

1 consumer in mind. And I think that kind of
2 gets back to what AnnaMaria was saying
3 yesterday. If our goal is that people make
4 wise decisions about the regulated process,
5 then their needs -- if that's really the goal
6 of the organization and it needs that because
7 that's what its mission is, and, you know,
8 from a legal perspective that's what its
9 mission is, it needs that effective
10 communication from a political perspective,
11 because if people take the wrong drugs or, as
12 Mona was saying, they feel like they were
13 misled by kind of legally-right information
14 but stuff that didn't really lead them, then
15 from a political perspective they FDA is
16 vulnerable if it can't do that right.

17 So, you know, do we need to say
18 something about how integral that the
19 communication function needs to be to the
20 development of the information on which FDA
21 runs?

22 DR. OSTROVE: Okay. The simple

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1 answer is, yes, probably. It's a lot more
2 complex than that because even if you do say
3 something about that, it goes back to; and I
4 wish we had someone like Bob Temple here, for
5 instance, to talk about the science, but it
6 goes back to -- well, not just the science,
7 but also the legal piece of it, to what the
8 basis for approval is just restricting say,
9 you know, the drugs and medical devices that
10 need to be approved, the PMAs, because that
11 basis may not take communication issues into
12 account. You know, the legal basis may not
13 take that into account. The legal basis may
14 be -- and again, you know, I'm talking way
15 outside of my area of expertise now, but the
16 legal basis may be really just based on does
17 the drug perform -- you know, from the legal
18 meaning of the term "safe and effective," is
19 the drug better than placebo? Or, you know,
20 in some cases better than what the active
21 comparator is when it may not be ethical to
22 use a placebo. And that may not take into

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1 account the fact that the patients will not be
2 using it in a controlled circumstance.
3 They'll be using it in a non- controlled
4 circumstance. They may want information about
5 quality of life issues, for instance, that are
6 not part of that or have not traditionally
7 been -- I mean, I think more of that is
8 getting in there, but traditionally has not
9 been part of that ultimate scientific
10 judgment. It just gets more and more complex,
11 you know, as you get into the details of the
12 legal and the scientific and the regulatory
13 basis for the decisions.

14 But on, you know, on a very basic
15 level in terms of I think, you know, the high
16 level question are communication
17 considerations built into that? I would say
18 they probably are not. Maybe they can be more
19 than they are even within the legal
20 requirements. I'm not sure. But it certainly
21 wouldn't hurt to acknowledge that, the need
22 for that to be at least considered.

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1 CHAIRMAN FISCCHOFF: Thank you.
2 Yes, just like it's not our job to know FDA
3 well enough to say whether they should write
4 Nancy a check or write somebody else a check
5 for staffing up, we can just say in order to
6 fulfill this part of this mission you need to
7 address this people. And my guess is that the
8 closer would discover that some of what we're
9 asking for isn't legal and which you can say
10 our hands are tied, you know, just like some
11 of it isn't legal given -- because your hands
12 are tied by OMB for things that we view as
13 essential and that's a leadership question to
14 solve that. But I bet that some of this is
15 just convention. You know, that the agency
16 staffed up in a particular way. The
17 considerations have changed and there isn't
18 the staff to do it. You know, it would be a
19 kind of an internal leadership rather than an
20 external function of leadership to change it.

21 MEMBER MAYER: I think we've made a
22 decision as a society, or at least Congress

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1 has mandated that in order to get products on
2 the market, let's say drugs in this case on
3 the market, we require very highly controlled
4 and very minimal amounts of data which are not
5 explored in a natural setting at all.

6 I think the place to realistically
7 begin to address these issues is in the
8 post-marketing environment where, as we know,
9 there's really been a dearth of information
10 real life information about the effects of
11 drugs, about compliance with taking
12 medications in the ways that they are
13 prescribed.

14 And I have great hopes for the
15 Sentinel Program. I think I've mentioned it
16 before. The idea that we can use these large
17 population databases from CMS, Medicare and
18 Medicaid, from the VA, from large
19 organizations like Kaiser and others to look
20 at how drugs are actually being used in the
21 population, once they're on the market, in
22 conjunction with other medications that may be

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1 taken in people who have comorbidities, who
2 don't meet the criteria or the population
3 group for whom the drugs were originally
4 prescribed, who are taking them off label and
5 the full sort of panoply of a variation that
6 happens in a real life situation. And it also
7 seems to me that it would be a really missed
8 opportunity not to do some of the kind of
9 research we're talking about in that
10 situation. And I don't know how this could be
11 put into place, but certainly FDA and the risk
12 communications at FDA could play some sort of
13 leadership role in terms of how that program
14 is being set up and the kinds of data that are
15 extracted. It just seems to me like a perfect
16 opportunity at the initiation of a new way of
17 looking at post-marketing for risk
18 communication data to be mined.

19 CHAIRMAN FISCHHOFF: Let's take a
20 break. Let's come back at 10:15 and begin the
21 public hearing then.

22 (Whereupon, the above-entitled

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1 matter went off the record at 9:56 a.m. and
2 resumed at 10:18 a.m.)

3 CHAIRMAN FISCHHOFF: Okay. We'll
4 now begin the open public hearing section of
5 your meeting. We're privileged to have two
6 speakers today. Oh, we have three now. The
7 first will be Julie Aker, followed by Jim Paul
8 and Jeff Secunda in that order.

9 I'll read the statement.

10 Both the Food and Drug
11 Administration, FDA, and the public believe in
12 a transparent process for information
13 gathering and decision making. To ensure such
14 transparency at the open public hearing
15 session of the Advisory Committee Meeting, FDA
16 believes that it is important to understand
17 the context of an individual's presentation.
18 For this reason, FDA encourages you, the open
19 public hearing speaker, at the beginning of
20 your written or oral statement to advise the
21 Committee of any financial relationships that
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1 may be affected by the topic of this meeting.

2 For example, the financial
3 information may include a company's or a
4 group's payment of your travel, lodging or
5 other expenses in connection with your
6 attendance at the meeting. Likewise, FDA
7 encourages you at the beginning of your
8 statement to advise the Committee if you do
9 not have any such financial relationships. If
10 you choose not to address this issue of
11 financial relationships at the beginning of
12 your statement, it will not preclude you from
13 speaking. Thank you.

14 And our first speaker will be Julie
15 Aker, President and CEO of Concentrics
16 Research.

17 Please. Welcome.

18 MS. AKER: Good morning, everybody.

19 My name is Julie Aker. I'm president and CEO
20 of Concentrics Research in Indianapolis,
21 Indiana.

22 In terms of disclosures, we do work

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1 with pharmaceutical and device companies that
2 have both Rx and OTC products. However, my
3 visit today here is paid for in full by
4 Concentrics Research.

5 The reason for my coming today is
6 to share some information with you about
7 research that's done with over the counter
8 products that has I think some good bridging
9 information to this group and to the work that
10 we are discussing and have been discussing.
11 And the good news is, this is information
12 that's already in place and these are methods
13 that are already tried and true.

14 So in terms of how we are, we are a
15 privately-held research company. We've been
16 doing consumer and patient-focused research
17 for about 25 years. We work with both Rx and
18 OTC drugs and devices and we consult on
19 labeling and program development. We've done
20 about 700 studies. We do an awful lot of work
21 in designing and conducting label
22 comprehension research. And when I say label

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1 comprehension, I don't mean just the exterior
2 facts label. I mean all items that would be
3 considered labeling, including PIs, PPIs,
4 brochures and other types of materials, and
5 especially Med Guides which are very relevant
6 to the discussion today.

7 We've worked on a lot of the
8 Rx-to-OTC switches, about 76 percent of those.

9 We've done over 120 label comprehension
10 studies. So this is an area that's certainly
11 near and dear to our hearts.

12 We're very active in industry and
13 FDA activities and we're currently working
14 with CDC, FDA, HHS and NIH in a variety of
15 different activities.

16 We also work in the REMS space and
17 that's part of the discussion that I wanted to
18 have with you all today. We're currently
19 working on about six programs, either in
20 process or in discussion. But we are also
21 seeing some challenges and kind of in the
22 spirit of sharing, you know, what's working

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1 and what's not working one of the things that
2 we're seeing is that a lot of the REMS
3 expectations are somewhat variable. There's
4 little or no comprehension testing in these
5 programs right now. And the recruitment and
6 study population expectations do not
7 necessarily result in the best overall
8 insights and efficiency for the study.

9 Some of the expectations applied
10 for recruitment of individuals to assess newer
11 drugs in which there would be very small
12 available populations and also existing drugs
13 are somewhat the same. So you can see that
14 there would be some real challenges there just
15 in recruiting. And so also the label
16 assessments of medication guides are largely
17 based on subject recall right now versus
18 comprehension. So we'll talk about that just
19 a little bit more.

20 If we look over here and kind of
21 work right to left, you know, we all agree and
22 we've been discussing this issue of desired

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1 outcomes, and obviously the desired outcome is
2 consumer safety and adherence. But in order
3 to have that desired outcome, the patients and
4 consumers need to be able to act on
5 information. In order to act on that
6 information, it must be relevant to them and
7 they must be motivated to do something with
8 it. We're all the same. We all go home and
9 do exactly the same thing. So part of this
10 step is really creating awareness and
11 hopefully causing the behavior to shift.

12 In order to cause that to happen
13 though they need to have access to clear
14 information. And then in order to have clear
15 information, we need to test comprehension
16 with not only consumers, but also health care
17 providers if we are talking about training
18 materials that we're going to be giving to
19 health care providers from which to do the
20 training. And then finally, development of
21 materials. So you can see that this is an
22 iterative process kind of working backwards

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1 from our desired outcome.

2 What we're seeing is that a lot of
3 these programs are skipping over this step
4 here. So there's the development of materials
5 and then going into testing over here where
6 we're evaluating how things are working or not
7 working and kind of skipping this stuff here.

8 And this is really what we want to bring out,
9 but this is extremely important to really
10 learn early on and to go directly to the
11 source. And who are the sources? The
12 consumers that are going to be using those
13 drugs and health care providers that are going
14 to be advising them.

15 This is a very busy slide, but it's
16 really exactly what a consumer's experience is
17 and they will tell you that this is exactly
18 the world that they live in. So it's a
19 combination of things that they see and hear,
20 things that doctors told them, various tools
21 that they're looking at and so forth. But
22 it's a very confusing space for them.

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1 So if we talk about comprehension
2 research, who should be tested? Well, we've
3 talked about these two broad groups of
4 consumers and health care providers. So if we
5 look at consumers, we want a broad and diverse
6 population. We've had some discussion about
7 this yesterday, you know, who should we really
8 be testing, who should that be. We would
9 argue that it should be a group of sufferers
10 that are both taking the medication, which are
11 today's consumers, but also people that suffer
12 from that condition that might be taking the
13 product tomorrow. Because we want to make
14 sure that whatever communications are in these
15 materials that they're clear enough to not
16 only the people today, but the people who
17 could be on this drug in years to come. And
18 so we advocate for a mixture of people that
19 suffer from the condition or the disease for
20 which the product treats, but combines the
21 two.

22 The other thing that we would argue

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1 is really important is testing literacy.
2 Health literacy testing is very important. We
3 want to make sure that we are really gearing
4 these materials to people of all literacy
5 levels and that's an easy matter to do if you
6 design the literacy testing into the research,
7 which we do.

8 Other things that we do, and this
9 is very well known in the over the counter
10 area. So if you go to CDER, you go to the
11 Office of Nonprescription Products. These
12 methods that I'm discussing are not new,
13 they're not novel, they are not just done at
14 Concentrics. These are already widely
15 accepted processes that are already in place
16 and acceptably by the Agency, just in a
17 different part of the Agency with over the
18 counter drugs. But they will also exclude
19 individuals who are currently working with
20 health care marketing regulatory organizations
21 so that there isn't any kind of predisposition
22 or biasing.

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1 From a health care providers
2 perspective, when we recruit populations for
3 these studies we're really looking for those
4 who order the medications, but then also those
5 who educate and support the consumers. So
6 we're talking about doctors that can be a
7 combination of primary care and specialists as
8 applicable and in some states nurse
9 practitioners and PAs, but then also those who
10 educate, which are comprised of the list above
11 as well as pharmacists.

12 I wanted to share, because we've
13 been doing a lot of theoretical discussion
14 just what goes on down in the trenches. And
15 we spend a lot of our life and our life's work
16 is really to listen to what consumers say. So
17 let me just pick out a few of these.

18 You know, a lot of consumers will
19 tell us my doctor will tell me what I need to
20 know, my pharmacist will tell me what I need
21 to know, or I'll look at those nice colorful
22 stickers that are on the packaging of the

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1 label and that will tell me what I need to
2 know. Many, many consumers will tell us that
3 they throw away the paper that comes with
4 their prescription. It's simply too much and
5 it's repetitive. Interesting enough, a lot of
6 consumers don't feel that information is for
7 them. They think that that is written by
8 lawyers for physicians to read. So they think
9 it's very technical information and it's
10 really meant for health care providers, not
11 the average consumer. Sometimes they use
12 their own judgment. Some don't know what some
13 of these terms are, like medication guide.
14 They don't know where it is or what it is.

15 What we've learned from consumers
16 is that, you know, they do tune into messages
17 under certain conditions, and this is very
18 interesting. They tune in when they're in the
19 caregiver role. So if you're giving
20 medication to a child or an elderly parent,
21 you're going to tune in. If a doctor or nurse
22 emphasizes or educates them, they're going to

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1 tune in a little bit more because it was
2 emphasized. It was important enough to be
3 brought out. Women tend to read things more
4 than men; we found that in our research. And
5 if it's a new product, folks tend to tune into
6 that labeling more than an existing product.
7 They're extremely overwhelmed with all the
8 information. I think we've all been talking
9 around that. They can't absorb everything.
10 It's just simply too much.

11 And importantly, and this is
12 something we may not have discussed, it's very
13 difficult for them to discern what level of
14 importance or danger or risk that we're
15 talking about. If you're overwhelmed with all
16 this information, it just kind of becomes
17 information wallpaper and it all looks the
18 same. So it becomes very difficult for a
19 consumer to really pull out that this is the
20 one warning I'm really, really talking about.
21 And again, normal literacy individuals don't
22 necessarily see things the same way.

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1 Health care providers that we
2 talked to usually will say I care deeply about
3 my patients. I want to do a good job with my
4 patients. I don't have time to do all of
5 these other types of things related to
6 counseling and training. They know it's
7 important. It's a time issue. They sometimes
8 refer the patient to the labeling, sometimes
9 to a web site. They tell the patient they can
10 call with questions or talk to their
11 pharmacist. They know that every product is
12 different, but sometimes every product has a
13 different series of paperwork that goes with
14 it or warnings, and that's very difficult to
15 keep track of when you're in a busy office.

16 I guess five core REMS questions
17 that I would pose based on our experience
18 would be do the stakeholders that are involved
19 in this process really understand their role
20 and how to perform it? Do the consumers know
21 their part? Does the doctor know their part?
22 Does the pharmacist know their part? Do they

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1 all know their role as it relates to some of
2 these REMS expectations and risk
3 communications? And are we asking the right
4 research questions, which I think was posed
5 right before the break, and that is a very
6 pivotal question.

7 Some of the expectations that we're
8 getting on some of the REMS are difficult in
9 and of themselves to interpret sometimes. For
10 example, these are quotes, evaluate patient
11 understanding, but not comprehension. That is
12 one that came from a letter. Evaluate
13 usefulness of the medication guide. Well,
14 what does that mean? Usefulness in terms of
15 comprehension, dissemination? Usefulness as a
16 tool? Usefulness in driving good outcomes?
17 So we all are trying to kind of get our own
18 nomenclature, you know, standardized somewhat.

19 Are we going to go to the source
20 too late, meaning are we going to consumers
21 and health care providers too late in the
22 process? We're doing a lot of development,

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1 we're doing a lot of testing. We would kind
2 of find out at the end what worked and what
3 didn't work. And are we keeping it simple and
4 targeted, and are we involving experts at the
5 right time?

6 I would just offer to you that you
7 may or may not know that the Office of
8 Nonprescription Products, which is under CDER,
9 actually does this kind of research all the
10 time. So in terms of resourcing and
11 partnering and all these things that we've
12 been discussing, this expertise actually
13 exists within the FDA. They've done this type
14 of work in comprehension research and risk
15 communications for 20 years. And if you're
16 thinking, well, over-the-counter drugs are
17 just not as complex as the typical
18 prescription drug, I would argue that that's
19 changing. The drugs that we're looking at for
20 switch right now are much more complex and
21 there are many more warnings.

22 You should know that there's a new

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1 guidance out today. It's posted on the FDA
2 web site. This is the web address. If you
3 don't get it because I'm flipping through the
4 slides too quick, come and see me and I'll be
5 happy to share it with you. This is a draft
6 guidance on label comprehension. Many of
7 those elements are very applicable to the work
8 that we're discussing here. It has a 90-day
9 review period.

10 I would also just put these types
11 of research up for your review, that when
12 we're doing consumer research we're looking at
13 label comprehension of all these different
14 types of tools. We're looking at actually
15 assessing decisions and judgment on warnings
16 and dosing and we're doing real-world in-use
17 type of work so that we can look at the
18 behavior and the outcome, so that we can see
19 if the safety is there and if the health
20 benefit is achieved. So these are the types
21 of things that -- there are overlays. The
22 point is that there are overlays from what is

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1 going on in OTC world into this space as well
2 without reinventing the wheel.

3 I won't read this busy slide to
4 you, but I did want to point out -- one of the
5 things that's been brought out in this meeting
6 is that we want research that is rigorous and
7 that is scientifically based. These types of
8 studies are. And so if we take kind of a
9 reference point that we're all comfortable
10 with, which is a clinical trial, and some of
11 the study procedures that you would expect,
12 you can see that there are many, many
13 correlations here to this type of consumer
14 research that's very, very much the same.

15 The methods that are used are not
16 focus groups. They are one-on-one interviews,
17 a diverse group of consumers and health care
18 providers. They use scenario-based questions.

19 The purpose for using scenario-based
20 questions and an open-ended-type of
21 questioning is that you get insight into not
22 only comprehension, but also judgment.

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1 Sometimes this is done through questions,
2 sometimes through simulations. Probes are
3 done after the questions are asked to find out
4 the reason behind the question or the answer
5 that was given and then verbatims are also
6 coded. Importantly, this is not a recall
7 test. This is a comprehension test.

8 Final thoughts. The
9 communications, especially the warnings, must
10 be tested in advance. The comprehension
11 testing is very, very important. It needs to
12 be done iteratively and proved over time with
13 those of normal in low literacy and it should
14 be tested in populations that not only take
15 the drug today, but could take the drug
16 tomorrow. There are well-established
17 comprehension methods that are available for
18 OTC drugs that we would encourage the
19 Committee to consider and that you can partner
20 with companies that are experienced in doing
21 this type of research. Keep it simple. And
22 it seems from this meeting that there are two

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1 large buckets of work that we've been talking
2 about. One has to do with industry-driven
3 types of research, which are answering global
4 questions to maybe build a framework that can
5 be used in any of those types of programs.
6 And then things that are more product-specific
7 where we use the framework but apply it to
8 that specific product. Finally, if we listen
9 to consumers we'll be able to move from the
10 theoretical to reality very quickly. And then
11 finally they will help us lead the way.

12 The last thing just in the spirit
13 of the partnerships that we've all been
14 talking, all things are possible when you
15 bring a good group of people together.

16 So thank you very much for the time
17 to present these ideas.

18 CHAIRMAN FISCHHOFF: Thank you very
19 much.

20 Our next speaker will be Jim Paul
21 from the Corvallis Group.

22 DR. PAUL: I won't be using the

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1 slides. I got up at like 5:00 this morning
2 and decided to scrawl something on my cell
3 phone. So I'll probably be reading most of
4 the information off of that.

5 My name is Jim Paul. I support my
6 wife in her business as a consultant in risk
7 communication. The company is the Corvallis
8 Group. My wife is a physician and writes
9 patient information as well as information for
10 physicians. I mainly do the books and make
11 sure the computers are in the system.

12 I do get involved in some projects,
13 and my background is out of the chemical
14 industry and I've done quantitative risk
15 assessment and risk management, and led a
16 program for our company to develop for
17 quantitative risk assessment and risk
18 management, basically training everyone within
19 the company. So that's a little bit where my
20 background is. And the work we did in the
21 chemical company, we looked at other
22 industries, so it's not just a chemical

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1 company focus, but it's other industries. And
2 what you find is there's a lot of similarities
3 between, you know, one industry and the next,
4 and the pharmaceutical industry is really no
5 different.

6 Technically, I have a Ph.D. in
7 physical chemistry, math and physics
8 background. So the quantitative risk
9 assessment kind of falls within my background.

10 It's also interesting working with an
11 individual who works on the communication end,
12 and we do lots of discussion back and forth
13 because we kind of cover, if you will, the
14 full range of information from risk assessment
15 all the way to getting it out to the patients.

16 My concern is the complexity and
17 the amount of both words and numbers and data
18 in some of the proposed patient information.
19 I don't believe it will be very effective in
20 getting the information across to patients to
21 help them make decisions. I think there's a
22 tremendous issue about being overloaded. One

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1 of the things that we found is that making
2 risk decisions and really understanding risk
3 is not so simple. When we went through the
4 training program with our own organization, we
5 were working with operators in the plant,
6 maintenance people and engineers. And even an
7 engineer who really doesn't have the training
8 in risk assessment really doesn't know how to
9 assess risk. You can look at frequencies and
10 you can look at outcome, but understanding
11 what risk is is another issue. So too many
12 cases where relatively poor decisions are
13 made, either too much, too little, something
14 along those lines.

15 So from our perspective there had
16 to be some critical training that goes to the
17 appropriate people. And if you look at
18 patients, I don't think we're going to be
19 training them in risk assessment. There's
20 just too much, and there's too much in the
21 documents that they have to go through.
22 They're not going to be able to make risk

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1 assessment judgments.

2 So you step back a little bit and
3 you start looking at the medical community.
4 They have the training, but they really are
5 not trained in risk assessment. It's almost
6 like -- it's a specific science and it would
7 be critical to put the training in the medical
8 community or the health care providers, and
9 the amount of information that would go to a
10 patient really needs to cover the critical
11 things that they need to know like -- if this
12 happens to me, when I need to talk to my
13 doctor. That's some of the critical things.
14 And I'm very concerned that if there's too
15 much information in what goes to patients,
16 everything is going to be lost and they won't
17 go to the doctor when they need to go to the
18 doctor.

19 That's what I have to say. I thank
20 you.

21 CHAIRMAN FISCHHOFF: Okay. And our
22 third speaker is Jeffrey Secunda for AdvaMed.

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1 Welcome.

2 MR. SECUNDA: Good morning. Jeff
3 Secunda from AdvaMed, Vice-President for
4 Technology Regulatory Affairs. And AdvaMed is
5 the trade association that represents the
6 medical device industry.

7 I want to reiterate what I said
8 yesterday in terms of the involvement of
9 industry in the process of creating the
10 message and disseminating the message.
11 Although it appears that from discussions that
12 I've heard, the panel understands the utility
13 and the relevance of having industry involved,
14 I think it's really critical that industry be
15 mentioned explicitly in the strategic plan as
16 being a beneficial stakeholder partner with
17 FDA. And furthermore, I think it's very
18 important that there be a clear and consistent
19 policy that guides when industry is involved,
20 and at what level in time they are involved in
21 the creation and dissemination of messaging.

22 The other point I want to make is

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1 more of a personal observation and it's been
2 reflected by other public commentators, and
3 that is in the acknowledgement, the awareness
4 of the difficulty that the human species has
5 in understanding risk and using risk. And I
6 think this is especially true today. You
7 know, a thousand years ago the risks were
8 pretty obvious, and people could make
9 decisions because the consequences of their
10 decisions were easily ascertained. Nowadays
11 the risks are much, much more complex.
12 They're much, much more subtle. And I think
13 that we are still, if you will, genetically
14 only able to make risk decisions that are
15 fairly obvious. So I think I would say that -
16 - and this is for FDA in general, but really
17 for all government agencies that are involved
18 in the public health -- that there needs to be
19 both an acknowledgment of the difficulty that
20 people have in understanding and utilizing
21 risk information, but also in trying to raise
22 the awareness of what risk information is and

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1 what it is not, and trying to enhance people's
2 ability to make use of the information. It's
3 good to have comprehension tests that, you
4 know, people will remember and recall and be
5 able to recite what the quantitative risk is
6 for a particular event or item. It's another
7 thing for them to use that information in a
8 way that is both beneficial to themselves, but
9 also to society as a whole. So this I would
10 probably put in the category of a campaign
11 that should be considered to bring our
12 understanding of risk up to date in the 21st
13 Century. Thank you.

14 CHAIRMAN FISCHHOFF: Okay. We have
15 some time for some general discussion. I've
16 also, with some nice thoughtful helpful input
17 from John, have drafted some conclusions and
18 recommendations that we might want to
19 consider.

20 Lee and I think we have a way that
21 we can do this in a useful and somewhat
22 less-rushed way than the last time and be

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1 within the law. I'll tell you what I've done
2 and, you know, if you don't like it, then
3 we'll do something else.

4 Which is, I've tried to synthesize
5 the topics that were here in five points, and
6 maybe those aren't the right five points, and
7 you'll see each of which has a conclusion.
8 Well, actually this is what's written and, you
9 know, not soliciting agreement just yet. But
10 the first one applauds FDA for what it's done
11 in developing the strategic guidance and then
12 has a recommendation for one or two things
13 that it might do next. So I have five things
14 structured in terms of conclusions and then
15 recommendations.

16 Because we're at FDA's home now,
17 we'll be able to have hard copies of this so
18 people can look at them. As well, we will
19 also be able to edit online so we can get the
20 technology right.

21 (Off-mic comment.)

22 CHAIRMAN FISCHHOFF: What?

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1 (Off-mic comment.)

2 CHAIRMAN FISCHHOFF: Yes. Okay.

3 And let's see, yes, I think editing them
4 online will help. And then one of the things
5 that Lee and I were struggling with was --
6 is, you know, in some sense we're in the
7 situation where you had to be here to
8 appreciate it. So how do we capture the
9 concrete examples of the discussion that we've
10 had for somebody who hasn't been here? And
11 under the law anything that goes into this
12 report needs to have been said at the meeting.

13 So we can't do any wordsmithing of the
14 recommendations afterwards. However, Lee,
15 with some input from me, and I guess input
16 from everybody -- does it go to everybody?

17 (Off-mic comment.)

18 CHAIRMAN FISCHHOFF: It goes to
19 everybody. It goes to the Committee. Has a
20 sense of the meeting summary, you know, that
21 goes to all of us and then to the leadership
22 afterwards.

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1 (Off-mic comment.)

2 CHAIRMAN FISCHHOFF: And then is
3 published online.

4 So I suggest the following process
5 and we can have general discussion now.
6 You'll have it and you can be reading this
7 while we're -- it fits on one page, for the
8 squinters. So the process that I propose is
9 that we consider these conclusions and
10 recommendations and see if we can wordsmith
11 them to a place where we feel comfortable
12 voting on them. They are, as you know,
13 non-binding. That in the discussion of each
14 of these topics try to, you know, restate, you
15 know, if only briefly the topics that you
16 think the examples or the arguments that you
17 think are particularly relevant to them. And
18 then Lee can write and with our approval draft
19 some accompanying text that will say this is
20 what we meant by this and we can pull in both
21 what's said right now as well as -- we'll have
22 the full transcripts. We can pull in other

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1 things.

2 So just make certain that, you
3 know, if something was said already, it
4 wouldn't hurt to repeat it, but we can put in
5 the narrative anything that was said during
6 the meeting, but nothing that comes along
7 afterward. So that's the process that I
8 propose, and we could start this now or have a
9 general discussion.

10 Mona?

11 MEMBER KHANNA: I would just say
12 call it what it is. You said draft strategic
13 risk communication guide. I would just say
14 strategic plan for the risk communication at
15 the Food and Drug Administration. I mean, who
16 knows? There might be a guide somewhere else.

17 CHAIRMAN FISCHHOFF: Yes. Yes.
18 No, I didn't have time to do that. So what's
19 it called?

20 MEMBER KHANNA: Strategic plan for
21 risk communication at the Food and Drug
22 Administration.

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1 CHAIRMAN FISCHHOFF: Okay.

2 MEMBER KHANNA: Take out guide.

3 CHAIRMAN FISCHHOFF: Okay. Okay.

4 Oh, so it sounds like you want to get right
5 into this. Shall we get right into --

6 MEMBER KHANNA: Oh, I just was
7 correcting a factual error.

8 CHAIRMAN FISCHHOFF: Yes.

9 MEMBER KHANNA: Whatever you
10 prefer.

11 (Off-mic comment.)

12 CHAIRMAN FISCHHOFF: Yes. So we'll
13 have a hard copy. So let me just ask the
14 process question. Would it be most useful to
15 the group to have a discussion focused around
16 these as opposed to a general discussion?

17 So let me just read this aloud so
18 you'll see what the scope is and then we can
19 go into the details. And again, you'll have a
20 hard copy fairly soon.

21 So the first one applauds the
22 strategic plan and then has a couple of

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1 suggestions about what to do next.

2 (Off-mic comment.)

3 CHAIRMAN FISCHHOFF: Oh, okay. But
4 this will be the first draft. You need the
5 first draft in the transcript?

6 PARTICIPANT: It's up to you.

7 CHAIRMAN FISCHHOFF: Okay. All
8 right. Let me read it aloud rather than
9 paraphrasing myself. And I'm sure there are
10 typos here. There's typos in everything I do.
11 So let me just say, I'm going to read through
12 the whole thing now so you'll get an idea of
13 the scope and be taking notes and thinking
14 about how -- and we'll be able to go through
15 all of it. We can add recommendations. We
16 can delete these. But here's, you know,
17 something I learned from my dissertation
18 advisor or one of them, that it's always good
19 to have a sharp hypothesis and be ready to
20 walk away from it. So there's a sharp -- it's
21 not necessarily accurate hypothesis.

22 (1) "The Committee applauds the

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1 strategic plan for risk communication at the
2 Food and Drug Administration as a major step
3 forward in enabling FDA to meet its mission of
4 service to the American public. The Committee
5 recommends continuing these efforts to make
6 communication central to the production,
7 summary and dissemination of evidence
8 regarding" -- let's make this FDA's regulated
9 products. "An important part of that
10 strategic planning is identifying the outcomes
11 that communications are intended to achieve."

12 (2) "The Committee applauds FDA's
13 efforts to create partnerships with other
14 public and private organizations that produce
15 and use studies regarding the efficacy of its
16 communications. The Committee recommends
17 expansion of these efforts to achieve full
18 leverage of FDA's expertise and resources.

19 (3) "The Committee applauds FDA's
20 commitment to creating the scientific
21 workforce needed to execute its strategic
22 communication plan. The Committee recommends

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1 that FDA develop and implement a plan that
2 will identify the range of behavioral and
3 decision science expertise that FDA must have
4 on its staff in order to execute its mission
5 and develop the organizational structure
6 needed to recruit and retain excellent bearers
7 of that expertise."

8 (4) "The Committee applauds FDA's
9 commitment to producing and evaluating its
10 communications to a scientific standard. The
11 Committee recommends that, as part of its
12 continuing efforts, FDA develop a work flow
13 system for ensuring that its scientific staff
14 create and summarize and deliver the
15 information that its communication researchers
16 identify as needed in time to allow proper
17 evaluation.

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

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1 samples. The Committee recommends that FDA:
2 (A) undertake an analysis of 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 welfare
7 concerns of FDA's mandate and the Paperwork
8 Reduction Act."

9 So we could either discuss, you
10 know, whether the importance -- I guess, think
11 about the process -- important not to lose
12 anything that's missing or I thought it was
13 there, but it wasn't clear in the wording --
14 before we, you know, go into deciding whether
15 we want these other things at all or as
16 written.

17 So let's think just first about
18 omissions and then we can think about whether
19 they could be folded in here with a refinement
20 of the text before we, you know, go into the
21 details, because we'll lose -- you know,
22 speaking as a cognitive psychologist, we're

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1 likely to lose that.

2 Mona?

3 MEMBER KHANNA: Just another
4 grammatical thing. Just where the cursor is
5 right now, move it back four spaces and get
6 rid of that comma, because you just added the
7 word "and."

8 CHAIRMAN FISCHHOFF: There are some
9 of us who like that extra -- that final comma
10 in sequences.

11 MEMBER KHANNA: I don't know.

12 DR. OSTROVE: It's actually
13 government.

14 CHAIRMAN FISCHHOFF: The government
15 has a position on this?

16 MEMBER KHANNA: On the comma?

17 DR. OSTROVE: Yes, the government
18 puts the comma before the "and."

19 MEMBER KHANNA: Oh, my God.

20 CHAIRMAN FISCHHOFF: I bow to force
21 majeure.

22 MEMBER KHANNA: Oh, my God. There

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1 goes all of my journalism training out the
2 window.

3 Did you just want to talk about
4 omissions?

5 CHAIRMAN FISCHHOFF: Yes.

6 MEMBER KHANNA: Okay.

7 CHAIRMAN FISCHHOFF: Are there
8 topics that are -- oops. Sorry. Yes.

9 MEMBER KHANNA: I have an omission
10 in paragraph No. 3.

11 CHAIRMAN FISCHHOFF: Okay.

12 MEMBER KHANNA: Where you say
13 "develop and implement a plan that will
14 identify the range of behavioral and decision
15 science expertise." That's not the only
16 expertise you want. I mean, you're going to
17 want medical expertise as well if you're
18 talking about communicating with health care
19 providers and patients.

20 CHAIRMAN FISCHHOFF: Yes. Maybe
21 I'll just make that "scientific expertise"
22 rather than --

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1 MEMBER KHANNA: I think so. I
2 think so.

3 CHAIRMAN FISCHHOFF: I was trying
4 to use -- I think behavioral and decision
5 science is what the draft plan uses, so I was
6 trying to remember that. Yes.

7 MEMBER KHANNA: Because if you had
8 to put a long list of expertise, I mean, it
9 would be a couple of lines.

10 CHAIRMAN FISCHHOFF: Yes. Yes.

11 MEMBER KHANNA: Okay. Thanks.

12 CHAIRMAN FISCHHOFF: Yes. I think
13 that the reason why the plan signals out these
14 is that there's lots of medical science
15 expertise and they wanted to flag what was
16 missing. But if you did it systematically,
17 you know, then -- you know, and it could also
18 be that if this were located in a core you
19 might need to have scientists who are resident
20 in that place who could then talk to the
21 people in the different units. So it might
22 actually require additional medical

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1 pharmacological science expertise.

2 MEMBER PETERS: Could I just ask a
3 clarifying question? In No. 4, I'm not sure I
4 really know what you mean by the second
5 sentence, "FDA develop a work flow system for
6 ensuring --"

7 CHAIRMAN FISCHHOFF: So what I was
8 trying to get at there is that -- I was
9 picking up -- I think it was Craig, maybe
10 Craig and Michael mentioned it, is that FDA
11 has got to crank this stuff out. You know, to
12 do its job, it's got to make this, you know, a
13 part of its routine operations and that's kind
14 of a production management problem. And there
15 are people who know how to design those kinds
16 of systems. So I don't know -- I put work
17 flow in parentheses because I didn't know what
18 people call that. So if there's a better term
19 of art for how to ensure that the whole, the
20 mechanics work, I'm very open to that.

21 MEMBER PETERS: So you mean
22 delivering it to the patient in the end

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1 though? Is that what you mean?

2 CHAIRMAN FISCHHOFF: Well, the
3 distribution system would be part of it. I'm
4 just saying, you know, this drug is coming in,
5 you know, we're reviewing this drug, we know
6 we're going to have a ruling on this date, you
7 know, and the communication may need to be
8 ready at the date that the review panel needs
9 it. And if there's not a heads up in some way
10 to the people who are developing the
11 communications, you know, then they're always
12 going to be playing catch up. The press will
13 have run with a misinterpretation of it.
14 People will be needlessly concerned or
15 needlessly mollified. So, you know, somehow
16 there's a work flow for what it's doing now.
17 This needs to be fed into the work flow,
18 including, as I was suggesting earlier,
19 pushing upstream the demands of the
20 communications so that it's not subservient,
21 playing catch up, you know, being asked to
22 play an impossible hand.

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1 MEMBER KHANNA: Would it help to
2 use the word "integrate?" Fourth graph. "FDA
3 develop a system for ensuring -- 'to
4 integrate.'"

5 CHAIRMAN FISCHHOFF: Except for a
6 certain branch of cognitive psychologists,
7 "production system" works here. So, you know,
8 if those cognitive psychologists will cut us
9 some slack, we could -- maybe I'll just call
10 it "work flow." There are people who use
11 that.

12 And you suggested putting --

13 MEMBER WOLF: Can you add the 'R'
14 in "ensuring to"?

15 CHAIRMAN FISCHHOFF: What?

16 MEMBER KHANNA: This is a spelling
17 error.

18 CHAIRMAN FISCHHOFF: Oh, okay.

19 MEMBER KHANNA: I thought the way
20 you explained it, Baruch, was you wanted to
21 make sure that this was integrated into the
22 daily processes. That's why I suggested using

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1 the word "integrate."

2 CHAIRMAN FISCHHOFF: Yes.

3 MEMBER KHANNA: Integrated. Yes.

4 CHAIRMAN FISCHHOFF: Okay. Musa?

5 MEMBER MAYER: In the first
6 paragraph, second sentence, "The Committee
7 recommends continuing these efforts to make
8 communication central." I think it should be
9 something like, "highest quality
10 communication," "best quality."

11 CHAIRMAN FISCHHOFF: Yes.

12 MEMBER MAYER: Because
13 communication is obviously central to
14 everything we do.

15 CHAIRMAN FISCHHOFF: Yes.

16 MEMBER MAYER: We're really talking
17 about elevating it to a thoughtful researched
18 level.

19 CHAIRMAN FISCHHOFF: How about
20 scientifically sound communication?

21 MEMBER MAYER: That's good.

22 CHAIRMAN FISCHHOFF: Yes. Yes,

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1 that's what I tend to use. Sometimes people
2 read it as though -- not the communication
3 science is sound, but that the evidence that
4 it repeats is sound. But, I mean -- and I
5 think we see this in the draft -- that the
6 communications be done to a scientific
7 standard.

8 MEMBER MAYER: That's good. I like
9 that.

10 MEMBER KHANNA: Specifically risk
11 communication, or all communication? Do you
12 want to say "risk" there?

13 CHAIRMAN FISCHHOFF: Well, so
14 here's a quandary. We're called the Risk
15 Communication Committee, but we're expected to
16 deal with risk and benefit communications. So
17 I think I would just leave it as
18 communication. Implicit there's some
19 over-reaching because FDA communicates on all
20 sorts of -- you know, FDA has public affairs,
21 pure public affairs communications, and it's
22 none of our business, you know, how it

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1 presents itself. But I think since we're
2 referring to the strategic planning document
3 which is talking about communications
4 regarding its regulated products, I think the
5 reference to communication, you know, ought to
6 be clear here.

7 DR. OSTROVE: And it's called the
8 Risk Communication Advisory Committee because
9 of the broad way that we define risk
10 communication -- in that, you know, we kind of
11 take the IOM and the general academic
12 perspective out there that risk communication
13 includes all messages, including the benefit
14 messages.

15 CHAIRMAN FISCHHOFF: Yes.

16 DR. OSTROVE: And so, you know, as
17 long as we understand what that context is, I
18 think we're good.

19 CHAIRMAN FISCHHOFF: Yes. And
20 since that's not immediately apparent, I would
21 just as soon take the risk out here, you know,
22 rather than letting people have to know what

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1 this term of -- that risk is a term of art for
2 benefit.

3 MEMBER MAYER: And also there are
4 other issues and other dimensions to the
5 communication about the products, other than
6 benefit and risk.

7 CHAIRMAN FISCHHOFF: Right, usage
8 and -- yes.

9 MEMBER MAYER: And it's important
10 to have those be clear and scientifically
11 sound as well.

12 CHAIRMAN FISCHHOFF: Yes. Okay.
13 Madeline and then Michael.

14 MEMBER LAWSON: I'm looking at the
15 recommendations, and I know we talked a little
16 bit earlier about the in-house capability and
17 staff resources. I just think that the
18 Committee has a responsibility to at least
19 recommend that FDA -- while we certainly are
20 not going to propose or recommend personnel or
21 where personnel would be assigned or recruited
22 -- but I think we have a responsibility to

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1 recommend that there should be a staff that's
2 designated to ensure that the Agency is
3 carrying out those responsibilities that we
4 feel are needed or that are missing.

5 And there was at one time -- and I
6 think I shared this with the Committee once
7 before -- there was a time when there was an
8 Office of Consumer Affairs or Consumer
9 Relations within the Agency. There was an
10 Office of Health Professionals. And those
11 offices had clear responsibilities with
12 communicating with the public, and I don't
13 that exists any longer. But my point is, I
14 think that we're saying that there are a lot
15 of things that need to be done that are not
16 being done and how we can improve. But I
17 think we do need to address the issue that
18 there may be a problem internally with the
19 capacity to do these things. And so we must
20 make the recommendation. How the Agency
21 follows through on it certainly is beyond our
22 control. But I do think we have a

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1 responsibility to make some recommendation
2 about the capacity that's necessary to do
3 those things that we are proposing. And that
4 it's done in such a way that it's not lost
5 within the Centers, so that perhaps there is a
6 centralized team that is responsible for risk
7 communications.

8 CHAIRMAN FISCHHOFF: I was trying
9 to capture that in my third recommendation.

10 And now that you mention it, I can see where
11 I missed it. So let me do some editing here.

12 Does that make it clearer? And
13 I'll read this aloud for those at the far end
14 of the room in just a second.

15 So Madeline raised the other
16 question of whether we want to make a specific
17 recommendation that there be a centralized
18 unit, which I didn't put in here. Here I just
19 said, FDA needs to figure out how to do that.

20 Do we feel strongly enough that there needs
21 to be -- what I called the core in my little
22 talk yesterday -- or do we want to leave that

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1 off?

2 So let me just read the rewritten
3 first sentence. This is No. 3. "The
4 Committee applauds FDA's commitment to
5 creating the in-house capacity" -- this is
6 lousy wording. Somebody help me here. So
7 I'll read it and then I'll -- "The Committee
8 applauds FDA's commitment to creating the
9 in-house capacity for supporting the
10 scientific workforce needed to execute its
11 strategic communication plan." So "in-house"
12 and "capacity" seem like those are important
13 words. "In-house" -- that was missing before
14 because it could have meant that someplace in
15 the world somebody ought to be responsible for
16 these people. "Capacity" is one of our charge
17 questions and is in the plan. And I feel like
18 this first sentence needs some wordsmithing.
19 Maybe somebody has a -- ?

20 (Off-mic comment.)

21 CHAIRMAN FISCHHOFF: Okay. Okay.
22 Yes, well that's already better. Yes. Maybe

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1 that's all I needed. Okay. Always hate to
2 give up a gerund, but I think you're right.

3 So the rewording is, "The Committee
4 applauds FDA's commitment to creating the
5 in-house capacity to support the scientific
6 workforce needed to execute its strategic
7 communication plan." And then the rest is
8 unchanged.

9 And so then the question, do we
10 want to make a specific recommendation that
11 FDA should create a core -- whatever we want
12 to call it - - seriously consider it, or do we
13 feel we didn't work that topic well enough?

14 Mike?

15 MEMBER WOLF: Well, this is kind of
16 what I was wanting to talk about, but and
17 actually keep the language somewhat vague so
18 we don't have to make a recommendation to that
19 regard. My suggestion was on the last
20 sentence that might get at that a little bit:
21 "The organizational structure needed to
22 recruit and retain excellent bearers of that

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1 expertise." I think the recruitment and
2 retention is kind of the byproduct of actually
3 having good positions and that have influence
4 and significance. I suggest maybe it being
5 "and develop the organizational structure
6 needed to make significant contributions to
7 FDA communications and research," or
8 something. Like the message here is that
9 you're building in-house capacity, develop and
10 implement a plan that will identify a range of
11 behavior of medical science expertise, but the
12 point is that you want to also have them in
13 the position where they could actually have
14 direct -- I'm thinking of one other federal
15 entity that I won't name that when I learned
16 about their process, they have content
17 experts, they have communications experts and
18 the content experts take the message, it goes
19 to the communication experts who make it more
20 palatable for the public and then it goes back
21 to the content experts, which can screw it all
22 up again.

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1 So you want to make sure whatever
2 risk communications core or communications
3 core, they're in the right position within the
4 infrastructure of the FDA, not that they are
5 -- whether it be that they shouldn't be
6 disaggregated, you know, or whether or not
7 they should be -- at least at some point in
8 the process of that information, that flow,
9 that work flow -- that they're well-
10 positioned.

11 CHAIRMAN FISCHHOFF: Let me try a
12 radical simplification, because this is pretty
13 detailed. This sort of talks about, you know,
14 kind of task analysis for doing it. It
15 worries, you know, about it. So let me --
16 kind of talk among yourselves.

17 DR. ZWANZIGER: But please use the
18 mics whenever you do.

19 CHAIRMAN FISCHHOFF: Oh, that's
20 right. Or talk among yourselves about
21 irrelevant things that are not covered by the
22 Federal Advisory Committee Act for the next 30

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1 seconds.

2 MEMBER WOLF: I think you have a
3 lot of it. I mean, you've done a wonderful
4 job here. So it's like you've got "developed
5 the organizational structure." I think that's
6 the key piece, right?

7 CHAIRMAN FISCHHOFF: Let me just
8 say, one reason for wanting to -- oh, poor
9 Mike. AnnaMaria, do we pay for neck rubs for
10 the people looking backwards for the --

11 I think the reason I wanted -- and
12 maybe this was wrong -- the reason I wanted to
13 have "recruit and retention" is, I think that
14 either the people at FDA -- you know, I can
15 imagine people thinking, ah, we'll do a favor,
16 you know, by bringing in a few of these -- I
17 want to afford the people who will do these
18 jobs the proper status. And the fact that
19 they need to be recruited and retained just as
20 the top pharmacologists need to be, I somehow
21 wanted that in there because I think it's
22 going to be a continuing struggle to give

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1 proper status to the people doing this job.
2 So that was what I had in my mind. So maybe
3 I'll leave those words, but I'll see if I can
4 simplify it a little bit.

5 The break is over.

6 How about this revision? Mike, you
7 had a --

8 (Off-mic comment.)

9 CHAIRMAN FISCHHOFF: Okay. So I'll
10 read it out loud. So, No. 3, the first
11 sentence I think is -- okay. I'll just read
12 the whole thing.

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

22 Is that better? Okay. Now it

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1 doesn't fit on the page.

2 MEMBER KHANNA: Change the type
3 size.

4 CHAIRMAN FISCHHOFF: We're going to
5 go to an 11.5 font.

6 MEMBER KHANNA: Right.

7 CHAIRMAN FISCHHOFF: Yes, so let me
8 go through the top and then expand them.
9 Maybe take it from the top? Okay. Yes.

10 MEMBER PALING: Mr. Chairman, I
11 have an additional proposal. We've not
12 omitted it because we've not yet discussed it,
13 but I have a strategy that I would like to
14 have put down and I just take your guidance
15 whether to bring it up now or let you work
16 through these and then I'll bring it up.

17 CHAIRMAN FISCHHOFF: Let me suggest
18 that you bring it up now. You know, my
19 preference would be for having sort of fewer
20 rather than more. I think five is kind of, by
21 my taste, the right number of recommendations.

22 So if it turns out we can reformulate one of

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1 these to incorporate that, that would be my
2 preference. But if we can't, then we should
3 go to six. I think given their complexity,
4 despite an audience that's good at chunking
5 these things, if you think of seven plus or
6 minus two, I think we're at the minus two in
7 terms of human -- it means something to the
8 psychologists here anyway. In other words,
9 the psychologist of the certain age.

10 So bring it on.

11 MEMBER PALING: Could I then have
12 down my yellow piece of paper that I gave you
13 as a draft, please? Thank you.

14 I agree with you of keeping the
15 number as short as is practical, however, I
16 strongly feel and you will agree that we
17 should have in that list the most important
18 topics, and this is one that I happen to think
19 is the most important topic.

20 All of these things in organization
21 obviously depend upon the support of the top
22 leadership of the organization, which we have

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1 seen great evidence of including the personal
2 appearance of the top gentleman, does have
3 that support. To my mind, all of the efforts
4 this Committee has been dedicating its time to
5 for a year-and-a-half are beginning to come to
6 a culmination of improvements. Among them is
7 of course this draft policy document, but also
8 we learned yesterday there's a new web site
9 which also is clearly involved in
10 communication, including risk communication
11 which is about to be revealed.

12 My personal belief is that if we
13 felt it appropriate I would like to recommend
14 that the top leadership of the EPA; I work for
15 EPA, to FDA make it a priority when announcing
16 these two big and important communications
17 initiatives to say two additional things. One
18 is to recommit to form a partnership, a deeper
19 partnership with the community in terms of
20 improving its communication and listening.
21 And the second is to continue its dedication
22 to give its best efforts to regulate products

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1 so that they are safe and effective.

2 And in doing that, I've done two
3 things. One is I have deliberately qualified
4 safe and effective, which I still view as the
5 biggest single easy benefit to precipitate
6 discussion in the public media with the media
7 as such, but also with the general public
8 about the limits of the FDA to -- absolutely
9 -- which we all know about and the FDA
10 understands, commit to being absolutely safe
11 for everyone under every situation.

12 So I had drafted something, and as
13 I said to Baruch, I'm not necessarily trying
14 to stick to these words, but I think that we
15 can help galvanize public discussion and
16 understanding of risk and regulation if we
17 were to recommend and it were to be followed
18 up the top leadership as a priority for a
19 month to make this as a goal, to make some
20 statement.

21 So what I put and I'm willing of
22 course to have it changed, is that the

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1 Committee recommends that as a top priority
2 the leadership of the FDA takes the
3 opportunity of the web site and also this
4 document to make a renewed commitment to
5 partnering with the public to improve their
6 communications and to continue to make their
7 best efforts to maintain the safety and
8 effectiveness of the products that it
9 regulates. It's a whole new topic. It's not
10 in the mission. But I happen to think that if
11 that were done, then it would be a very good
12 forum to bring in the uncertainties and how
13 risk communication is done, and it would
14 really deliver benefit that our professional
15 colleagues at the FDA would do well to
16 consider, given the opportunity of these two
17 new public communications forums.

18 CHAIRMAN FISCHHOFF: If you pass
19 that back, I will type it up and put it in
20 here and I'll put it as a sixth item. My
21 thinking when you gave this to me was that I
22 tried to incorporate my reading, which nobody

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1 need agree with, of the discussion that we had
2 had into my second bullet, that I didn't think
3 we had had a discussion of the leadership and
4 I didn't think it was our task to tell the
5 leadership to affirm its commitment to safety.

6 So I thought that was outside of our purview.

7 But I'll type this up. So that was
8 my thinking and, you know, as we go through
9 this let's think about it and we can do it.

10 So let me just take 30 seconds to
11 type it in verbatim in John's wording.

12 MEMBER MAYER: So you don't want to
13 discuss it now?

14 CHAIRMAN FISCHHOFF: I think as a
15 matter of process I'll put it up here so
16 everybody can see it. You know, here was my
17 strategy for dealing with these issues. I was
18 closer to taking John's wording in another --
19 he had two things here. I was closer to
20 taking his wordings in the other. So my
21 thinking, let's go through the five and then
22 consider, you know, again as a matter of

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1 brevity can we fold this into something else
2 that we've got? And if it's a distinct item,
3 then we aren't satisfied, then let's discuss
4 that at the end.

5 So I'll just take a second to type
6 it up.

7 Okay. Party's over.

8 Mike?

9 MEMBER GOLDSTEIN: This is a great
10 step forward, Baruch, so thank you for helping
11 us get clear and succinct about this.

12 The first one, your last sentence
13 is great. "An important part of the strategic
14 planning is identifying the outcomes that
15 communications are to achieve." I would
16 suggest that we add some other aspects of the
17 plan, the research plan, like the research
18 priorities or the research road map to meet
19 those objectives. In other words, to specify
20 or recommend that FDA specify some strategies,
21 some research strategies for addressing those
22 outcomes and then making priorities of those.

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1 So it would be an actual research plan that
2 could be implemented over time and looked at
3 over time.

4 MEMBER DeSALVA: I have a related
5 comment. I took a sort of a similar note
6 wondering if there is was way to add some heft
7 to the end of that paragraph. And what I
8 jotted down was this: "An outcomes-focused
9 planning process can further define the key
10 priorities for the improvement of capacity,
11 policy, and research and evaluation."

12 So the spirit of that is to say
13 that if we add as a next step in plan
14 development this sharper focus on outcomes,
15 there will be a discovery process that, you
16 know, adds new strategies and tactics.

17 CHAIRMAN FISCHHOFF: Could I have
18 your wording?

19 MEMBER DeSALVA: Okay.

20 CHAIRMAN FISCHHOFF: It looks like
21 this would be a replacement for the final
22 clause there, right?

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1 MEMBER DeSALVA: Okay. I had it as
2 an additional sentence, but --

3 CHAIRMAN FISCHHOFF: Read it out.
4 Let's see how it --

5 MEMBER DeSALVA: "An
6 outcomes-focused planning process can further
7 define the key priorities for improvement of
8 capacity, policy, and research and
9 evaluation."

10 CHAIRMAN FISCHHOFF: Okay. The key
11 priorities for?

12 MEMBER DeSALVA: Improvement of
13 capacity, policy, and research and evaluation.

14 MEMBER GOLDSTEIN: So the output
15 would be a strategic plan and part of that
16 would be the research road map or agenda.
17 Yes. That's great.

18 CHAIRMAN FISCHHOFF: Okay. And you
19 would have had -- oh, I see what you -- okay.
20 All right. I see what -- okay.

21 MEMBER KHANNA: Baruch, just a
22 comment on that specifically.

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1 Could we put the word -- AnnaMaria,
2 would you object if we put the word "science"
3 before research and evaluation, just to keep
4 with the words that have been used in the
5 document. Capacity, policy and science. Just
6 for parallel construction.

7 You didn't have to take it out.
8 Science. Right.

9 CHAIRMAN FISCHHOFF: Yes. Well,
10 science is -- okay.

11 MEMBER GOLDSTEIN: What I think is
12 important is that it's not just a set of
13 question that they want answered, but it's a
14 plan, an actual road map or plan.

15 CHAIRMAN FISCHHOFF: Okay. So I
16 think that what you are suggesting in terms of
17 research would be represented here. And I
18 think that the two of us probably disagree on
19 whether FDA should have its own -- to what
20 extent should have its own research plan as
21 opposed to working with other people or
22 working on --

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1 MEMBER GOLDSTEIN: I don't know if
2 we disagree.

3 CHAIRMAN FISCHHOFF: What?

4 MEMBER GOLDSTEIN: I don't know if
5 we disagree, because we really haven't talked
6 it out.

7 CHAIRMAN FISCHHOFF: Yes. Right.
8 So let them work it out and they have the
9 wisdom of our transcript to talk about the
10 different -- you know, what you need inside to
11 have the staff. What do you need to do --

12 MEMBER GOLDSTEIN: Yes, I don't
13 know the answer to that question.

14 CHAIRMAN FISCHHOFF: Yes.

15 MEMBER GOLDSTEIN: I do think it
16 has to be part of the plan to have the
17 questions answered. And can I make another
18 suggestion while I have the floor?

19 CHAIRMAN FISCHHOFF: Please.

20 MEMBER GOLDSTEIN: For No. 2, in
21 the first sentence the focus is on efficacy
22 and this is again where I think we need to go

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1 beyond efficacy. So "partnerships with other
2 public and private organizations that produce
3 and use studies regarding the efficacy
4 effectiveness," and we could use some other
5 words, if you'd like. Or we could just say
6 "effectiveness," if you want to be concise.

7 CHAIRMAN FISCHHOFF: So
8 "effectiveness."

9 MEMBER GOLDSTEIN: No. Efficacy is
10 what you learn about a specific message in the
11 context of a controlled assessment of its use
12 in a small controlled trial. Effectiveness is
13 actually what you find out in the real world
14 setting.

15 CHAIRMAN FISCHHOFF: Yes.

16 MEMBER GOLDSTEIN: The impact of
17 your intervention is creating.

18 MEMBER MAYER: Can I ask who the
19 intended target of this document is? Is this
20 people who understand all of these ways of
21 communicating, or is it for a larger part of
22 the FDA, or what?

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1 CHAIRMAN FISCHHOFF: I mean, Mike,
2 just on this one question I would say, you
3 know, pursuant to Musa's point, those in the
4 know know the difference between efficacy and
5 effectiveness. Effectiveness is really what
6 you're interested in, which is the end result.
7 You only look at the efficacy, you know, say
8 do I have something worth putting out there
9 that might have an effect?

10 MEMBER GOLDSTEIN: Yes.

11 CHAIRMAN FISCHHOFF: But for a
12 general audience we don't need to split that
13 hair.

14 MEMBER GOLDSTEIN: Sure. That's
15 fine.

16 CHAIRMAN FISCHHOFF: And we should
17 take the effectiveness hair. I view the
18 audience as, you know, and all the people
19 who've been participating in FDA's planning
20 process, you know, as well as its friends on
21 the Hill.

22 MEMBER GOLDSTEIN: Yes. No, I

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1 would agree with that.

2 CHAIRMAN FISCHHOFF: Or potential
3 friends.

4 MEMBER GOLDSTEIN: We just have to
5 be sure.

6 CHAIRMAN FISCHHOFF: Yes.

7 MEMBER GOLDSTEIN: Again, we're
8 talking about communication, so you're right.
9 We have to know who the audience for this is
10 and we want to make sure that they understand
11 that we're talking about real world
12 applications.

13 CHAIRMAN FISCHHOFF: Yes.

14 MEMBER GOLDSTEIN: Real world
15 studies. Not just in a laboratory with a
16 focus group. So that's important that that
17 get communicated and understood.

18 CHAIRMAN FISCHHOFF: Okay. Craig?

19 MEMBER ANDREWS: This is very
20 brief. Just wordsmithing along lines of what
21 you just said.

22 All the way down, it's the last

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1 line and with parallel construction. I'm
2 sorry. The fifth point, the last point. All
3 the way down. The last one.

4 MEMBER KHANNA: The fifth paragraph

5 MEMBER ANDREWS: Yes. It's before
6 "welfare." I thought we would emphasize
7 "public." I think that's important, regarding
8 the battle here with OMB.

9 MEMBER BRUHN: Two things. The
10 first is a wordsmithing item. And that is,
11 your recommendation one, the last line.
12 Shouldn't it be "improving?"

13 CHAIRMAN FISCHHOFF: Yes.

14 MEMBER BRUHN: And then so once you
15 get that down, go back down to the last
16 recommendation. This is something we might
17 want to consider as a discussion.

18 In the middle there, "The Committee
19 recommends that the FDA undertake an analysis
20 of the public health implications." You know,
21 analysis, seems to me that this is a very
22 large scientifically-based extensive review.

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1 And I don't know if we want to burden them
2 with that. And I would change the word
3 "analysis" to "address." And then they can
4 decide in what depth they address that issue.

5 And if it just requires, you know, a few
6 common sense logical statements, that's what
7 they do.

8 CHAIRMAN FISCHHOFF: So I think
9 you're absolutely right. And "undertake"
10 sounded ponderous and it wouldn't get done.
11 It would probably have to go through OMB
12 approval. So how about "identify?"
13 "Characterize" might be too analytical.
14 "Address" -- they can't address it because
15 their hands are tied. So I would view
16 "address" as actually taking on the problem.
17 And here I think they just need to identify.
18 You know, make the case for them. "Make the
19 case" sounds -- I think that that's maybe out
20 of rule. So if they identify them -- but
21 maybe there's a better word. But I think
22 we're better than we were before, but maybe

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1 not quite there.

2 Musa?

3 MEMBER MAYER: While you're in that
4 sentence, italicize the word "not" to give it
5 emphasis.

6 CHAIRMAN FISCHHOFF: Okay.

7 MEMBER MAYER: How about
8 "enumerate?"

9 CHAIRMAN FISCHHOFF: No.

10 MEMBER MAYER: Or underline it.

11 CHAIRMAN FISCHHOFF: I rarely feel
12 that strongly, but no.

13 AnnaMaria?

14 MEMBER DeSALVA: Actually, since we
15 have a new item now at the very end of the
16 list, it has reminded me of something
17 significant, which is that because this is a
18 strategic plan that's going to change the
19 enterprise to some extent, there are going to
20 be new products and services that come out of
21 it, it should have its own communications
22 component. So in other words, how does the

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1 Agency then communicate about its new risk
2 communication platform. And leadership
3 communication is a component of that, but
4 ordinarily once we went through the process of
5 defining a new organizational strategy, you
6 know, new capacity, new outputs, new impacts,
7 you would want a part of that plan to provide
8 a road map for then how FDA would communicate
9 to its stakeholders about its new strategy.
10 You know, internally, externally taking the
11 opportunity for leadership to evangelize the
12 new message. You know, if you do end up with
13 a research agenda that's partially owned
14 internally and partially, you know,
15 proselytized externally you could have a
16 platform for doing that as part of the
17 communications plan. So it would just --

18 CHAIRMAN FISCHHOFF: Let me offer a
19 friendly amendment to the first part of John's
20 suggestion and give me 30 seconds to -- oh,
21 well, 45.

22 MEMBER BRUHN: Lee, while Baruch is

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1 working away, we have a question. The public
2 comments, the first speaker had some great
3 slides. Are those going to be available on
4 the web? Thank you.

5 CHAIRMAN FISCHHOFF: There's a
6 friendly amendment of John's suggestion sort
7 of taking out the -- it says that implicitly
8 but not in -- sort of in the spirit of
9 AnnaMaria's -- so that's a first draft written
10 under duress. I'm sure it could be
11 wordsmithed further.

12 MEMBER PALING: Just let me say I'm
13 happy with anything that achieves the general
14 goal of using this opportunity to involve the
15 leadership in starting a public discussion
16 about the whole issue of risk communication.
17 So I'll accept anything that you believe and
18 thank you for your tolerance.

19 CHAIRMAN FISCHHOFF: Thank you for
20 your inspiration. And I took out, and we
21 should consider this, I took out making a
22 directive to the leadership, but to say this

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1 is good and the leaders will want to do it,
2 because I'm not sure that our role is to tell
3 the as-yet unappointed leaders to --
4 unconfirmed leaders what to do. But if this
5 hot stuff, they'll want to be associated with
6 it.

7 Okay. Musa?

8 MEMBER MAYER: I think I misread
9 this, but if I misread it, then maybe others
10 will. I'm looking at your friendly amendment
11 here. I thought at first when I read it in
12 the end of that sentence that we were asking
13 FDA -- that we were making a comment about
14 FDA's evaluative capacity to improve its
15 ability to make sound choices regarding safety
16 and effectiveness of the products it
17 regulates. It does imply that and I think
18 that is not the purview of this Committee, nor
19 would I agree to a recommendation like this,
20 because we haven't even been dealing with the
21 evaluation component of FDA.

22 But now looking at it again,

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1 perhaps you were referring to the public
2 thing?

3 CHAIRMAN FISCHHOFF: I meant that
4 the public would incorporate safety and
5 effectiveness in its decisions, but I agree
6 that the wording was poor.

7 MEMBER MAYER: Yes.

8 CHAIRMAN FISCHHOFF: So how about
9 that?

10 MEMBER MAYER: Well, it seems vague
11 to me. What do you mean exactly? How would
12 you know that this was occurring?

13 CHAIRMAN FISCHHOFF: If we did all
14 the stuff above, then if we evaluated how the
15 communication was -- so let's step back. And
16 so the goal here is to say this is a major
17 initiative. FDA, I mean, is not only kind of
18 seizing the day in terms of its own mission,
19 but I think it's defining, you know, kind of
20 way ahead of the curve in terms of, you know,
21 at least some other federal agencies like the
22 one that Michael described who shall remain

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1 nameless. So this is important for FDA and I
2 think important for the government. And if
3 FDA can figure out how to do it, it will
4 legitimate it to other agencies and provide
5 them a sort of road map.

6 But John also wanted to express
7 this in terms of that FDA is doing -- not just
8 because it has -- because this is fulfilling
9 its mission, but because this is part of its
10 partnership with the American public, in
11 helping the public to make these good
12 decisions. So that's what we are trying to
13 get in here and maybe it's overloaded and
14 there's some other way. But those are the
15 things we wanted to do. You know, run with it
16 and, you know, express this as part of its
17 commitment.

18 MEMBER MAYER: Can I follow up on
19 that?

20 CHAIRMAN FISCHHOFF: Yes.

21 MEMBER MAYER: There is nowhere in
22 the draft nor in these statements here any

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1 specific mention of partnering with the
2 public. Partnering to me implies soliciting
3 feedback from the public. This is completely
4 absent. We've been talking about an internal
5 process and a process that involves experts in
6 risk communication, as I understand it. And
7 to bring in the concept of the public here as
8 a sort of afterthought, it seems disingenuous
9 to me. I mean, it either ought to be
10 throughout or not at all.

11 CHAIRMAN FISCHHOFF: Yes. And I
12 think, you know, again in terms of, you know,
13 sort of language there, you know, partnership
14 is a term of art. I mean, it has several
15 meanings. One is the kind of
16 interorganizational things that we've talked
17 about here. And another one is I think it was
18 in the spirit of John's in saying that we're
19 -- is more of an almost spiritual partnership
20 to say we're in this together. We want to
21 help you do that. And since it has at least
22 those two meanings, and perhaps others, and

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1 that it's probably safest just to take it out.

2 MEMBER WOLF: I would also change
3 it to make "informed choices." Would that be
4 better than "sound?"

5 CHAIRMAN FISCHHOFF: Okay. Right.
6 So probably the "sound choices" -- I mean,
7 FDA would like them to make sound choices, but
8 the soundness of the choice, you know, may get
9 you into patient/physician interactions that
10 are outside of its demand. What FDA can do is
11 make certain that the information is accurate
12 and comprehensible, and delivered where it
13 needs to be. So its regulatory function is
14 producing and getting out information. And,
15 you know, it's limited by our ability to make
16 sound choices even if it does it well. I
17 guess FDA can get us to wizen up but not
18 smarten up. I don't know. Anyway, all right.

19 With John's approval, I will --
20 shall we take it from the top?

21 MEMBER KHANNA: We still have some
22 wordsmithing to do on that last one. The

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1 first sentence is --

2 MEMBER WOLF: Can we say "through
3 its strategic communication initiative?"

4 CHAIRMAN FISCHHOFF: Yes, there's
5 like a missing verb there, right?

6 MEMBER WOLF: Yes.

7 CHAIRMAN FISCHHOFF: So, help me.

8 MEMBER WOLF: Yes, so just
9 "opportunity through its strategic
10 communication initiative to publicize."

11 MEMBER KHANNA: Or we could make it
12 very simple and just say the FDA "use" its
13 strategic communication initiative. Take
14 those four words out.

15 MEMBER WOLF: There you go.

16 CHAIRMAN FISCHHOFF: Yes. Yes.

17 MEMBER WOLF: Readability analysis
18 on this?

19 CHAIRMAN FISCHHOFF: This will not
20 go on any labels. Who knows actually? No.
21 This is not my best writing.

22 MEMBER MAYER: Can I say something?

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1 CHAIRMAN FISCHHOFF: Musa?

2 MEMBER MAYER: Now I'm stuck on the
3 word "publicize." What do we have in mind
4 here exactly, that FDA have a big media
5 initiative?

6 MEMBER WOLF: We can just say
7 "demonstrate." "Initiative demonstrate its
8 renewed?" Would that work?

9 CHAIRMAN FISCHHOFF: Okay.

10 MEMBER DeSALVA: Yes, I think we
11 have two ideas here and what I was trying to
12 say earlier is that in my mind at least as a
13 communicator it rolls up to one idea. And
14 that is that the plan is going to introduce
15 change. It's going to be positive change, but
16 there's going to be meaningful change in terms
17 of the way the Agency communicates about risk
18 and benefit and what types of guidance it
19 gives its stakeholders. And so the plan needs
20 to include strategies and tactics that help
21 stakeholders understand what the Agency is
22 doing, why it's introducing changes and what

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1 those changes are. So it's very practical.
2 It's a good communications underpinning to
3 make sure that the Agency is successful in
4 implementing these changes.

5 Part of that, in my view, is a
6 leadership platform. Part of that is, you
7 know, the leaders of the Agency explaining why
8 this is important and expressing their
9 commitment. But normally when you have a plan
10 of this nature there is a communications
11 dimension. I realize that we're talking
12 about, you know, communications dimension of a
13 risk communication strategic plan, but still
14 it needs to have its own communications.

15 CHAIRMAN FISCHHOFF: Yes, in effect
16 this is calling for that there's a public
17 affairs dimension of getting the word out,
18 making sure that, you know, expectations are
19 out there.

20 MEMBER DeSALVA: Yes.

21 CHAIRMAN FISCHHOFF: And the
22 communications is more public health

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1 communications, helping people to make
2 decisions, but we need the public affairs to
3 communicate about --

4 MEMBER DeSALVA: Right. But I
5 understand Musa's sensitivity to the word
6 "publicize" because the spirit of it is not to
7 be opportunistic to say, you know, let's take
8 this as an opportunity to glorify the work of
9 the Agency. It's actually much more practical
10 than that. And if benefits accrue to the
11 Agency in terms of its perception or how
12 people perceive it, that's great. But it's
13 not the purpose.

14 MEMBER PALING: Do you have a
15 different word other than "publicize?" It
16 says most closely what I was intending, but
17 I'll take your word.

18 MEMBER DeSALVA: Well, I think it's
19 about communication and education, so, "The
20 Committee recommends that FDA" -- right.

21 MEMBER PALING: It's redundant. I
22 mean, it's poor wording, but it may be worth

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1 having "communicate" twice in the same
2 sentence. Communicate about a communication.
3 Maybe that's actually what we want to say.

4 MEMBER DeSALVA: Yes, exactly. Or
5 that "the strategic plan include its own
6 communication strategy to ensure that the
7 Agency stakeholders understand and fully
8 benefit from the renewed strategy, or the
9 renewed risk communication strategy."

10 CHAIRMAN FISCHHOFF: And I'll see
11 if I can put this together.

12 MEMBER DeSALVA: Okay.

13 MEMBER MAYER: Why would it not be
14 enough to just say "communicate its strategic
15 communication?" Wait a minute. "Share its
16 strategic communication initiative?"

17 CHAIRMAN FISCHHOFF: The writers
18 among us just can't type "communicate" twice
19 in three words.

20 MEMBER KHANNA: You can say
21 "promote." Do you want to say "promote"
22 instead of "communicate?"

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1 CHAIRMAN FISCHHOFF: No, no,
2 because we want this to be --

3 MEMBER KHANNA: Communicate?

4 CHAIRMAN FISCHHOFF: Yes, we want
5 them to tell -- you know, in a sense it
6 doesn't have to promote it. And as AnnaMaria
7 was saying, it just needs to get the words out
8 and, you know, that it -- I mean, you know,
9 the hope is that it will speak for itself.

10 Okay. All right. A little bit
11 better. No, maybe not.

12 MEMBER MAYER: What about "brand?"
13 Is that kind of -- "brand?" That's not quite
14 hitting it, is it?

15 CHAIRMAN FISCHHOFF: No. No. But,
16 I mean, it's an expression of the brand.

17 MEMBER KHANNA: What about
18 "emphasize?"

19 MEMBER MAYER: "And communicate and
20 educate the public." "Communicate to and
21 educate the public."

22 CHAIRMAN FISCHHOFF: Maybe we just

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1 do "educate," then we save a word.

2 MEMBER GOLDSTEIN: I think
3 AnnaMaria was saying not just the public, the
4 stakeholders.

5 CHAIRMAN FISCHHOFF: I almost did
6 "its publics," which some people like and it's
7 kind of weird.

8 MEMBER MAYER: How about "share the
9 strategic communication initiative with its
10 stakeholders?" Or is that denatured?

11 CHAIRMAN FISCHHOFF: I don't know
12 what "share" would mean to -- kind of a little
13 new- agey for me. I don't know, does "share"
14 for people? It doesn't work for me, but --
15 I'm sort of losing my critical faculties.

16 MEMBER KHANNA: I prefer "educate"
17 over "share."

18 CHAIRMAN FISCHHOFF: "Inform."
19 That's good. Where did that come from?
20 "Inform." How's that? Okay.

21 "Inform" is weak. You know, I
22 think we're looking for a dynamic verb, but

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1 one that's not manipulative.

2 MEMBER GOLDSTEIN: "Persuade."

3 CHAIRMAN FISCHHOFF: Get your --
4 no, no, no, no, no. That's manipulative. Get
5 out our thesauruses. Can we ask for help from
6 the audience? Can I reopen the public hearing
7 if somebody's got a good verb?

8 All right. Let's leave this.
9 Let's go to the top and let the back of our
10 minds be working on the word choice.

11 Is there an English major? I won't
12 put anybody on the spot.

13 Okay. So let's read over the first
14 one. I won't read it aloud. Can everybody
15 see this? Yes. Okay. I'll read it aloud
16 because then it's in the record. But I'll
17 drone so you don't really have to pay
18 attention.

19 "The Committee applauds the
20 strategic plan for risk communication at the
21 Food and Drug Administration as a major step
22 forward in enabling FDA to meet its mission of

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1 service to the American public. The Committee
2 recommends continuing these efforts to make
3 scientifically sound communication central to
4 the production, summary and dissemination of
5 evidence regarding FDA's regulated products.
6 And important part of that strategic planning
7 is identifying the outcomes the communications
8 are intended to achieve. An outcomes-focused
9 planning process can further define the key
10 priorities for improving capacity, policy and
11 science."

12 Should we vote on it while we're
13 focused on it? Can we do that? Yes?

14 Okay. Those in favor of this
15 recommendation?

16 Those opposed?

17 Those abstaining?

18 Okay. No. 2. "The Committee
19 applauds FDA's efforts to create partnerships
20 with other public and private organizations
21 that produce and use studies regarding the
22 effectiveness of its communications. The

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1 Committee recommends expansion of these
2 efforts to achieve full leverage of FDA's
3 expertise and resources."

4 So there's a commentary here. This
5 feels pretty abstract, but here was a place
6 where we had all of these interesting
7 questions, like teaming with AHRQ, going to
8 people in industry who are doing work like
9 that. And so, you know, in the narrative
10 we'll try to pull in some of those examples
11 without our having to vote on -- okay, pick up
12 the pace, I guess. Musa.

13 MEMBER MAYER: Another way to do
14 that might simply be to say the Committee
15 would like to serve as a resource for these
16 partnerships.

17 CHAIRMAN FISCHHOFF: Yes, that's a
18 great idea.

19 MEMBER FINCH: And I'm not sure if
20 it's getting to the -- we talked about, I'm
21 going to call it a best practice model with
22 the Women's Health Program in terms of their

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1 literature and how they go through the
2 testing. I'm not sure if we are capturing,
3 tapping into that or being a partnership to
4 that, or using that resource.

5 CHAIRMAN FISCHHOFF: Yes. So I
6 think that was what I had in mind as a kind of
7 concrete example that if FDA is already doing
8 some of this internally and given that we
9 didn't -- we had a briefing from that program
10 at our very first meeting, didn't we? Yes.
11 So in some sense it's in our record, but maybe
12 since we didn't air any -- let's just put that
13 into the narrative. I think that's probably
14 the right -- since we didn't have a full
15 description of that program, rather than
16 mentioning it in the recommendations since we
17 --

18 DR. ZWANZIGER: You have the option
19 of referring to, you know, the previous parts
20 of the transcript here. I mean, you can just
21 say take examples from the transcript.

22 CHAIRMAN FISCHHOFF: Why don't we

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1 just get in the draft summary that example,
2 among others, and then if people have others,
3 we can do it. As long as, you know, somebody
4 has said it, you know, yesterday or today,
5 then we can do it. And, you know, we don't
6 know what mine fields there are in any of AHRQ
7 or, you know, any of these other things. Am I
8 hearing that they just do focus groups makes
9 me less -- I'd like them to be able to do even
10 more.

11 MEMBER KHANNA: Do you want to put
12 the word "a" before "resource?"

13 CHAIRMAN FISCHHOFF: Oh, yes. I
14 do.

15 MEMBER PETERS: And just a friendly
16 amendment to the first sentence,
17 "organizations that produce and use studies
18 relevant to the effectiveness of FDA's
19 communications?"

20 CHAIRMAN FISCHHOFF: Yes, that's
21 better. And by "organizations that produce,"
22 I thought of, you know, there's all this

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1 research going on. You know, Christine
2 mentioned a problem and we solved this
3 already, or know that this doesn't work, so
4 there's other people producing it. And then
5 there's consumers who need to know, you know,
6 just how good this -- this is the best we can
7 do. How good is it likely, you know, to be?
8 So if people aren't going to wash their hands,
9 the people who are expecting that to stop H1N1
10 ought to know about it.

11 MEMBER PETERS: But it's also not
12 always specifically about something that the
13 -- the research is also --

14 CHAIRMAN FISCHHOFF: Yes.

15 MEMBER PETERS: -- is broader than
16 that.

17 CHAIRMAN FISCHHOFF: Yes.

18 MEMBER PETERS: It's not always
19 specific to FDA.

20 CHAIRMAN FISCHHOFF: Yes, so
21 studies- relevant. Right.

22 MEMBER PETERS: Yes.

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1 CHAIRMAN FISCHHOFF: Yes. Okay. A
2 deeper amendment than I realized. Yes.

3 Okay, any other tweaks?

4 MEMBER GOLDSTEIN: I'm not sure if
5 this is necessary -- I'm just thinking, if we
6 could link this paragraph to the previous
7 paragraph more directly linking it to the
8 planning process that would be useful. Maybe
9 not. Maybe it's not necessary.

10 CHAIRMAN FISCHHOFF: I think the
11 next one follows better. And maybe we ought
12 to like when we're done flip the order,
13 because what's now 3 has a reference to
14 capacity and 2 we've identified the capacity
15 and then we come on.

16 MEMBER GOLDSTEIN: Okay. In a
17 sense it's leveraging the capacity.

18 CHAIRMAN FISCHHOFF: Yes.

19 MEMBER GOLDSTEIN: What is now 2?

20 CHAIRMAN FISCHHOFF: Yes, yes, yes.
21 All right. Let's look at them separately and
22 then we can decide what the best order would

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1 be. We can vote on the reordering if need be.

2 So any changes to the wording?

3 Should not have implied that any changes.

4 Just a tweak. So I withdraw that verb.

5 Okay. Those who approve this
6 recommendation?

7 Those opposed?

8 Those who abstain?

9 Okay. Thank you.

10 No. 3. "The Committee applauds
11 FDA's commitment creating the in-house
12 capacity needed," maybe -- take it from the
13 top.

14 "The Committee applauds FDA's
15 commitment to creating the in-house capacity
16 needed to support the scientific" -- I see why
17 I didn't have double "needed." Let me take it
18 back out again.

19 From the top. "The Committee
20 applauds FDA's commitment to creating the
21 in-house capacity to support the scientific
22 workforce." I need help here. This doesn't

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1 read right.

2 MEMBER MAYER: "Necessary" rather
3 than "needed?" Up there.

4 CHAIRMAN FISCHHOFF: Oh, okay.
5 Where? Here?

6 MEMBER MAYER: There.

7 CHAIRMAN FISCHHOFF: That wasn't
8 what was bothering me.

9 MEMBER MAYER: Okay.

10 MEMBER WOLF: Could you just say
11 "creating the in-house scientific workforce
12 necessary to execute?"

13 MEMBER PETERS: It's not just that
14 though.

15 MEMBER WOLF: It's the "capacity?"

16 MEMBER PETERS: What about "to
17 creating the in-house and/or external capacity
18 necessary to execute its strategic
19 communication plan?"

20 CHAIRMAN FISCHHOFF: So I actually
21 wanted this just to be in-house. You know,
22 and I thought of the previous one as sort of

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1 partnering, you know, with other people who
2 are -- that's taking advantage of what else is
3 out there and I think we want them to -- I
4 want them at least to build up internally.

5 MEMBER DeSALVA: Is it better to
6 say "creating the in-house capacity to develop
7 the scientific workforce necessary?" No?

8 CHAIRMAN FISCHHOFF: No.

9 MEMBER MAYER: Because that implies
10 once it's developed it's over.

11 CHAIRMAN FISCHHOFF: How about
12 this? So now it reads "The Committee applauds
13 FDA's commitment to creating the in-house
14 scientific workforce needed to execute its
15 strategic communication plan." Then "The
16 Committee recommends that FDA develop an
17 organizational structure that ensures that
18 individuals with the needed expertise are
19 recruited, retained and effectively integrated
20 with its operations."

21 MEMBER PETERS: Is this saying
22 though that we are asking them to be doing all

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