should be for patient
4 comprehension.

5 DR. PETERS: Christine.

6 DR. BRUHN: Thank you. I believe
7 that it is implied that the single document
8 would replace the PPI and the MG and I would
9 think it would be helpful to clearly state
10 that that's what we wish. And it's certainly
11 what I wish.

12 In regards to the statement about
13 the drug box, it was not my understanding that
14 that be done on advertising, but rather that
15 is a way of conveying benefits and risk
16 information to the public that appears to be
17 strong, as far as comprehension. And if we're
18 speaking about the drug box as a standard
19 format, it's as that single document that FDA
20 approves that's communicating information to
21 the public.

22 I strongly endorse John's wife's

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1 brilliant recommendation about using visual
2 means and although I've only had a chance to
3 skim it because it was on her desk, it looks
4 like other groups such as Consumers Union has
5 come up with some icons. It's tough to find a
6 good icon for everything.

7 But icons help not only those who
8 are of limited literacy, it helps those whose
9 language is not English. And it helps even
10 college-educated people who can look and
11 quickly see what they're doing. So I believe
12 that it's appropriate to explore the
13 development, to do -- to undergo research to
14 identify appropriate icons that communicate
15 effectively to the public about proper use
16 such as when to take the medicine, how to take
17 it, and you know all of that when you need it
18 and what it's for type of information.

19 I know that's saying a lot all at
20 once. I'm sorry I'm not more organized. And
21 frankly, I don't understand number five. So
22 when we go through these depth-by-depth, I

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1 don't know if it's just my mind is not working
2 any more or if a word was left out, but we do
3 need to look at some of the wording in greater
4 depth.

5 Thank you.

6 DR. PETERS: Dr. Davis, and then
7 Dr. Lesar.

8 DR. DAVIS: Visuals are powerful,
9 but they need evidence that people understand
10 the visual. A picture is worth a thousand
11 words, but which thousand? Or maybe
12 hopefully, five words. And then the second
13 thing is I think what's so compelling about
14 this to me is it's clean and it's to the point
15 and it has evidence that people understood it.

16 I like this for us to begin to get
17 between the lines on. One of the things I
18 would like it's got precautions. Number three
19 talks about use instructions. I also like the
20 idea of very concrete, specific use
21 instructions so that means it's got to be
22 tailored to the patient, but pretty soon we

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1 should have the technology to be able to do
2 that. You know, take two pills in the
3 morning, take two pills at bedtime. That's
4 it.

5 DR. PETERS: Dr. Lesar?

6 DR. LESAR: So about the risk-
7 benefit box, and it clearly has a -- for the
8 direct-to-consumer advertisement it probably,
9 looking at what the evidence is, it's most
10 likely should be included in that information.

11 From a consistency standpoint, it probably
12 should be in the patient information from a
13 consistency standpoint, but again, that's
14 something that could be easily tested because
15 I think we do have fairly good testing methods
16 for all the things we're talking about, about
17 what's the eventual effectiveness of any final
18 document. So I think we can start with a
19 theory, but to me it appears that we can
20 effectively test these things.

21 DR. PETERS: I'm going to take a
22 minute just to say something myself. In terms

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1 of the testing, the other thing I'd suggest
2 and I think it was Ms. DeSalva who brought it
3 up earlier, it needs to not just be tested,
4 but it needs to be tested specifically in
5 populations who could potentially, they
6 shouldn't be, but potentially could be hurt by
7 it. And so to test in populations that are
8 low numerate and older at the same time, for
9 example, but the testing in the end is key
10 because we can use our theories and we can use
11 things that we've developed perhaps originally
12 with college students, in my case. But in the
13 end, the people who are using them need to be
14 -- and who need to be able to understand this
15 and who are maybe our more vulnerable
16 populations, have to be able to understand the
17 information, but they also have to be able to
18 use it.

19 Dr. Goldstein?

20 DR. GOLDSTEIN: I'm thinking still
21 general principles, rather than specific
22 recommendations. I just want to follow up on

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1 what Dr. Davis just said about tailoring. I
2 think there's lots of evidence. We've heard
3 about it today, particularly from the fellow
4 from the U.K., the importance of tailoring
5 information based on the -- first of all, you
6 can tailor on the basis of the drug. You can
7 tailor on the basis of the population, where
8 they are in terms of their disease burden, in
9 the process of an illness you can tailor on
10 the basis of individual characteristics even.

11 That's possible, too. So there's some
12 limitations to tailoring, but we know that
13 tailor communication works better and that
14 we're going to have a hard time finding one
15 size fitting all anyway.

16 And that leads to the second point.

17 We also heard that layered information is
18 valuable, that people prefer actually less and
19 the opportunity to learn more and again
20 technology can help us here, not with the
21 paper document so much as with ways of
22 embedding information in different layers,

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1 literally, in electronic documents or linking
2 people to other sources and information when
3 they want more. So those are just two
4 principles that I heard very strongly. And
5 the third one actually is context and there
6 are all kinds of context. There's the context
7 of care, so in the moment of care, sort of in
8 the office at the bedside also, where people
9 are, whether they're in a home or in some
10 other place where they could be reached. So
11 we have to think about context as well.

12 DR. WOLFE: This is just a word
13 tweaking. I think that the first principle is
14 or at least seems to imply that we've agreed
15 that the FDA should be taking over this
16 process of both proving of the content of this
17 and requiring it. And in point six what you
18 have is FDA produced -- I think what you mean
19 is FDA approved, because the FDA isn't really
20 doing the production. I think -- is that what
21 you mean?

22 DR. FISCHHOFF: Yes, I think that's

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1 probably right.

2 DR. WOLFE: So FDA approved and
3 required, so just and again, as several people
4 have said the med. guide is the model. The
5 med. guide is now FDA approved and it's
6 required to be distributed and I think that
7 what we're willing to do, the discussion seems
8 to be to put this model out for other things.

9 DR. FISCHHOFF: Thank you. So on
10 the spirit of that, let's now, since it's 1:30
11 almost. Let's -- I'd like to -- let's take
12 each of these. If somebody has a friendly
13 amendment in the spirit of the recommendation
14 as it is here, like -- then let's have that.
15 That will be, you know, and then let's put it
16 a simultaneous vote, keeping our hands up long
17 enough.

18 Do we have to put our heads down?
19 Okay. Hands up long enough for Lee to see
20 what the degree of support is and then I'll
21 try to figure out what's the best way to do
22 it. So is there a friendly amendment to the

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1 wording of the first recommendation?

2 I'll make that one even -- since
3 we're working on that now.

4 DR. ZWANZIGER: Could we read it
5 out loud?

6 DR. FISCHHOFF: Okay, FDA should
7 create a single -- I think somebody was giving
8 out NSAIDs, no -- craned necks from Committee
9 service, hazard pay. FDA should create a
10 single, standard document for communicating
11 essential information about pharmaceuticals
12 which would replace the current set.

13 DR. ZWANZIGER: Could we all please
14 use the mics and it would be really good to
15 read these so that they get in the transcript
16 along with the discussion.

17 DR. FISCHHOFF: Okay. Mona.

18 DR. KHANNA: So my comment is do
19 you want to specify what you mean by current
20 set? Do you want to say PIs, medication
21 guide, etcetera?

22 DR. FISCHHOFF: Somebody tell me

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1 what is the current set? Somebody tell me
2 what to write here.

3 DR. BRUHN: PIs and MGs.

4 DR. WOLFE: CMIs, PPIs, CMIs, and
5 MGs.

6 DR. FISCHHOFF: Okay, remember,
7 this doesn't have force of law, but we should
8 be serious about it. Okay. What about this
9 word create, endorse, doesn't matter. It
10 doesn't have the same weight for you all or do
11 you have a preference of what you would rather
12 see here?

13 DR. BRUHN: I like --

14 DR. FISCHHOFF: Pardon?

15 MS. HENDERSON: You just should be
16 clear. I think pertinent to what someone else
17 just mentioned, create to me implies that we
18 would be the authors, and so I don't know if
19 that's what you intended.

20 DR. FISCHHOFF: Approve, adopt,
21 mandate. What would be the word that would --
22 I think that's the spirit is we would like you

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1 to have to guide the process.

2 MS. HENDERSON: Or adopt.

3 DR. FISCHHOFF: Adopt, okay. Let's
4 since time is short, let's just stick with
5 that. Okay, let me propose -- please,
6 Madeline.

7 MS. LAWSON: I would just like to
8 add and you can word it --

9 DR. FISCHHOFF: Please use the mic.

10 MS. LAWSON: I would just like to
11 suggest that in some way you add a word that
12 would include FDA would adopt a single
13 standard with input from the health
14 professionals or from the stakeholders. I
15 think we want to have input into the process.

16 DR. FISCHHOFF: Okay, I'm going to
17 make this -- let me read this again.
18 Actually, I can't type and read at the same
19 time. I think there's research of that.

20 So here's the recommendation and
21 I'm going to close the debate here because
22 it's already 1:33. If we couldn't get closure

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1 because we didn't have the time when we'll do
2 something different in the process next time.

3 So FDA should adopt a single
4 standard document for communicating essential
5 information about pharmaceuticals which would
6 replace the current set of PPI, CMI, and MG
7 through an appropriate consultative process.

8 And everybody who would like to
9 approve that, please put up your hand
10 simultaneously.

11 Is there anybody opposed, please
12 put up your hand?

13 Okay, thank you.

14 (The vote taken on the first
15 recommendation was unanimous.)

16 I just thank you in the spirit of
17 time management, as much as any.

18 The second one -- I'll read you the
19 current version and then maybe we'll try the
20 same process of some friendly amendments and
21 wordsmithing. This is actually a
22 recommendation, sort of the recommendation we

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1 made last time.

2 That standard document should
3 include quantitative summaries of risks and
4 benefits, along with use and precaution
5 information.

6 Are there friendly amendments?
7 Okay, those are in favor of this
8 recommendation, please put up your hands.

9 Thank you.

10 Those who are opposed to this
11 recommendation.

12 Okay, thank you.

13 (The vote taken on the second
14 recommendation was unanimous.)

15 I think the guy from -- the guy
16 with the oxygen bottle left. I can't remember
17 who it was. I don't mean to be disrespectful.

18 The next one is -- so this is
19 offered as an endorsement of the specific drug
20 fact box so one could, like the general idea
21 of tabular representation, but not -- you call
22 this the drug fact box?

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1 So the recommendation is FDA should
2 adopt the drug facts box as its standard
3 format. It should establish a standard format
4 for a second tier of elaborating information.
5 That's not quite English. So I would
6 appreciate a little wordsmithing there.

7 Anna Maria?

8 MS. DeSALVA: I just thought that
9 we had a good discussion about the need to
10 test to better understand its full effect, so
11 I would like to see that reflected somehow,
12 just the acknowledgment that it's full of
13 facts, potential unintended effects need to be
14 identified.

15 DR. ANDREWS: Also, Baruch, a
16 little wordsmithing here --

17 DR. FISCHHOFF: Please.

18 DR. ANDREWS: -- that would go
19 along with what Anna Maria just said. Perhaps
20 it should -- I'm sorry, should adopt a drug
21 facts box format as its standard. There might
22 be adjustments, expansions of this that should

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1 be explored through research.

2 DR. FISCHHOFF: Yes, yes. And as
3 in the presentation that we saw today, they've
4 made a lot of progress, but it is a work in
5 progress. They're trying to figure out how to
6 make it work. I think that's actually better.

7 That's good wordsmithing.

8 Ellen?

9 DR. PETERS: I'd actually argue a
10 little with the second sentence in there? I'm
11 not so sure that we know for sure that we want
12 that in the first tier and that something else
13 would go in the second tier? I would say that
14 the FDA should determine first and second
15 tiers of information. It's not clear to me
16 that that should always go in a first tier of
17 information, if that first tier of information
18 is supposed to be a very quick summary.

19 DR. FISCHHOFF: Mike?

20 DR. GOLDSTEIN: I don't know if
21 this helps, but we can say that we want to
22 support multiple tools, most important of

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1 which is the standard format for the drug
2 facts box. In addition, we want other tools
3 for those people who want further elaboration
4 of information.

5 DR. FISCHHOFF: There is a
6 subsequent recommendation that deals with --
7 okay, please, Terry.

8 DR. DAVIS: But Mike, we don't want
9 to get back to where we came from. Too many
10 papers.

11 DR. GOLDSTEIN: Yes. It depends
12 just how we want to define. We want the
13 essential material and something that is
14 disseminated widely in all the different ways
15 that we're describing. We also want to
16 provide access to information for those who
17 want more. It can't all be in one document
18 for those who want more. So we have to have
19 another way of helping them get other
20 information.

21 DR. FISCHHOFF: So let me take out
22 the tiering and let's just -- let's try this

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1 wording. I still don't like elaborating
2 information, but anyways. So the current
3 wording, FDA should adopt the drug facts box
4 format as its standard. It should specify a
5 process or engage in a process for creating a
6 standard for elaborating information. Poor
7 phrase and so on. The adoption should be
8 supported by a rigorous evaluation process,
9 building on existing research.

10 One thing that I had in mind in
11 formulating this is that in the questions that
12 were put to us, there was a question as what's
13 the best, basically what's the best format for
14 this elaborating information, that is, should
15 it be question and answer. Should it be a top
16 ten list and so on. And I didn't feel we had
17 made enough progress there to have anything,
18 so I wanted to peg that we needed to do more
19 work there, but not to be -- yes, Bruce?

20 DR. BURLINGTON: Yes, it looks to
21 me as though the first and third sentence in
22 that recommendation are somewhat incongruous

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1 in that one is recommending a specific work at
2 a specific point in time, rather than just a
3 concept based on the drug set facts box. And
4 the third sentence says but it needs more work
5 before we're ready to finish it. So if it
6 needs more work before we're ready to finish
7 it, then we have a concept we need to polish.

8 DR. FISCHHOFF: So the way I read
9 this, this was -- the way I read Craig's
10 amendment that the previous wording said it
11 was accepting the box as its standard format
12 and you're saying it's accepting the format of
13 the box which is a more conceptual thing as
14 its standard. So that's the way this is
15 intended to read.

16 Okay, the current reading is -- and
17 that's the spirit in the record. So the
18 current wording is FDA should adopt the drug
19 facts box format as its standard. It should
20 engage in a process for creating a standard
21 for elaborating information. This adoption
22 should be supported by a rigorous evaluation

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1 process building on existing research. Not my
2 best writing.

3 Could we put this to a vote? How
4 many people would support this recommendation
5 as worded?

6 How many people would oppose it?
7 Okay, thank you.

8 (The vote taken on the third
9 recommendation was unanimous.)

10 The next one is FDA should -- let
11 me make it bigger. FDA should rely on its
12 existing review process to derive the
13 authoritative information that the standard
14 document requires including pharmaceutical
15 companies' submissions and expert panel
16 summaries.

17 So what I was trying to say here is
18 that -- I was trying to capture that FDA is
19 the owner of the best information, either what
20 it develops itself or what's submitted for it,
21 and for these to be authoritative summaries it
22 should build on the Agency's expertise.

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1 That's on the content side.

2 Sid and then over there.

3 DR. WOLFE: This is essentially
4 adopting the model that the FDA has already
5 been using for a long time for the
6 professional labeling. So it should be based
7 on the same data and I think it says it very,
8 very clearly.

9 DR. FISCHHOFF: Okay, thank you.
10 Mike and then Musa.

11 DR. GOLDSTEIN: It, of course,
12 should be updated when postmarketing
13 information and about risks and benefits comes
14 out.

15 DR. FISCHHOFF: Yes.

16 DR. GOLDSTEIN: It's an iterative
17 process.

18 DR. FISCHHOFF: Yes.

19 MS. MAYER: And as I said before,
20 it should be a retrospective process,
21 ultimately to include all prescription drugs.

22 DR. FISCHHOFF: Okay. So the

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1 current -- if I've captured the spirit of what
2 we had here, so the proposal is FDA should
3 rely on its existing review processes to
4 determine the authoritative information that
5 the standard document requires including --
6 that phrase ought to be earlier. Anyways,
7 including pharmaceutical companies'
8 submissions and expert panel summaries. It
9 should create a process for ensuring up-to-
10 date information on all drugs.

11 Let's put this to a vote. How many
12 people would support this?

13 How many people would oppose this?

14 Okay, thank you.

15 (The vote taken on the fourth
16 recommendation was unanimous.)

17 I would like to make an unfriendly
18 amendment to option five and just delete it.
19 As I thought about it, I think we had
20 inadequate discussion here. Just to capture
21 the idea, we had discussions about how
22 integral pharmaceuticals, how integral the

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1 communications are to the pharmaceuticals.
2 The drug that's tested has different
3 communications than others, but thinking about
4 others, there's legal standing to the
5 redefinition of pharmaceuticals. We sometimes
6 don't have the expertise of that and we
7 certainly didn't discuss it. So I'm going to
8 -- if I was clever -- I'm going to delete
9 that. Okay. I don't like their functions.
10 Okay.

11 Number five, FDA approved and
12 required communications should be subject to
13 rigorous empirical evaluation of their
14 usability.

15 Mike?

16 DR. GOLDSTEIN: Here's what I would
17 add. Wording like effectiveness or something
18 that goes beyond useability.

19 DR. FISCHHOFF: I tried to capture
20 -- let me just say -- let me increase the font
21 on six because I tried to -- is it six? I may
22 not have done it right, but it attempted to

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1 address that by separating, excuse me, one we
2 want the standard and then what is that
3 standard.

4 DR. GOLDSTEIN: I just don't like
5 the word usability. It just seems too --

6 DR. FISCHHOFF: Take a look at 36
7 and see what -- at the next one. So the next
8 one suggests FDA should establish performance
9 standards for the usability of documents. So
10 defined in terms of the individuals who have
11 used it.

12 Let me just give you the process,
13 the thinking that I had here because I wanted
14 to separate these into sort of actionable
15 chunks that people could accept and reject.
16 So five, let's see, and maybe this is the
17 wrong strategy. Maybe it's close enough. So
18 five says FDA approved and required
19 communications should be subject to rigorous
20 empirical evaluation. The second is, six is
21 FDA should establish performance standards for
22 the usability of the standard document defined

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1 in terms of individuals who have received it.

2 So I think actually what you're asking for is
3 probably missing here.

4 Seven was that FDA should conduct a
5 systems analysis of the dissemination process
6 to see who actually gets it. And then the
7 next two have to do with how to staff up for -
8 - so how would you -- what would be kind of a
9 friendly amendment for usability?

10 Coming from a human factors
11 background, usability for me would capture
12 what you're talking about, but maybe it might
13 not capture it for somebody else. So friendly
14 amendments.

15 DR. WOLFE: Usability including
16 effectiveness or something --

17 DR. GOLDSTEIN: See, effectiveness
18 is sort of the language that's used in
19 determining the quality or the impact of the
20 communication in the clinical world.

21 DR. FISCHHOFF: Okay, so this
22 would, in some sense, putting effectiveness in

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1 this context would put this -- have the same
2 mindset that looking at -- I like that better.

3 DR. GOLDSTEIN: Yes, it goes with
4 what AHRQ -- they have a whole set of
5 evidence-based -- I think they call them
6 effectiveness.

7 DR. FISCHHOFF: Okay.

8 DR. GOLDSTEIN: Centers.

9 DR. FISCHHOFF: Tim and then Craig.

10 DR. LESAR: I was just going to
11 throw in outcomes based might be the thing. I
12 think that's what you're going for that the
13 evaluation is outcomes based. End point,
14 outcome effectiveness, not surrogate, whenever
15 possible.

16 DR. FISCHHOFF: Craig?

17 DR. ANDREWS: Friendly amendment on
18 six, something that was learned at the FTC
19 with some embarrassment on performance
20 standards. Establish performance standards
21 with time limits for the effectiveness.

22 DR. FISCHHOFF: What does that

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1 mean?

2 DR. ANDREWS: It could be ten years
3 and then they finally reach consensus -- 20
4 years.

5 DR. FISCHHOFF: So let me reject
6 that because I think that takes us into the
7 legal side of FDA and we want to say what they
8 ought to do and let's just leave it to them to
9 do that. If we were writing a reg. I would
10 support that, but I think for here I prefer to
11 leave it that way.

12 DR. ANDREWS: It was an early
13 corrective advertising case.

14 DR. FISCHHOFF: Okay. We haven't
15 voted on five or six. But they're sort of
16 tied, so --

17 DR. BURLINGTON: When I look at
18 five and six together, as they now appear to
19 read, I worry that we're setting the bar
20 impossibly high. We heard that we're not even
21 up to the standard they've achieved in Europe
22 where they are asking only for pretesting for

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1 content and comprehension. And certainly
2 taking a step towards content and
3 comprehension would be an advance.

4 Asking that we also have outcomes
5 research, that is, did people really change
6 their behavior as a result of that
7 communication, that's a huge step further.

8 DR. FISCHHOFF: Okay, are there
9 other --

10 DR. WOLFE: The Brits have defined,
11 at least as Dr. Raynor told us this morning,
12 defining effectiveness as could they find the
13 information, a, and b, were they able to
14 express it as in understand it. So I think
15 that in this context that's at least what I
16 think.

17 DR. FISCHHOFF: Maybe Craig could
18 say not so timely because it's going to take a
19 while. So I'm going to propose to live with
20 ambiguity on that figure that they'll do
21 something suitable in terms of being
22 realistic, but not taking forever.

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1 DR. FISCHHOFF: Mike?

2 DR. GOLDSTEIN: I was just going to
3 say the standards for what we have in terms of
4 evidence change over time and they do for a
5 lot of things. You're right. Right now we
6 have very little evidence for the
7 effectiveness of any communications. We
8 shouldn't not use something at all without all
9 of the high-level quality evaluation first,
10 but we should strive for effectiveness and
11 using the best evidence possible to shape
12 these documents.

13 DR. FISCHHOFF: Okay, thank you.

14 So number five is FDA approved and required
15 communications should be -- I don't want to be
16 redundant -- FDA approved -- is required
17 redundant? No.

18 Okay, FDA approved and required
19 communications should be subject to rigorous
20 empirical evaluation of their effectiveness.

21 For those who support this
22 recommendation, put up your hands.

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1 For those who oppose this
2 recommendation, put up your hands.

3 Okay, thank you.

4 (The vote taken for recommendation
5 five was unanimous.)

6 The next one, let's go directly to
7 that because we tied the conversation there.
8 FDA should establish performance standards for
9 the effectiveness of the standard document
10 defined in terms of individuals who have
11 received it.

12 So those who -- and the next one
13 talks about who -- number seven -- let me read
14 number seven now. Was my attempt to break out
15 the separate question of seeing who gets it
16 which was sort of the kind of topic that was
17 studied in the document, the study that was
18 reported yesterday. So I thought from a
19 research perspective, those were distinct
20 operations.

21 So six, FDA should -- we'll put
22 this to a vote. FDA should establish

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1 performance standards for the effectiveness of
2 the standard document defined in terms of
3 individuals who have received it.

4 Are those -- is this a friendly
5 amendment?

6 MS. MAYER: Yes. And the standard
7 document and related documents, something. I
8 mean we have provided for another level of
9 specificity elsewhere.

10 DR. FISCHHOFF: Just for -- let's
11 finesse that.

12 John?

13 DR. PALING: Just a thought again.
14 You could take the spirit of it to be defined
15 in terms of patients and other individuals who
16 have received it. I'd like that spirit not
17 necessarily be written in but be understood.

18 DR. FISCHHOFF: I had individuals
19 rather than patients, just actually thinking
20 of the surrogates who are -- that David was
21 talking about. So --

22 DR. GOLDSTEIN: I like caregivers,

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1 if you wanted to.

2 DR. FISCHHOFF: What?

3 DR. GOLDSTEIN: You could say
4 patients and caregivers.

5 DR. FISCHHOFF: Individuals. I
6 hope they're all individuals.

7 FDA should establish -- we're
8 putting this to a vote, should establish
9 performance standards for the effectiveness of
10 the standard documents defined in terms of
11 individuals who have received it.

12 Those who support it, please put up
13 your hands?

14 Those who opposed, please put up
15 your hands?

16 Okay.

17 (The vote taken on recommendation
18 six was unanimous.)

19 DR. FISCHHOFF: The next one is and
20 let me expand eight while we're looking at
21 this one. FDA should conduct a systems
22 analysis of the dissemination process by which

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1 the standard document reach consumers at times
2 relevant to their decisionmaking about
3 products' adoption and use.

4 Musa?

5 MS. MAYER: Why is this necessary?

6 DR. FISCHHOFF: I thought that
7 having -- if it doesn't get to people, then
8 it's of -- I thought that what we heard
9 yesterday was the -- in some sense not bad
10 success, maybe not up to the legal standard of
11 getting paper out. It just wasn't the right
12 paper. And it didn't consider people who were
13 in marginal populations who don't get their
14 things in an orderly process. I thought it
15 just called for another kind of analysis that
16 would bring in David Moxley's issues and
17 others. So that was the spirit of this. It
18 just requires a different kind of science.

19 Okay, Terry.

20 DR. DAVIS: It seems to me that the
21 meat was in the first three or four. I'm just
22 wondering if we're cluttering it up. Less is

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1 more is what we're saying. Are we practicing
2 what we're preaching and are we slowing them
3 down by adding all this other stuff?

4 DR. FISCHHOFF: So my thinking was
5 that having a perfect piece of paper is in
6 some sense less than half of a job because we
7 haven't worried about the people who aren't
8 going to get that piece of paper. And that's
9 why I wanted it -- that was my rationale for
10 having it here.

11 DR. BRUHN: But we are suggesting
12 that it be mandated that every drug have this
13 stuff with it.

14 DR. FISCHHOFF: But if -- vote
15 against it, if you don't like it, but my
16 rationale was that unless there's equal
17 commitment to getting, ensuring that the
18 information gets to everybody, that it just
19 won't happen. We'll go back to a mechanical
20 system that somebody is going to crank out a
21 piece of paper. So I think we need equal
22 diligence on this side of it. So that was my

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1 rationale.

2 So let me call for friendly -- so
3 if you understand the spirit of this, let me
4 call for friendly amendments on the wording
5 and let's put it to a vote. Those who support
6 this recommendation, number seven. Oh, let me
7 read it again.

8 FDA should conduct a systems
9 analysis of the dissemination processes by
10 which the standard documents reach consumers
11 at times relevant to their decisionmaking
12 about a product's adoption and use.

13 So those who support this
14 recommendation, please put up your hands.

15 Those who opposed it?

16 We have one in opposition. Thank
17 you.

18 (The vote was taken on
19 recommendation seven. All but one voted for
20 the recommendation.)

21 Number nine, and I'll bring up --
22 number eight, and I'll bring up ten so that we

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1 -- nine so that we look at it, it's more
2 visible.

3 So eight followed from seven. FDA
4 should identify populations for which the
5 standard document or the dissemination system
6 is inadequate. It should address their needs
7 where that is within its capabilities and
8 partner with other organizations where it is
9 not.

10 Any friendly amendments on the
11 wording?

12 Okay, those who support this
13 recommendation, please raise your hands.

14 Those who oppose this
15 recommendation, please raise your hands.
16 Okay, thank you.

17 (The vote taken on recommendation
18 eight was unanimous.)

19 And the final one, last, but not
20 least is that FDA should continue to
21 strengthen its practice of relying on the best
22 available social and behavioral science for

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1 designing and evaluating communications,
2 including research on textual, numerical, and
3 visual displays. It should foster research
4 relevant to improving the usability of its
5 standard documents.

6 I had in light something -- I think
7 we haven't discussed it enough, but I think
8 there's a skill set for determining what's
9 most important which is kind of a decision
10 science, risk analysis thing which is not, I
11 think, not represented. You need those skills
12 to determine what really matters. It's a
13 behavioral-informed risk analysis. So I had
14 that there. I didn't know if we had enough
15 discussion of that.

16 So obviously the spirit here is to
17 thank the Agency for listening to us and you
18 know, for embarking on this path I added in --
19 since we're talking primarily about displays,
20 I added in Christine's point which had been a
21 recurrent theme and then we have this question
22 here. So Mona?

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1 DR. KHANNA: You just need to
2 change the word usability to effectiveness to
3 be consistent.

4 DR. FISCHHOFF: Where is that?
5 Okay. Thank you.

6 DR. GOLDSTEIN: And then if I can
7 make another friendly amendment, add
8 dissemination too there. There's a science of
9 dissemination.

10 DR. FISCHHOFF: Yes, yes. It's
11 kind of compounded clauses, phrases. It's
12 kind of messy.

13 DR. GOLDSTEIN: I was just going to
14 add, this is wordsmithing, but --

15 DR. FISCHHOFF: Please.

16 DR. GOLDSTEIN: Effectiveness and
17 dissemination -- putting dissemination in the
18 second sentence, rather than in the first
19 sentence.

20 DR. FISCHHOFF: Okay, yes, yes,
21 yes. Right, and then we're doing its
22 research, yes, absolutely.

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1 DR. GOLDSTEIN: Dissemination of
2 its standard documents.

3 DR. FISCHHOFF: Okay.

4 DR. PETERS: And I would just
5 support your last sentence that's currently
6 not -- only part of the point. I would
7 support that as it should be part of it.

8 DR. FISCHHOFF: Any other thoughts
9 on this? Yes, okay. I'm going to put it in.

10 All right, it's gotten long, so I'm
11 going down, okay, bear with me. I think I can
12 squeeze it in at 34. I'll go to 32. It
13 doesn't offer me 32, so. I could never have
14 done this on a PC.

15 So the final recommendation: FDA
16 should continue to strengthen its practice of
17 relying on the best available social and
18 behavioral science for designing and
19 evaluating communications, including research
20 on textual, numerical, and visual displays.
21 It should foster research relevant to
22 improving the effectiveness and dissemination

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1 of its standard documents. It should include
2 analytical research for identifying
3 information, the information most critical to
4 decisionmaking.

5 Any friendly amendments on the
6 wording?

7 Mike.

8 DR. GOLDSTEIN: I know I'm beating
9 a dead horse, but putting tailoring in there,
10 I'd favor putting -- should include analytical
11 research by identifying information most
12 critical to decisionmaking and tailoring the
13 material to relevant populations.

14 DR. FISCHHOFF: Okay.

15 (Pause.)

16 DR. FISCHHOFF: Let's make it
17 target audiences. By having audiences, then
18 it implies that there's more than one.
19 Tailoring has -- some people like tailoring.
20 Some people don't. So I'd like to kind of
21 avoid that word per se, but the idea that we
22 need to recognize that there are populations

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1 out there. I think that -- I hope that would
2 capture the spirit.

3 Okay, let me put this -- I'll read
4 this out. FDA should continue to strengthen
5 its practice of relying on the best available
6 social and behavioral science for designing
7 and evaluating communications, including
8 research on textual, numerical, and visual
9 displays. It should foster research relevant
10 to improving the effectiveness and
11 dissemination of its standard documents. It
12 should include analytical research for
13 identifying the information most critical to
14 decisionmaking of target audiences.

15 Those who support this
16 recommendation, please put up your hands.

17 Those who oppose it, please so
18 indicate?

19 Okay.

20 (The vote taken on recommendation
21 nine was unanimous.)

22 Well, let me thank you all. Don't

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1 bother getting up. Let me thank you all for
2 your participation and all the way through
3 this your contributions.

4 Let me thank the audience for
5 having come and for the contributions that
6 many of you made either directly to us or in
7 the breaks. And I hope together we've made
8 things better for the American people. Thank
9 you.

10 DR. WOLFE: Thank you for a
11 skillful job of running these two days.

12 (Applause.)

13 DR. FISCHHOFF: Thank you.

14 (Whereupon, at 2:05 p.m., the
15 meeting was concluded.)

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