

1 standardization, and if so where should it
2 come from?

3 DR. HAUSER: It should come from
4 the FDA. The petition clearly states that we
5 are looking for a single document solution
6 that would be FDA approved.

7 Obviously the FDA working with the
8 manufacturer on the wording.

9 DR. FISCHHOFF: Thank you. Sid.

10 DR. WOLFE: I think the confusion
11 here is between whether the content is FDA
12 approved, which is what your petition is.
13 Your petition, NACDS and the NCPA I believe,
14 right?

15 DR. HAUSER: That's correct.

16 DR. WOLFE: Both organizations
17 have apparently - and the FDA doesn't have to
18 get involved in this - filed a petition for An
19 FDA-approved labeling.

20 I mean I think the confusion
21 between approved voluntary, mandatory, is that
22 what we have now is neither FDA approved and

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1 is more or less entirely a voluntary program.

2 So I think what you are saying is,
3 you think it needs to be FDA approved as
4 opposed to what we have that clearly has not
5 worked. But I would still ask the same
6 question to you: does voluntary mean that if a
7 patient goes in and gets a prescription for
8 some drug, it is up to the pharmacist as to
9 whether to give out the FDA approved labeling?

10 Is that the question? Is that your response
11 or what is it?

12 DR. HAUSER: That is not my
13 understanding. I would welcome anyone else
14 here who is a petitioner to speak. There are
15 multiple organizations including consumer
16 organizations that may or may not be present.

17 DR. WOLFE: What do you think
18 voluntary means, then? That's all, that's the
19 question.

20 DR. HAUSER: As it's listed in the
21 petition it would be a voluntary program; the
22 single document solution would be a voluntary

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1 program that they could choose to participate
2 or not in the program.

3 DR. WOLFE: So it could coexist
4 then with what is going on?

5 DR. HAUSER: Potentially, yes.

6 DR. WOLFE: Some people could say,
7 I'll do the voluntary but FDA-approved
8 program, and others could say, I'll do the
9 voluntary and FDA not approved program.

10 So I guess you don't feel strongly
11 enough about it in your petition to think that
12 it is so good that it should be done for
13 everyone; is that the idea?

14 DR. HAUSER: I can speak for our
15 members, regardless of the petition. They
16 want a single document solution that would be
17 FDA approved. They would distribute that
18 information. That's what they are asking for.

19 DR. WOLFE: So your members would.
20 They have agreed to volunteer to do it.

21 DR. HAUSER: Absolutely.

22 DR. WOLFE: But others may not?

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1 DR. HAUSER: Absolutely. I don't
2 want to speak for the other petitioners.
3 There are multiple listed.

4 DR. WOLFE: Thank you.

5 DR. HAUSER: You are welcome.

6 DR. FISCHHOFF: It looks like we
7 have another response to that question.
8 Please come. And then in terms of the panel,
9 Anna Maria next, and then we'll start at Terry
10 and go around.

11 Okay, please.

12 MS. PAHL: I hadn't intended to
13 speak to this at all, but my name is Tish
14 Pahl, and I am counsel to one of the
15 petitioners who will be speaking tomorrow,
16 Catalina Health Resource.

17 And we were involved in the
18 drafting and submission of the citizens'
19 petition.

20 As to the question of voluntary
21 versus mandatory, I'm going to punt a bit, not
22 surprisingly, although perhaps not for the

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1 reason you might think. And that is because
2 the issue of what a pharmacy is mandated to do
3 really exceeds the scope of the petition. The
4 medication guide regulation is mandated by the
5 pharmacy, CMI is not.

6 The medication guide is a
7 regulation that was subjected to notice and
8 comment that had opportunity for people to
9 comment upon.

10 So the idea that the single
11 document solution could become a regulation is
12 possible, but it is really beyond the scope of
13 the petition.

14 The key to the petition is to bring
15 some order to the cacophony of noise out there
16 for the patient to find one document that is
17 FDA approved that the patient can have
18 confidence in, and that those in industry and
19 in health care can rely upon to communicate to
20 patients.

21 But the legal mechanism by which
22 that document becomes available from the

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1 manufacturer who, as Eli Lilly so articulately
2 expressed, that would be a part of the
3 approved labeling.

4 So there is an FDA approval
5 process. There is then that process by which
6 that FDA approved document would be put into a
7 pharmacy communications system into their
8 software in order to be able to make it
9 available to the patient, and these are legal
10 questions. They are policy questions. And it
11 would take a long time to do that.

12 So there are the immediate needs
13 and the long term needs. Some of this might
14 be able to proceed by guidance. Some of it
15 probably undoubtedly by regulation.

16 So if we waffle a bit on the
17 mandatory versus voluntary, it's because we
18 recognize that this is a very complicated
19 legal area. And hopefully you won't be having
20 to hear too much more from the lawyers at the
21 rest of the meeting today.

22 So that is all I have to say.

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1 DR. WOLFE: By way of
2 clarification, if I understand what you are
3 saying it's that FDA could move ahead in the
4 direction of deciding what the content would
5 be, and that that -- maybe I'm putting you on
6 the spot so you won't answer -- at the same
7 time there is a separate regulatory process,
8 and the two might converge, and if FDA got its
9 mind around the content there might be
10 adoption anyway before it became mandatory.
11 Is that --

12 MS. PAHL: Well, one of the
13 mandatory component is that it would -- in
14 order for it to become a part of the approved
15 patient labeling, that is something that would
16 most likely have to proceed by regulation in
17 the same way that the revision of the
18 physician labeling did, in the same way that
19 the medication guide was subject to notice and
20 comment rulemaking, and that is not a short
21 process.

22 So that is one of the steps that

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1 would have to begin. So part of the reason
2 why we speak to voluntary is because we are
3 hoping that people will get on board quicker,
4 because voluntary will happen faster than
5 mandatory.

6 Thank you.

7 DR. FISCHHOFF: AnnaMaria, and
8 then the right side of the table.

9 MS. DeSALVA: Okay, thanks. I
10 have a question for any of the petitioners
11 that I think will be helpful for discussion
12 later, at least for me.

13 And the question is this: it seems,
14 in listening to all of you talk, that a
15 single document, one-page solution, is
16 certainly in many respects logical, and
17 appealing, intuitively appealing.

18 I have two fundamental questions
19 about it. One is, is it clear that it will
20 drive the intended outcome with the patient in
21 terms of understanding and adherence and
22 behavior? And is it -- has it been

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1 demonstrated that it will and also, what
2 barriers will exist that may be difficult to
3 reconcile in moving to that kind of a model.

4 So my real question is, has there
5 been any work yet done to vet the viability
6 and the impact of the single document
7 solution?

8 DR. McEVOY: We're not a petitioner,
9 but I think the answer to that question is no.

10 And a point that I'd like to make about the
11 earlier question, should it be a regulated
12 process or not, or should there be a
13 certification process, somewhere that
14 standards are really clearly established.

15 A reminder that in 2001 FDA
16 approved PPI, a piece of FDA approved PPI was
17 part of the process. It performed no better
18 than what the private sector information did
19 on nitroglycerine. In fact in our comments in
20 2001 we used as an example sildenafil Viagra,
21 which as potentially lethal effects if used in
22 combination with nitroglycerine. I don't

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1 remember the precise number, but that
2 contraindication has been in professional
3 labeling for several years, and many of the
4 nitroglycerine PPIs that were approved by FDA
5 did not reflect that contraindication.

6 So I think the answer is really a
7 complex one, and I think stakeholders
8 including FDA need to be very carefully and
9 diligently involved in that process in terms
10 of how do we proceed to move forward, so that
11 we do end up with information that is better;
12 that has been demonstrated to be better.

13 And I would recommend that what is
14 being petitioned not be adopted unless it does
15 meet what you just said, that it does
16 demonstrate the issues that are in question:
17 is a single page adequate? What information
18 should be there? And how will it actually be
19 created?

20 MS. BOUGH: Marcie Bough with the
21 American Pharmacists Association. If I can
22 just add on to my colleagues' comments that we

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1 may not have the outcomes or what a study
2 would show of the usefulness of a one-page --
3 let me clarify, one document; Apha is not
4 particularly focused on it being one page, but
5 one document -- of the important information
6 that would be useful to the patient that is
7 determined after pilot studies showing the
8 effectiveness of some sort of one document
9 that may vary in length depending on the types
10 of information that are needed on those
11 specific medications, especially with the
12 evolution of REMS and the different types of
13 tools that may be included in those.

14 I think to address the question of
15 voluntary or mandatory, APHA's position would
16 be that we would encourage a mandatory process
17 to limit confusion and variation in the
18 process that pharmacists use to dispense this
19 type of medication, but also so we wouldn't
20 have one system working in this -- on this
21 road, and another working some place else
22 where there may be differences if a patient

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1 went from -- to one pharmacy and received
2 their medication; they went to a different
3 pharmacy and got another medication or even
4 the same medication, and received different
5 amounts or types of information on that same
6 medication.

7 But in addition to being a
8 mandatory process, let's assume that FDA got
9 the funding and the staff and the resources to
10 pursue this, and include that type of
11 information that the patient received as the
12 approved labeling through the approval process
13 or post-approval information, that might allow
14 us to have some either clarity or assurance
15 that the information is both balanced in risk
16 and benefit, so that the patients are
17 understanding that there may be a higher level
18 of risk with some of these medications, and
19 that they are receiving the appropriate
20 information to go with that.

21 So I would agree that we might not
22 have the research that shows it would be the

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1 best way to address this issue. But given the
2 multiple sources of information that we have
3 now, we certainly think that maybe one
4 document would help us get to an improved
5 outcome.

6 Thanks.

7 DR. FISCHHOFF: Thank you very
8 much.

9 Terry.

10 DR. DAVIS: I want to get very
11 patient centered for a minute about the safe
12 use of medicine.

13 We go to our provider, we get a
14 prescription. They put us on medicine, or
15 change the dose of it. Then we go to the
16 pharmacy and get this. And then we get -- we
17 get home, and we have this, and we have the
18 pill bottle.

19 The research that I have done with
20 your new committee member, Mike Wolfe, and
21 Ruth Parker with over 1,000 patients, we've
22 published six studies on the patient

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1 understanding the label on the medicine.

2 And what we found is, even though
3 warning labels are short and seemingly simple,
4 they are not clear to patients. And when we -
5 - metformin was one of the drugs on the
6 primary label -- take one tablet twice daily.
7 Thirty percent of people with low literacy
8 misinterpreted this.

9 Then with glyburide, take two
10 tablets twice daily. The percentage
11 misunderstanding was even higher. But when we
12 asked, show us, spill it out, show us how many
13 pills you would take, only 30 percent of
14 people with low literacy spilled out four
15 pills.

16 So one of the things, when we are
17 thinking about one document, we also have the
18 pill bottle. What is on the pill bottle, I
19 believe, use instructions, I believe people
20 need the operating instructions on this, and
21 on -- and that the label on the bottle needs
22 to look like it goes with this. They all need

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1 to be one systematic piece of information for
2 safe use.

3 But you look at the bottle also,
4 and you need to be clear about when you are
5 going to take it, how many you take it, and
6 how long you take it.

7 Because just how you take it, you
8 think, well, you pop it in your mouth. What
9 is the big deal? But people are more confused
10 than we think.

11 DR. FISCHHOFF: Thank you.

12 Madeline please.

13 MS. LAWSON: I think I would sort
14 of add on to that. But my question of the
15 chain drugstore community pharmacists, I think
16 you had also, you were talking about the
17 single document that would be distributed by
18 the pharmacists. Do you have any strong
19 feelings about it being distributed by the
20 physicians?

21 I have heard a few people mention
22 that this should be done through physicians

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1 rather than at the pharmacists. And it is --
2 it really is important that the patient has
3 very good communications with their physician,
4 and if there are questions about their
5 medications they are more likely to raise
6 those questions with the physician rather than
7 the pharmacist.

8 So I wondered if you, or any others
9 who are petitioning, having concerns about
10 having it done through the physician rather
11 than through the pharmacist.

12 DR. HAUSER: Right, thanks.
13 Absolutely the conversation we believe should
14 occur with the physician. However the handing
15 out of any type of paper information, written
16 information that goes along with the
17 prescription we feel should be handed out at
18 the patient the receives the prescription from
19 their pharmacist.

20 But we would absolutely love for
21 those conversations to occur with the
22 physician. Because oftentimes more than not

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1 they are not occurring, and the patient is not
2 aware when they come to the pharmacy anything
3 about the risk associated with the product
4 that they were just prescribed.

5 DR. FISCHHOFF: John. Could I ask
6 you for the sake of the transcriber just
7 reidentify yourself. Just give your name.

8 DR. HAUSER: Sure, Ronna Hauser
9 with the National Association of Chain
10 Drugstores.

11 MS. BOUGH: Marcie Bough with the
12 American Pharmacists Association.

13 To answer the last question, we
14 would encourage medication guides or any
15 patient information to be available both at
16 the point of prescribing with the physicians
17 and at the pharmacy. And if there were a
18 mandated process so that what was provided at
19 the pharmacy was consistent, easy to read,
20 user friendly, we would have a better
21 assurance that somewhere along the
22 prescription-dispensing line it is being

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1 provided to the patient.

2 If we can figure out the logistical
3 challenges for making some of this information
4 available at the point of prescribing, whether
5 we use means of electronic communication or a
6 paper version of like a MedGuide, we would be
7 willing to help try to facilitate that.

8 But regardless of that, we
9 certainly encourage information being
10 available to both. We would not support
11 trying to change a system; that it was
12 required only at the point of prescribing, and
13 not at the pharmacy; but encourage both.

14 MS. LAWSON: Could I just follow
15 up please?

16 DR. FISCHHOFF: Please.

17 MS. LAWSON: Has there been any
18 discussion between the pharmacy associations
19 and the medical associations to talk about how
20 possibly you could do this?

21 MS. BOUGH: There has. Generally
22 it comes to how are we going to get the paper

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1 MedGuides as they exist now to the physicians.

2 The logistics behind it.

3 I think one of the things that we
4 hear is that physicians may not be aware of
5 the extent of what the MedGuide looks like, or
6 all of the information that is in that that
7 they receive at the pharmacy.

8 I think there is probably a lack of
9 awareness both on the physician and for what
10 medications have MedGuides. But we know that
11 that is also the case in pharmacies that don't
12 have good systems for kind of coordinating the
13 effort for all of the medication guides to be
14 either the paper version or in instances where
15 there is an increased success rate of getting
16 them dispensed to the patient when they are
17 automated into the printing system with the
18 label itself.

19 DR. FISCHHOFF: Thank you.

20 John.

21 DR. PALING: I have been very
22 encouraged to hear all of the presentations,

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1 and I get this strong feeling that there is so
2 much discomfort with the present situation
3 that from all sides there is good will and
4 strong motivation to make changes.

5 So while clearly it is true that
6 the devil does lie in the details, I think
7 that there is an imminent possibility of major
8 changes in a positive direction. And I thank
9 every one of the presenters, because they were
10 all colored to the betterment of my own
11 understanding of this situation.

12 Two questions, one to the
13 representatives of the pharmacist community.
14 I had heard before, and have confirmed
15 empirically, there is effectively no risk
16 communication specifically taught to
17 pharmacists. That happens within -- that fact
18 exists in my own university and I think from
19 what I'd understood that that is not commonly
20 done.

21 I would invite you to correct that,
22 and I would be very anxious to learn, just a

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1 guess, what percentage of professional
2 pharmacists get training at risk
3 communication, not patient communication, risk
4 communication, because that is an inherent
5 part of that. And that is question one.

6 Question two, of the second
7 speaker, and I do apologize not to have
8 remembered your name, I picked up on the fact
9 that you said the previous investigation might
10 be tainted because they weren't in fact using
11 the best of the CMI materials.

12 Paraphrasing you as I heard you,
13 you said there are now better sources, with
14 both content and format, but sadly there has
15 been very little take up of it. That's what I
16 heard.

17 So my obvious question is, what is
18 your interpretation for why in fact there has
19 been so little take up of what I feel both you
20 and I would view as a significantly improved
21 communication tool?

22 DR. FISCHHOFF: Let's take the

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1 questions in reverse order, and we will call
2 on our guests first, and then we have a
3 resident expert on the first question.

4 So please.

5 MR. JOHNSON: Paul Johnson from
6 Wolters Kluwer Health. I think one of the
7 biggest reasons why -- well, there are a lot
8 of reasons why it hasn't been adopted. But I
9 think part of it is uncertainty on the part of
10 pharmacies and the people who distribute this
11 as to what is going to happen down the road.

12 In mean in looking at the history
13 of CMI, I mean the product, what you saw in
14 the survey has been in the marketplace for 20
15 -- 30 years. I mean a very very long time.
16 And I think there has always been thoughts
17 about how can we change what exists now to
18 make it better. And with the Keystone
19 guidelines coming out, it's -- some people
20 continue to try to do that, whereas at Wolters
21 Kluwer we thought, what is out there is out
22 there; it is entrenched. That information, or

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1 at least some quality information, is better
2 than no information to the patient. But we
3 wanted to say, but since the action plan is
4 here now, these guidelines are what has been
5 defined as what is the quote de facto standard
6 for what CMI should do.

7 We set about to create a new
8 product that would specifically match those
9 guidelines, kind of like what Gerry was
10 talking about. So but because the pharmacy
11 systems are what they are, you know, it's very
12 difficult for pharmacies, software vendors,
13 and even sell programmers to on a dime take
14 that information and incorporate it.

15 Because in the examples that I gave
16 you are the examples of what we believe to be
17 the Keystone compliance CMI, and it's an XML
18 document. It's a different technology than
19 what is widespread in pharmacy practice.

20 And while some pharmacies and
21 software vendors are trying to find ways to
22 create new systems, as systems get updated

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1 they are recognizing that that kind of
2 information is available. They can take that
3 and design their system such that it can use
4 that.

5 So I mean that's the reason why
6 it's been I think slow to adopt is a lot of
7 technology limitations. I think things that
8 could happen in addition to upgrades in
9 technology on the part of the software
10 providers and pharmacies is, as we have been
11 talking about, allow other methods of
12 distribution of that same information other
13 than just paper.

14 I mean I think with the advances of
15 technology that we have today, everybody has
16 got a Blackberry. Everybody has got an
17 iPhone, everybody has got a laptop or
18 computer. If people would choose to accept
19 their written information in that manner, it's
20 much easier to implement this kind of new
21 document into an electronic format, and people
22 would then have it anytime they want it. They

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1 know exactly where it is. They know exactly
2 where to go to get it. Whereas with the
3 leaflet, they may misplace it. They may throw
4 it away; who knows.

5 But for people who don't have
6 access to that kind of technology we believe
7 that there should still be the option for
8 those people to receive a printed document
9 from their pharmacy that still meets those
10 guidelines.

11 So does that answer your question
12 or is that confusing?

13 DR. PALING: Let me put my
14 interpretation on your words, and these are
15 not the words that came from your mouth. I'm
16 hearing that the people who at one stage you
17 said could alter the formatting and put
18 smaller font and you had no control over them,
19 namely those that purchase your products, if
20 they were sufficiently discomfited by the lack
21 of what I view as my lack of effectiveness of
22 the communication document, could choose to do

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1 better if they were that discomfited, but it's
2 not happening.

3 And that is me clearly loading and
4 twisting, but I think accurately reflecting my
5 message from what you've said.

6 MR. JOHNSON: I would agree.
7 There has to be some incentive. There has to
8 be an incentive for the people who distribute
9 CMI to distribute what it is that -- what's
10 needed. And if they don't, it could be a
11 positive incentive, or it could be a negative
12 incentive.

13 DR. SLEATH: Can I ask a
14 clarification point? Because you seem to be
15 blaming the pharmacists a lot here, and I
16 teach pharmacists. I don't think pharmacists
17 are going in there altering this as much as
18 you are making it out for us to believe. So I
19 would like you to explain exactly how and
20 when, and maybe the National Association of
21 Chain Drug Stores can help or the other
22 pharmacy organizations here.

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1 I know pharmacists, and they're
2 already very overworked, et cetera, so I
3 cannot see them going in here altering this
4 information, so I guess I don't really buy
5 that argument.

6 Then when I see your good example
7 of information, this is at a really high
8 reading level, and even Carol pointed out that
9 only 10 percent of the leaflets were written
10 at less than an 8th grade reading level.

11 So if those are the criteria, it
12 doesn't seem like it's being followed. But
13 I'd like you to elaborate on exactly how and
14 when the pharmacists are going in and changing
15 this because it doesn't make sense to me.

16 MR. JOHNSON: Sure. It is not the
17 individual pharmacist, the guy standing behind
18 the counter counting the tablets. That
19 document that you have in your hand there,
20 both of those documents are below an 8th grade
21 reading level. Those two, yes.

22 DR. SLEATH: I'd have a hard time

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1 believing that.

2 MR. JOHNSON: On the Flesch-
3 Kincaid scale, if you take that information
4 through Microsoft Word, and run the Flesch-
5 Kincaid scale on it, both are less than 8th
6 grade reading level.

7 DR. FISCHHOFF: Let me, since we
8 are at 3:00 o'clock, I'd like to sort of break
9 off this conversation. Because she is on the
10 panel and you are not, you can continue this
11 conversation afterwards. The restrictions are
12 on what we can say. So let me thank you again
13 for your comments, and you will have an
14 opportunity to discuss this.

15 Let me ask Betsy while you have the
16 open mike to respond to John's second question
17 about the risk communication training of
18 pharmacists, and then we'll ask Musa and Mike
19 to speak, and then we will take our break.

20 DR. SLEATH: I think that -- I
21 recently saw something where the American
22 Association of Colleges of Pharmacy is

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1 attempting to look at how well pharmacy
2 curriculums are teaching risk communication,
3 so I think that it is an area that does need
4 improvement, and I think it's not just true in
5 pharmacy, it's true in the other medical
6 professions as well.

7 The other part of that is that it's
8 the risk communication -- sorry, I don't feel
9 well, so I lost my train of thought, so we
10 will turn it over to somebody else and maybe
11 I'll get it back. I apologize.

12 DR. FISCHHOFF: Okay, thank you.

13 Musa and then Mike, thank you.

14 MS. MAYER: So I want to go back
15 to an issue we were beginning to discuss
16 before, and that is the point of
17 communication, and the point of decision --
18 patient decision making as occurring with a
19 physician as opposed to at a pharmacy.

20 To add to that I just want to
21 introduce the thought that since I'm a cancer
22 advocate and represent cancer patients, there

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1 is a whole class of among the most toxic
2 medications with sometimes the lowest risk --
3 I mean the greatest risk and the smallest
4 benefits, and the largest cost, although that
5 is not what we are discussing, that simply are
6 outside the purview of what we are discussing
7 today because they are given in a physician's
8 office or in a hospital setting by infusion or
9 injection.

10 And I know from personal experience
11 and the experience of hundreds and hundreds of
12 people that I have spoken with about this,
13 there is rarely full disclosure of risks and
14 benefits, and there is often -- most often --
15 no -- nothing -- that is at least obviously
16 available to patients. In the age of the
17 Internet they can go online, of course, but
18 nothing available to patients that would
19 really fully inform them in the way that we
20 are talking about.

21 And to me that makes it doubly
22 important that we not just frame this

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1 discussion in the context of pharmacy
2 dispensing.

3 There is also another class of
4 regulated products, and that would be devices,
5 for which that is additionally true. So I
6 think it is a broader discussion than we've
7 had so far.

8 DR. GOLDSTEIN: I have some
9 comments that I can make, but I will hold them
10 until after the break.

11 In response to what I've heard from
12 the group that presented, I want to thank
13 them, too, and what resonated with me is the
14 call that I heard repeatedly for evidence and
15 to make decisions based on evidence. And I
16 really appreciated particularly Dr.
17 Shiffman's presentation because he was
18 providing us with information we need to know
19 about the impact of some of the tools we
20 already have.

21 And the question I have for those
22 of you -- we may not get all the answers,

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1 again, today -- is how the answers are going
2 to change based on the populations of people
3 we ask. I think we do want to be consumer
4 centered. We want to be patient centered.
5 Those are overlapping but different
6 populations; one may be a subset of the other.

7 We may get very different answers, and as
8 somebody pointed out, we need to use adult
9 learning principles and realize that people
10 are at different stages of their need. We
11 can't just ask a focus group of people who are
12 consumers about what they need, and we can't
13 just ask people with cancer what they need
14 from chemotherapy.

15 We have to know much more
16 specifically about the needs of the different
17 types of patients at different points during
18 their trajectory of illness. Because they
19 need different things.

20 And anyway what I'd like to know
21 from the audience is, if anybody has
22 considered testing the same tools, but with

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1 different populations, consumers, patients,
2 patients who have an illness for awhile, who
3 know more about that, may be more of an expert
4 patient, to get feedback to give us evidence
5 whether there is a need to be -- to have
6 differential, if you will, interventions for
7 people at different stages of their
8 conditions. Has anybody done that work?

9 (No response.)

10 I think we need to do some of that
11 work.

12 DR. FISCHHOFF: Let me again thank
13 all of our members of the public who spoke
14 with us, and your willingness to engage in
15 this exchange.

16 We will break for 15 minutes, and
17 meet back here at 3:25 for an open discussion.

18 (Whereupon, the above-entitled matter went off
19 the record at 3:13 p.m. and resumed
20 at 3:29 p.m.)

21 COMMITTEE DISCUSSION

22 DR. FISCHHOFF: Okay, let me thank

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1 everybody for coming back. We have now until
2 5:00 o'clock for a general discussion of the
3 committee members, and the floor's open.

4 Would you like to start?

5 DR. GOLDSTEIN: Should I start?

6 DR. FISCHHOFF: That's right. You
7 had a comment before that you abbreviated.

8 DR. GOLDSTEIN: Well, one of the
9 questions that was asked before had to do with
10 training and the role of the clinician at the
11 point of service, if you will. And I've had a
12 lot of experience training physicians and
13 other health care providers about the way in
14 which they talk with patients about
15 medications and other things. And if we just
16 rely on physicians alone we are going to miss
17 a lot of the opportunity to educate
18 effectively, if we're talking about
19 effectiveness.

20 We can improve that through better
21 training and better tools at the point of
22 care. But I really believe we need a system

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1 that includes the information provided in a
2 way that is effective at the time when they
3 get their medication as well as repeated
4 opportunities to check in.

5 What is interesting, and I asked
6 the question about the different types of
7 patients. There is also different points of
8 time in their care. So when we are evaluating
9 a tool, it seems to me we are missing
10 opportunities if we are just evaluating it the
11 very -- or just one time when a patient gets
12 it. Especially for most chronic conditions,
13 patients are going to be taking medicines
14 repeatedly, and you could be following a
15 cohort of patients over time to see the effect
16 of this tool as well as other tools on their
17 knowledge, on their comprehension, on their
18 behavior over time.

19 So to what degree can one tool or
20 multiple tools be used to help a patient who
21 themselves are in the process of becoming more
22 active, engaged, more effective, more

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1 competent as a patient to use the material
2 that they are getting in an effective way.
3 And to think that just one CMI or medication
4 guide is going to help that one patient is
5 missing lots of opportunities to build
6 knowledge, confidence, and effectiveness as a
7 patient.

8 So in designing our studies we do
9 have to be careful in picking the questions
10 that we are asking, first of all, picking the
11 population that is most likely to answer the
12 question that we have. Initial comprehension
13 about taking a medicine for the first time is
14 very different than continuing to take the
15 medicine and how they are incorporating that
16 medication into their ongoing self management
17 of their condition.

18 DR. FISCHHOFF: So you are talking
19 about both the patient changes as a patient,
20 even if the disease is relatively in the same
21 situation.

22 DR. GOLDSTEIN: Exactly.

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1 DR. FISCHHOFF: And the condition
2 may change as well, in which case the
3 information needs may change.

4 DR. GOLDSTEIN: Yes, so we have to
5 think about the different patient populations
6 based on whether or not they have a condition,
7 how long they've had it. We also have to
8 think about the needs of patients over time.
9 We have to think about tools that are
10 iterative themselves, that provide an
11 opportunity for building in a dialogue that
12 builds upon their current need at each point
13 in the contact cycle.

14 Those are three separate questions
15 actually that could be researched using
16 different kinds of interventions.

17 DR. FISCHHOFF: Sid, then Craig
18 and then Musa.

19 DR. WOLFE: I just have a quick
20 comment on what Mike said. An example that
21 comes to mind are statins used for primary
22 prevention on a mainly healthy, not too

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1 healthy or it wouldn't be effective, but as
2 opposed to secondary prevention.

3 There within one drug you have two
4 relatively distinct patient populations. One
5 of them has had an MI or stroke or heart
6 attack or angina or whatever, and the other
7 has not. So I think that -- I mean I'm not
8 sure that you can fine tune this all the way,
9 but there is right away an example of
10 something where you would have a different
11 part, maybe the same medication guide could
12 address both of those groups of people.

13 But I think that what you say makes
14 some sense. But of course this applies to
15 some extent to the physician, too, because the
16 physician labeling may, and does, for statins,
17 have primary prevention and secondary
18 prevention, and the physician similarly needs
19 to know how to respond to and talk at this
20 initiatory place of the action before the
21 guide comes up, and I'm not sure the
22 physicians know how to talk differently

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1 necessarily with these different people at
2 different stages. I mean that's where you're
3 training people, you must know that even much
4 more than I.

5 I just have a -- really a question
6 of everyone here which is -- on the committee,
7 understanding that FDA can't respond, as was
8 said, because it's a pending petition, this is
9 a bit of a ode to Dr. Goyan. Dr. Jere Goyan
10 was a pharmacist who was the head of the FDA,
11 and he initiated this whole thing back in `78
12 and `79. And there was a final regulation in
13 `80.

14 He was vilified by what is now
15 called the American Pharmacy Association. The
16 pharmacists were adamantly opposed to FDA-
17 approved labeling. All of them. It's
18 interesting today that three of the pharmacy
19 organizations either are supporting a petition
20 or they are all supporting the concept of a
21 petition. They differ a little bit on whether
22 it should be voluntary.

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1 So I would like to know, given that
2 this public law has standards that have not
3 been met, given that there are medication
4 guide regulations already out there, how many
5 people here at this point think that it's a
6 good idea to keep doing the private sector
7 they write their own labeling?

8 I for one think it's a terrible
9 idea. I would like to hear what my colleagues
10 on these committees have to say.

11 DR. FISCHHOFF: Thank you. Let's
12 see, Craig.

13 DR. ANDREWS: Just a quick comment
14 on Mike's point, and then maybe we can get
15 past to what Sydney had raised, just real
16 quick.

17 I had a thought about the process.
18 It's really important, not only at the first
19 time of dispensing at the pharmacy level, but
20 as most of us know there are familiarity
21 effects. A lot of the research shows there is
22 biasing, so people have that first time, they

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1 will probably ignore the information.

2 In fact at some pharmacies they do
3 a good job at the first time and actually sit
4 down with you and explain and go through. The
5 question is, have you received this before,
6 and if the answer is yes, then nothing.

7 And I think what may happen, let's
8 say there are side effects or other things
9 that would happen later on; it could be
10 serious due to this biasing effect. So anyway
11 just a quick comment.

12 DR. GOLDSTEIN: If I could follow
13 up on that, too. The experience that a
14 patient has with the medication is going to
15 affect what they do next and the questions
16 that they have. So just to take the analogy
17 of the statins further, not only is there
18 primary prevention and secondary prevention,
19 but then there are those who have developed
20 symptoms. Say they have muscle symptoms after
21 taking it for three months. That person is at
22 a very different stage. Say they've had no

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1 events; that is different from a person who
2 has had events while they are on the statins.

3 Nonetheless, the meaning of the information
4 is going to be different for those patients,
5 and they are going to have different questions
6 of their clinician. They are going to have
7 different questions of their pharmacist. So
8 they may need different sources or types of
9 information.

10 So I think it's a tough complex
11 issue, the degree to which we can make sure we
12 are asking the right question of the right
13 population of patients, and testing
14 interventions that are targeted for them at
15 their different stages of illness. We're more
16 likely to get good evidence based materials,
17 rather than thinking that one size is going to
18 fit all.

19 MS. MAYER: To respond to that, and
20 what you were talking about before, Michael, I
21 think that it is pretty clear that the drug
22 labeling information that these patient guides

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1 are based on really represents initial studies
2 in treatment, and there are many many examples
3 where only even as few as a few weeks to a few
4 months are all that have been looked at.

5 And yet many drugs are taken
6 chronically by people with all kinds of
7 comorbidities year after year after year. I
8 think you raise a really important point.
9 It's maybe beyond what our charge was to
10 discuss today, but it is really crucial that
11 patients simply do not have a resource to go
12 to to understand what is known and probably
13 what is more importantly not known, aside from
14 their physician who may not have the time to
15 discuss it in depth. The consequences of
16 taking a drug, for example, like an NSAID for
17 arthritis sufferers, what does that mean after
18 one year, after two years, after five years?
19 What happens to the risk? What do we know
20 about that?

21 That is just one very common
22 example. The other point, the other thing I

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1 wanted to do was to respond to Sydney. I
2 agree with you 100 percent.

3 DR. WOLFE: Other responses?

4 DR. FISCHHOFF: Musa, could you
5 expand on both what you are agreeing with and
6 why you are agreeing?

7 MS. MAYER: Yes, I'm sorry. I
8 think that there has been ample time for a
9 voluntary program to succeed, if it were going
10 to succeed. And the proliferation of
11 confusing and contradictory and untested
12 materials really tells us we need something
13 very different.

14 And I am basing my sense that this
15 really does need to be mandatory rather than
16 voluntary on the success of FDA's system as
17 far as it has gone, at least requiring initial
18 high quality evidence for the approval of
19 drugs.

20 As I said before, there is
21 absolutely no reason why we should not take
22 just as seriously FDA's charge to make sure

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1 that patients know what it is that they are
2 taking and what the full risks and benefits.
3 This is a foundation of medical treatment, so
4 I agree completely.

5 Now whether an earlier comment was
6 that FDA did no better, their track record was
7 no better. But that is not really an argument
8 against regulation; that is an argument to
9 improve either the resources or the quality of
10 the personnel or the evidence base so that in
11 fact we do have an authority that knows what
12 they are talking about.

13 DR. FISCHHOFF: Okay, thank you.

14 Madeline.

15 MS. LAWSON: I, too, agree with Dr.
16 Wolfe. I do think that it now needs to be
17 mandatory.

18 But I would suggest that the
19 agency, that FDA would take the lead and bring
20 it together, to really have input from the
21 health professionals, that it's not done in a
22 vacuum.

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1 I think that is important because,
2 I mean, after all the patients' point of
3 contact is with their, the health care
4 providers. And so we want to have the best
5 minds to come together to look at what is the
6 best approach. So I do think that that should
7 be done, and I would suggest and recommend
8 highly that that is done. But I agree that it
9 should be mandatory.

10 DR. FISCHHOFF: Tim and then John.
11 Tim first.

12 DR. LESAR: I guess I would
13 basically agree that unless there is some
14 other way to produce some defragmentation of
15 the system that would produce the endpoint of
16 a usable consistent product that is used in
17 all pharmacies only because patients don't go
18 to just one pharmacy, they don't just go to
19 one doctor, and they are the end user. They
20 are the ones who are the endpoint; they are
21 the ones who should get consistent information
22 they can interpret. And if I see -- I don't

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1 have another way, but regulation is not the
2 goal so much as that defragmentation, the
3 consistency that you can achieve through that,
4 and certainly it's one way to do that.

5 Now if there are other ways to do
6 that, that's fine. But that is what we need
7 to do is exactly that.

8 DR. FISCHHOFF: Let me make just a
9 procedural point. So we have five questions
10 and answers from FDA. There seems to be
11 enough interest in this, I am adding this to a
12 sixth point on which we will try to provide
13 some sort of summary advice to FDA.

14 I am taking notes furiously. I
15 will try to assemble things in a position
16 where we might be able to think about
17 recommendations that are just advisory from
18 the committee sometime tomorrow.

19 The procedure for that is -- and we
20 will try to do that towards the end because
21 some of the presentations that we will have
22 tomorrow are pertinent to this topic as well

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1 as to the other ones. There is procedural
2 guidance from FDA. We had a vote at our last
3 meeting, and I luckily got it right. But just
4 to take a little procedural pause.

5 An interesting part of the written
6 guidance is that it relies on social science
7 evidence for how to conduct votes. So let's
8 hear it for FDA. And so one of the things
9 that it says is that all of the discussion --
10 that you should have a proposal that is clear
11 enough that people can discuss, then revise
12 the proposal, have no further discussion, then
13 the vote should all be simultaneous so that
14 there isn't any kind of social pressure or
15 consultation with one another.

16 So we will try to -- I will try to
17 propose something that seems to capture the
18 sense of the meeting, and then we will go
19 through that procedure towards the end.

20 DR. WOLFE: Just briefly, that is
21 completely acceptable to me. All I was saying
22 is, as I look through these questions, which

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1 are good questions, it seems that the so-
2 called elephant in the room as it's overly
3 stated is that all of these things are
4 important questions, and I am far more
5 confident that we will have a good discussion
6 and that they will occur if it's in the
7 context of FDA regulating this as opposed to
8 it being done on the outside.

9 DR. FISCHHOFF: And so I encourage
10 everybody to address this hypothesis.

11 DR. PALING: I'm sorry, I'm not sure
12 what the hypothesis was. I was joining in
13 giving an opinion because you had asked not
14 just for a suggested conclusion, but also the
15 rationale as to why we had that conclusion,
16 and that is what I was going to contribute.
17 But I will defer to whatever you wish, Mr.
18 Chairman.

19 DR. FISCHHOFF: We're having an
20 open discussion now, and we will, I'm
21 guessing, have a vote tomorrow.

22 DR. PALING: I, too, would support

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1 what has been said, and the reason came from a
2 break we had not 15 minutes ago. Betsy and
3 two or three colleagues stood around with our
4 friend at the back, and we were discussing the
5 very topic -- well, how come someone makes
6 these changes. Who is the someone and how are
7 they made?

8 And what I learned for the first
9 time there was, again, trying to honestly
10 replicate what I learned. The company
11 provides text, and what happened to that text
12 differs according to whom it is sold. It is
13 formatted differently. Bits of it can be
14 missed out and so on. And really they have no
15 control, therefore no responsibility, for what
16 is finally presented as the product to the
17 patient.

18 So with that as my main guidance
19 and giving me considerable concern, I think
20 the only way around that, and it's really the
21 best argument that I have heard for why it
22 needs to be regulated. So there is my answer

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1 as my rationale for supporting what was
2 suggested.

3 MS. DeSALVA: Thanks. I want to
4 pick up on something that Michael is saying in
5 a very compelling way and that we heard a
6 little bit, I think, articulated by some of
7 the people in the public session, and that is
8 -- well, I would want to pose to the group is,
9 recognizing what our core questions are here
10 to address, is the central question that one
11 document can be a solution for fixing this
12 problem of too much, too uncoordinated patient
13 information.

14 Or is the central question, what is
15 the right system of communication to get to
16 the right outcome? And it may be that a
17 document at the right time that provides the
18 key information and consolidates both risk and
19 benefit information is a part of that system.

20 But the concern that I think I have
21 heard others express and that I share is that
22 we have had this sort of very imperfect

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1 circumstance where all of these methods of
2 communication have grown up for the wrong
3 reasons, and they haven't been harmonized.
4 And if we focus on an imperfect solution or a
5 partial solution, then we will miss the
6 opportunity.

7 So sometimes, at least in my
8 business, and I think probably in lots of
9 businesses, it's helpful to kind of take the
10 guard rails off and blue sky the way that
11 things should be. And I wonder if we just
12 pretended for a minute that there wasn't this
13 history, and we didn't allow ourselves to be
14 limited by regulation and the reality for a
15 minute of legal and liability concerns, and
16 just pretended that there was a really
17 important or exciting new product, a new drug,
18 a new technology, that had a lot of promise,
19 but that the communication around that drug
20 was just as important as the technology in
21 terms of getting to the right outcome, and
22 that we had to design the optimal

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1 communication method or system of
2 communication to help that patient take that
3 journey from diagnosis and initial
4 prescription of the drug, all the way through
5 if it's a chronic condition many years of
6 successful treatment. What would that model
7 look like?

8 And there would be a lot of inputs
9 to that model in terms of discovering or
10 understanding what the needs are of that
11 patient at any given time. Different types of
12 patients. And I would hope that what could
13 possibly come out of this, that review, and I
14 am always conscious at this point that I am
15 not a researcher, that many of you know much
16 more about these models than I do. But what
17 might come out of that review are some key
18 themes, some core principles, some insights
19 that would allow us to basically create a
20 model for communication across that continuum
21 that wouldn't be burdensome, that wouldn't be
22 so fragmented that it would become difficult

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1 to implement, and that what eventually grows
2 up is a coordinated system of communication,
3 and there is guidance, and maybe we are able
4 to look at that based on the major chronic
5 conditions, and it is different if you are
6 treating an acute condition versus a chronic
7 condition. And even within that certain
8 patient populations will have distinct needs.

9 So I would put that forward to the
10 researchers in this group to say, is that --
11 will that exercise be just unhelpful, or is
12 there merit to thinking about how things
13 should be, and is the central question about
14 this one document or about a system of
15 communication.

16 DR. FISCHHOFF: So let me just,
17 again, invite everybody to respond to
18 AnnaMaria. When your turn comes, and I think
19 strategically -- I bet you have some ideas,
20 and if you propose that you will probably get
21 more reactions. People would take the bait if
22 you made a proposal because either they'd like

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1 it or they wouldn't. So I invite you to do
2 that.

3 Betsy and then Christine.

4 MS. HENDERSON: I'll take the bait.

5 Thank you for those comments. I
6 think that would be a great discussion, and
7 certainly a discussion that needs to be had.

8 I would only reiterate I think the
9 plea that we are needing some practical advice
10 from this committee, and while you might --
11 and I am just speculating -- if you all had
12 this discussion about how things might be
13 perfectly, that would include what doctors did
14 in doctors' offices, and what they did at
15 various times during the patient's disease
16 state and all of that, that will not be as
17 helpful to us as getting some solid advice for
18 the things that the FDA might do or at the
19 very least influence within that system.

20 So if you are going to have that
21 discussion, it would be great if at least
22 somewhere in there you would include some

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1 practical aspects for the things that the FDA
2 might do.

3 Okay, well, you weren't on the
4 mike, so for the audience's sake, you are
5 asking -- Terry is asking for the boundaries.

6 We don't regulate the practice of
7 medicine, and we don't regulate the practice
8 of pharmacy. We regulate the products. And
9 so we regulate the product manufacturers.
10 Through that regulation we are obviously able
11 to influence certain things, and with all of
12 the new legislation that we recently got last
13 year, the FDA Amendments Act has given us more
14 authority to have the manufacturers, require
15 of the manufacturers to put certain risk
16 management things into play.

17 So for example we can require
18 MedGuides; we could do that before. We can
19 require certain -- what is called elements to
20 assure safe use of products. And I don't want
21 to go too far into what the Amendments Act
22 allows us to do. But just to say in some

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1 sense while we don't regulate the practice of
2 medicine, we do regulate the manufacturers and
3 the use of the products, so we can say you
4 have to have a pregnancy registry for example.

5 We don't believe a product can be used safely
6 unless a doctor is specifically trained to use
7 that product.

8 But I think it would a very far
9 reach trying to go down to the communication
10 path. It would be a pretty far reach, just as
11 an example, to say well, FDA then, we think
12 the products can't be used safely unless
13 patients really counsel their physicians in
14 the following way. And that would be ideal,
15 but I think it would be a far legal reach for
16 us, and I'm not an attorney either and don't
17 play one on TV. But it would be a very far
18 reach for us to think that we could impact or
19 require of doctors to do a certain kind of
20 counseling at a certain time.

21 We could require manufacturers to
22 provide a certain piece of paper, or if

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1 someone believed a videotape was a better way
2 to be educated, or on your PalmPilot or
3 whatever, we could require the manufacturers
4 to make certain information available to the
5 health care system for use.

6 But we can't tell doctors what to
7 do. We don't have any authority to tell
8 doctors, you must counsel your patients at
9 this certain time or in this certain way. So
10 does that help?

11 DR. DAVIS: Okay, so the FDA can
12 regulate the -- FDA can regulate the
13 manufacturers, but you cannot regulate anybody
14 giving this information to the patient, either
15 the pharmacist of the doctor; is that
16 accurate?

17 MS. HENDERSON: Yes, I would say
18 that that is an accurate way -- that that is
19 accurate. We don't -- we don't tell doctors
20 how to practice medicine, so the issue of off
21 label use is a good one.

22 We can regulate whether or not the

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1 manufacturer can have a certain indication on
2 their label because if they haven't given us
3 the clinical evidence that we would need to
4 have, if they have not submitted an
5 application to say drug x is used for this
6 disease, for example, they have not done
7 clinical trials to demonstrate safety and
8 effectiveness for a certain indication, we
9 regulate the manufacturers and don't allow
10 them to put that on their label if they have
11 not done the appropriate studies to
12 demonstrate it works and is safe in that
13 condition.

14 However a doctor in his best
15 judgment, if a drug is on the marketplace, a
16 doctor in his best medical judgment can give
17 that drug to any patient for whom he feels it
18 to be appropriate.

19 DR. DAVIS: But just so I'm clear
20 about the boundary deal, the boundary is like
21 if we are talking about what the patient gets.

22 It's not voluntary any more. But then that

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1 is going to be given at the pharmacy --

2 MS. HENDERSON: Oh, yes, and we --
3 for example Nancy brings up MedGuides.
4 Medication Guides are a regulatory
5 requirement. We regulate that there is
6 professional labeling and, in some cases,
7 patient labeling that must be distributed with
8 a medication. So that is all perfectly fine,
9 and to say that we should require with every
10 prescription that is distributed, a patient
11 ought to get a certain kind of information is
12 great.

13 What I was hearing was a plea for
14 talking about the whole system. And that is
15 fine; you are free to discuss the whole health
16 care system. But we only play, the FDA just
17 plays a part in that health care system. And
18 I am happy to let you know when you start
19 talking about things, if you were to make a
20 recommendation to the FDA, for example, I am
21 happy to interrupt you and say, that is a
22 great suggestion, but at least as of right now

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1 we can't do that.

2 DR. FISCHHOFF: If I could, in
3 thinking about working with Lee and Nancy on
4 the design of the meeting, I think the thought
5 that I had in mind, I won't commit the two of
6 you, is that the documents -- we have
7 documents now. They are working to a degree
8 that is up to evaluate, but they could always
9 be improved.

10 So the documents to my mind provide
11 a way of identifying the evidence that is
12 critical; to ensure that that evidence is
13 provided to whoever is creating the document
14 provides a platform for evaluating how well
15 information is gotten across to -- which will
16 be to different degrees to varying degrees of
17 population.

18 So the document provides a way to
19 formalize our argument, to formalize the
20 decision, to formalize what the information
21 is, what our evaluation criteria, and the best
22 of all possible documents will not work for

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1 everybody.

2 And so the way I think about it is
3 that you would like everybody to be within two
4 degrees of separation. For somebody who can
5 take that well characterized, pertinent,
6 clearly described information and then
7 translate it into those terms, and the
8 translation may be across barriers of
9 numeracy, barriers of language, barriers of
10 access.

11 And to that end, one of our
12 speakers tomorrow is a member of the committee
13 who rotated off. You may even be -- no, no,
14 you're not sitting at his chair because you
15 are not part of the committee -- but is David
16 Moxley whose specialty is in reaching
17 underserved populations.

18 So if we can think about, you know,
19 you could disagree with this model, but the
20 thought is, let's get the information right,
21 see what are the performance standards that we
22 want out of it, and then see how we make

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1 certain that the health care system, some of
2 which is outside of FDA's purview, the public
3 health system, our social system, can ensure
4 that that good information is then translated
5 for everybody.

6 So let me -- let's see, we have
7 Betsy, Christine, Ellen and Sid in that order,
8 and then Mona.

9 DR. SLEATH: I was just going to
10 say that I agreed with Sid that I think this
11 needs to be mandatory. Just looking at the
12 numbers, to me it is appalling that in Carol's
13 study that even though 75 percent of them met
14 minimum criteria, the format issues were way
15 low, like only 3 percent had the black box
16 warning; 7 percent used bullets; those kinds
17 of things.

18 So I think it needs to be mandated.

19 And the other reason I think it needs to be
20 mandated is because John asked about
21 counseling and pharmacies, and what I was
22 going to say before but had forgotten was that

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1 Bonnie Svarstad who has actually been involved
2 in some of these evaluations did a great study
3 that found that as counseling regulations for
4 pharmacies were more restrictive by state,
5 counseling improved and communication
6 improved, and so to me you therefore at least
7 need a leaflet with some type of minimum
8 criteria. Because in those states where the
9 laws are less restrictive and a lot of risk
10 communication is not occurring in pharmacies,
11 something needs to be getting the points
12 across to the patients.

13 And I'd like to urge, I urged the
14 gentleman from the company that I spoke with
15 on the break, he told me that pharmacists are
16 involved in writing a lot of this stuff. Now
17 that is good, but it's also bad. I think that
18 you need health educators and people that
19 specialize in how you present information to
20 people really involved in creating these
21 leaflets. It's not just what is the technical
22 part of them; it's how it's presented.

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1 DR. FISCHHOFF: Thank you.
2 Christine.

3 DR. BRUHN: Thank you. I believe
4 it's quite clear that the current system is a
5 failure, even adherence, the 75 percent one
6 could find adherence, adherence was with a
7 minimum of 60 percent of the guidelines. That
8 is really a pretty bad grade to me, even for
9 those who met.

10 So I would like to, in addressing
11 the first question there that we have in our
12 document, does existing information work or
13 should there be a single tool. I think it's
14 quite clear that physicians should still
15 receive medical guides, a more detailed and
16 comprehensive review of what a drug shows, and
17 what the counter-indications are and so forth.

18 But as far as the consumers are
19 concerned, the recommendation of a single
20 tool, one page or as close as it could be,
21 that met the Keystone guidelines and so forth,
22 is quite appropriate. An advantage of having

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1 that single and more understandable tool is
2 that it could be translated into Spanish and
3 perhaps other languages, and that would extend
4 this information to other audiences.

5 I remember our member, who is not
6 here now, always came up with, what does this
7 mean to the Spanish audience. And that is a
8 very large audience, and clearly even college
9 educated people do not read what is
10 distributed now, and you can be certain that
11 translating all of that to another language
12 would not be very effective because it is not
13 read either.

14 My concern is, does having
15 something -- well, first of all it's
16 appropriate that FDA approve it. Although I
17 don't have data to support this I believe that
18 the public expects that FDA, the Food & Drug
19 Administration, has some role over what is
20 written and communicated with the drugs they
21 receive. So I believe having a mandatory
22 information that FDA approved is logical and

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1 consistent with this expectation.

2 I would also like to be sure,
3 however, that having something FDA approved
4 does not absolve a manufacturer from not
5 disclosing everything about a drug should
6 there be an interaction. I would hate them to
7 come back and say, but the FDA did not require
8 me to put this side effect even though I knew
9 the side effect existed.

10 So I guess I have some legal
11 concerns about something that is FDA approved,
12 and I believe the manufacturer is still
13 responsible for providing information to FDA
14 so that the potential benefits as well as the
15 risks of medication is clearly communicated.

16 DR. FISCHHOFF: Thank you. Ellen,
17 Sid, Mona, John and Mike.

18 DR. PETERS: I was looking at
19 question five on our list of discussion
20 topics, which has to do with how would you
21 prioritize the types of research relating to
22 patient information. And as I went down them

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1 I realized that I know a bit of information
2 about the research on different pieces of
3 this, but how would I actually do this for the
4 FDA was another question. How would I apply
5 it? Could I ever possibly give advice in the
6 abstract about the amount of information that
7 patients need to receive from the pharmacy?

8 And my answer to that would be no,
9 I don't think we know anything from the
10 research world that can tell you concretely
11 for metformin or whatever drug you have in
12 front of you what quantity of information
13 should be provided.

14 But there is, I think, an
15 opportunity that the FDA could have if they
16 chose it to do something like a pilot test
17 within the FDA to pick six different -- and I
18 mean different -- drugs and devices. To
19 Musa's point, some drugs are very different
20 from other drugs; devices also. Very
21 different from sort of the usual drugs. And
22 use them as a test bed to start to develop a

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1 standard format that would allow expertise
2 with that standard format to then be able to
3 be developed in American consumers, in our
4 patients.

5 But that requires more than just
6 social science advice of course. That would
7 have to start with more of what we'd call the
8 normative analysis of what should patients
9 know specific to those drugs. Because there
10 is specific information that changes from
11 drugs to drugs in terms of what really is most
12 important. And so whether that is a drug
13 review panel or some other expert panel, I'm
14 not sure, but I think that would have to be a
15 starting point, and would have to be drug
16 specific to some extent.

17 Then at that point there are
18 different ways of approaching it. Because now
19 you have, okay, what is most important, and
20 hopefully in priority order by the way because
21 as an information presentation person I am
22 going to immediately tell you I want you to

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1 boot out half of that and not tell it to them,
2 or provide it at least in a secondary tier of
3 information.

4 So that is the first thing I'm
5 going to tell you. So working with some
6 people, multiple people I would say, who have
7 expertise in different aspects of that would
8 be important. Something that could be
9 interesting would be to have a competition
10 perhaps on top of that, to have a competition
11 that goes out into a world of people who often
12 have a lot of expertise themselves on how to
13 present medical information.

14 I spoke with someone earlier who
15 does that for a living, and I'm sorry I can't
16 see you in the audience, but her job was quite
17 interesting. And take whatever products you
18 end up with in terms of these standard formats
19 for these four, five, six drugs, and test
20 them. Test them in terms of -- either in a
21 laboratory test where you use convenience
22 samples of people who differ in age, literacy,

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1 numeracy, or take advantage of the
2 pharmaceutical associations who themselves are
3 volunteering their services in a sense, and
4 have them go out to their pharmacies asking
5 the pharmacists to call on the citizens to
6 take responsibility for this and answer some
7 of these questions so that we can build a
8 knowledge base and actually come up with a
9 better standardized format perhaps that will
10 work across multiple drugs, and work across
11 multiple devices.

12 Long term in terms of a strategic
13 risk communication process, once we are able
14 to identify some of the elements that should
15 be going into this, I still think that long
16 term this can be pushed back into the drug
17 review panel process in order to then identify
18 the appropriate information long before it
19 gets to the consumer. Let's know about it
20 ahead of time and be communicating at the same
21 time as the drugs are going out into the
22 market.

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1 DR. WOLFE: I didn't realize what
2 you were going to say, but my comment sort of
3 follows what you had to say. I mean the
4 origin of all this is the FDA approved
5 labeling for professionals. It is negotiated
6 between the company and the FDA, and in
7 increasing numbers of cases there is a
8 discussion about it when there is an FDA
9 advisory committee.

10 As you know there are maybe one out
11 of four approved drugs actually go through an
12 FDA advisory committee. But when they do that
13 is one of the things that the advisory
14 committee talks about. And I think what you
15 are saying is that since that is the origin of
16 anything you would want to put in possibly
17 into the patient labeling, it is very
18 appropriate to have that same process followed
19 there.

20 Ironically what has been going on
21 is that the manufacturer has not been involved
22 in this at all. It's their drug; they

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1 negotiate the professional labeling with the
2 FDA; it is discussed at the advisory
3 committee. But then these other parties come
4 in there and write these labels. I mean I
5 hate to keep mentioning legal liability
6 issues, but they are very real for drug
7 companies. And if something is missing or
8 there, whatever, that shouldn't be there in
9 the current version of these voluntary non-FDA
10 approved labels, the manufacturer can't have
11 any responsibility for that.

12 I mean they should have
13 responsibility just as they do for the regular
14 labeling. There is a case before the Supreme
15 Court called Levine v. Wyeth which involves
16 the very issue of labeling, whether or not
17 something that should have been in the
18 professional labeling was in there.

19 So I think to start out as we must
20 with the professional labeling and work down
21 from there, as you said, we can't possibly
22 want or expect even most of the things in the

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1 labeling to be there.

2 But a process, an algorithm that
3 would say every drug is labeled, there are
4 differences between drugs, but we are going to
5 use some kind of system to winnow down from
6 the full scope of information that is there
7 for the professional labeling to something
8 that reasonably takes the most important
9 things, the most useful things.

10 I mean right now as you know in a
11 number of the professional labels there is a
12 section called, information for patients. And
13 it is meant to guide the physician into
14 discussing those kinds of things with the
15 patient. So we already have some clues right
16 now.

17 So I think that the process as you
18 suggest should well involve the advisory
19 committee. Because if you are going to
20 approve a drug with a professional label, at
21 the same time, that is the time to start out
22 with the patient information.

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1 DR. KHANNA: I think Dr. Peters
2 and Dr. Wolfe have captured the essence of
3 what we've been discussing in a nutshell. I
4 just wanted to add something in addition for
5 consideration, and that is the focus has been
6 on pharmacies that are dispensing the
7 medication with prescriptions that have been
8 brought in or called in, and I'm sure that
9 includes mail order pharmacies as well, which
10 are increasingly a larger and larger -- have
11 had increasingly larger and larger penetration
12 into the -- into filling prescriptions.

13 I also wanted to mention the
14 samples that are dispensed in physicians'
15 offices. When we talk about risks with
16 medications, oftentimes we are talking about
17 with new medications that are introduced to
18 the body system where you have drug-drug
19 interaction possibilities, and side effects
20 and contraindications that may have been
21 missed, et cetera, you certainly do have the
22 risk of medications that have built up into

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1 the bloodstream but when medications are
2 introduced into the system that is oftentimes
3 the highest point of risk. And a significant
4 number of medications are dispensed in
5 doctors' offices via samples, and I don't
6 think they are accompanied by the kind of
7 information that we are talking about, and the
8 kind of information that we have all seen.

9 And I do know also for a fact that
10 for some patients who can't afford the
11 copayment of medication prescriptions, et
12 cetera, et cetera, they often go for many many
13 weeks on samples from the doctor's office.

14 So I would add for consideration
15 using the same information that we are talking
16 about dispensing through pharmacies also
17 dispensing them at any point of medication
18 dispensing, including doctors' offices.

19 DR. PALING: I had a very simple
20 addition to what Betsy was saying. She was
21 giving the opinion that when these documents
22 were being generated, they shouldn't just be

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1 done with the help of pharmacists, but I think
2 she said also with the pharma companies.

3 I immediately wanted to jump in and
4 say, and please let's confer with patients and
5 make sure they also are giving their input,
6 not in terms of the factual content but in
7 terms of how they felt other patients would
8 view it. And I think in our present economic
9 climate it shouldn't be too much to be able to
10 recruit people who are -- lay people who will
11 give you their time to make these documents
12 more patient focused. Thank you.

13 DR. FISCHHOFF: Thank you.

14 Mike and then Craig.

15 DR. GOLDSTEIN: So I would certainly
16 endorse the recommendation that was made to
17 make sure that the information that we think
18 is most crucial that has the highest priority
19 is based on what in fact is already in the
20 product labeling.

21 And I actually looked at a couple
22 of examples before I came, of the labeling

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1 that section, section must have a different
2 number for different drugs, the patient
3 counseling information. And that has already
4 been identified for at least the physician as
5 the key information that should be conveyed
6 about the risks -- mostly the risks. I do
7 think we also want to make sure that the
8 information that is conveyed includes the
9 benefits too, as Ellen has reminded us
10 repeatedly.

11 So that is the place to start, and
12 if we were to say that there is a hierarchy or
13 a set of priorities, it would be the most
14 crucial information that is relevant for any
15 patient.

16 I think that is the least common
17 denominator. And then I just also like the
18 blue sky idea, if we can identify ways that we
19 can then make a system available that allows
20 other levels of information that are less
21 crucial but still important to people, and are
22 important to people at different stages of

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1 their illness, available in some way.

2 So it would be some way of linking.

3 Someone in the audience earlier mentioned
4 technology, and we do have technology now that
5 is more and more able to help at least some of
6 our patients get the information they need.
7 We probably need to think about a safety net
8 system for that too, because not everybody has
9 access to it.

10 But I strongly support the idea of
11 identifying that crucial information and using
12 the tools that are already available developed
13 by the folks who know the drugs best to figure
14 out what the messages should be.

15 And I also want to second the idea
16 that in testing we have to make sure then that
17 patients are involved in deciding what the
18 actual materials look like. Because if we
19 just picked it out of the product labeling
20 that is designed for clinicians it wouldn't be
21 enough.

22 And that gets to the question of

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1 testing for not just whether the information
2 was conveyed, but whether it is actionable,
3 whether it is comprehended, whether it leads
4 to understanding of the risks in ways that
5 will lead them to behavior. Ask my clinician
6 if I develop suicidal thinking, or know to get
7 the test if I develop a certain symptom.

8 DR. FISCHHOFF: Mona had a follow
9 up and then Craig.

10 DR. KHANNA: I've heard this idea
11 mentioned a couple of times, and I wanted to
12 go against I guess the grain and voice my
13 objection to it.

14 I really don't think there is any
15 such thing when talking about medications as
16 non critical information, noncrucial
17 information. I don't think there is a
18 hierarchy. I think all information about
19 medication is important. Side effects are
20 important, contraindications are important,
21 dosage is important, how to take a medication
22 is important.

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1 I don't think you could say if you
2 were on let's say an SSRI, an anti-depressant
3 medication and let's say that the literature
4 says that you can develop suicidal ideation
5 after four to six weeks. I don't think you
6 should wait for a patient and after four weeks
7 say, by the way here is additional
8 information. You can start to develop
9 suicidal ideation. I think all the
10 information should be laid out at the start.

11 I have complete sympathy with
12 overwhelming people with information. My job
13 as a television reporter was to distill out
14 the most important information. But I just
15 don't see how there could be a hierarchy of
16 most critical and less critical information
17 when it comes to medications.

18 DR. WOLFE: What I was saying was
19 that if you look at the professional labeling,
20 there is a huge amount on the
21 pharmacokinetics. There are a lot of things
22 that just are really mainly not relevant.

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1 I think when you get to the risk
2 information that is probably correct, and one
3 of the thresholds for triggering a MedGuide
4 is, could the patient labeling help prevent
5 serious adverse effects.

6 The earlier detection -- we have a
7 petition, we had a petition which we wound up
8 suing the FDA on, to have a medication guide
9 and a black box warning on Achilles tendon
10 ruptures with fluoroquinolones. And this is
11 an example where early on if someone gets
12 tendinitis and they are taking one of these,
13 the labeling could prevent serious adverse
14 effect. No cases of Achilles tendon rupture
15 should be occurring if the patient and the
16 doctor knew that this is an early symptom.

17 So I think that using the very
18 criteria, anyone of which could trigger a
19 medication guide, and my idea of a medication
20 guide is for every drug, I think that in some
21 way or other you need to convey all the
22 information so it doesn't come as any

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1 surprise.

2 I mean we have this book which at
3 least some of you know about, Worst Pills,
4 Best Pills. And one of the chapters is drug
5 induced disease, 140 drugs that can cause
6 sexual dysfunction. About half the people
7 taking Viagra have a drug-induced sexual
8 dysfunction. And if the patient doesn't know
9 that this can happen once they start a drug,
10 and they are less likely to know that if
11 neither the doctor nor the pharmacist nor the
12 medication guide tells them.

13 I think I agree with you on the
14 risk, that somehow we have to figure out a way
15 of putting the risk, in terms of frequency, of
16 severity, and all those kinds of things.

17 DR. FISCHHOFF: Craig and then
18 Sokoya and then Mike.

19 DR. ANDREWS: I concur with
20 everyone on the mandating of this for the FDA,
21 especially if you go from pharmacy to pharmacy
22 and it's inconsistent, I just can't imagine

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1 that happening as far as what might happen to
2 patients.

3 So I think that is a no-brainer, at
4 least to me.

5 The other hard part I think is on
6 testing of these sort of blue sky ideas, and I
7 know we are going to get into this tomorrow a
8 little bit. We are going to talk a little bit
9 about possibilities, down here on number five
10 it was mentioned with maybe kind of an
11 extended drug facts label.

12 There are issues certainly on what
13 Mona was talking about a second ago about all
14 of the risk. What I like about that
15 particular format is that it is grouping it
16 together. So there are ordering effects and
17 grouping effects as far as processing that are
18 very very important. And I think on the CMIs
19 it's all over the place, at least on little
20 bits and pieces of risk.

21 There is some precedent on this
22 too. On the food side there are fellows at

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1 the FDA like Alan Levy who has tested the
2 nutrition label formats, and this goes back --
3 here is an article, Performance
4 Characteristics of Seven Nutrition Label
5 Formats. And so they went through extensive
6 testing on information processing, on
7 adjectival formats, metric formats,
8 highlighted formats. So it can be done.

9 And I would encourage adequate
10 testing on these different prototypes,
11 whatever it might be, including control
12 groups, on consumers, the entire information
13 processing steps like Mike was talking about,
14 through obviously comprehension rather than
15 just subjective comprehension full accuracy et
16 cetera.

17 One other concern though I do have
18 and I always wanted to see this tested, and
19 this goes back to some issues with the FTC
20 with online disclosures, and also I thought of
21 this with direct DTC advertising, where it
22 says, go to this website. And I always

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1 wondered, how many consumers actually do that?

2 So I think that is an issue.

3 DR. WOLFE: That's actually been
4 looked at, and the answer is, not very many.

5 DR. ANDREWS: Really? So that is
6 an issue. Here we have, we are trying to make
7 it more understandable, easier format, but yet
8 you have to have this information for
9 consumers. Will they actually do that I think
10 is a big issue, and how do you motivate them.

11 DR. FISCHHOFF: Sokoya and then
12 Mike.

13 MS. FINCH: I concur with the
14 comments made before, but also I just wanted
15 to add that instead of a website maybe there
16 could be a toll-free number that folks can
17 dial. I don't know if there has been research
18 on that.

19 DR. WOLFE: In 1997 when FDA sort
20 of opened the door on direct to consumer
21 advertising, and putting out a guidance, they
22 basically told these companies, from now on

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1 you don't have to put everything there in your
2 DTC ad, you can refer them either to an 800
3 number or a website. And unfortunately a lot
4 of people don't go there, so they are missing
5 some information.

6 MS. FINCH: Okay, one of the things
7 I want to touch upon is in our literature that
8 we read on the studies that were taking place,
9 one study hinted that the population, they
10 were not able to survey the racial ethnic
11 populations. And so another survey also
12 hinted at that.

13 So I wonder, as we get more studies
14 coming in, if we can actually kind of enforce
15 or require studies to touch upon that
16 population, so that when we see the CMIs and
17 the PPIs that maybe there is a different flow
18 in terms of readership. The health literacy
19 may be different.

20 And then the other thing is I kind
21 of want to put a plug in to translation of
22 materials. I know we are not there yet, but

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1 we have a rising Hispanic population, and it's
2 a population that is not going anywhere, it's
3 going to grow.

4 So I just wanted to put a plug in
5 to the possibility of translation of materials
6 for Spanish. And it could be done in
7 hopefully in ways that will be amenable to
8 accepting that, like in the other form of
9 photo novellas, they were more apt to look at
10 pictures, and arrive -- derive the information
11 from pictures with little text. So just an
12 idea.

13 DR. FISCHHOFF: Thank you. It
14 strikes me that the structure of that
15 argument, at our meeting last May when we
16 talked about direct to consumer advertising,
17 we had presentations on evidence and then had
18 discussion about the differences in the
19 interpret -- the access and interpretation of
20 information of different communities. So if
21 the evidence is out there that people have
22 different access and different

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1 interpretations, then that makes the argument
2 -- there is your scientific basis for making
3 the argument that the sampling needs to
4 parallel the dimensions of difference in the
5 population, just as Ellen's work has shown --
6 among others -- has shown, that there are
7 people at different levels of numeracy then
8 one needs to somehow reach more and less
9 numerate populations, and one may need some
10 with different populations. So I think that
11 is probably the scientific basis for making
12 that demand within the sampling plan.

13 Mike, Ellen, Terry and then Tim.

14 DR. GOLDSTEIN: I just want to
15 discuss this, the idea that we are throwing
16 around about prioritization versus everything.

17 I don't think that is an either/or really. I
18 do think it is really important for the
19 professionals who know the literature,
20 especially the ones that have worked with the
21 drugs, to convey the key critical information
22 about dangers, especially acute dangers, or

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1 serious dangers that lead to death or
2 something else really serious, as something
3 that is of the highest priority to get across.

4 Then there is all the other
5 information that patients want to know, which
6 is also important, I'm not saying we shouldn't
7 provide that information, and offer that
8 information. Yet we do have to -- if we are
9 going to help comprehension, knowing that
10 people can't possibly read everything that we
11 give them, pick those things, put it in a box,
12 put it some place where it is easy to
13 understand, convey that in a way that we make
14 sure that that information is, A, getting
15 across -- that is just the first part -- but
16 B, being understood.

17 So that when somebody walks out of
18 the pharmacy with their medicine for the first
19 time they know if they do develop some change
20 in their behavior that that might be a sign
21 that they are at risk for suicide as an
22 example.

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1 DR. PETERS: So Michael, eerily
2 once again I was really going to repeat part
3 of what you just said, but I want to say it a
4 little bit differently. I want to say it in a
5 sense that including it all is a great idea in
6 many ways, and certainly there is information
7 that absolutely has to be included about the
8 risks of a drug, how to get the most benefit
9 out of a drug, because people have to know how
10 to take it.

11 And as an example that was given
12 earlier, people may not know how to follow
13 directions on drug bottles all the time.

14 My point though has to do with a
15 balance that exists. When you do research on
16 this, there is a tradeoff that exists between
17 completeness of information and comprehension
18 of that information. And it ends up being the
19 responsibility then of the information
20 provider to choose what that balance is,
21 knowing that the balance exists. And so as a
22 TV reporter my guess is you went for less

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1 complete but got really good comprehension of
2 what you were able to do in a one-minute
3 broadcast.

4 Now much more can certainly be done
5 in some kind of patient information materials,
6 but it is always a balance, and you have to be
7 responsible for choosing where on that balance
8 point you need to be in order to activate
9 patients the best, in order to enable them to
10 make the best choices of how to take their
11 medication and how to monitor for side
12 effects.

13 Thank you.

14 DR. FISCHHOFF: Thank you.

15 Terry, Tim and then Mona.

16 DR. DAVIS: In thinking about what
17 is the need to know and do versus the nice to
18 know, I want to make a pitch for being
19 inclusive as to who the stakeholders are, the
20 parents, the clinicians, and some experts,
21 pharmacology experts, I mean what is it? How
22 much of this is really warning we need to

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1 know, and how much did lawyers put out there?

2 What is the pharmacology of this for one
3 thing.

4 And then just in research that we
5 have done with childhood immunizations and
6 newborn metabolic screening, the parents said
7 some things, the clinicians said some things,
8 the experts said some things, but we came to a
9 consensus, like with the childhood
10 immunization, some things you ought to know
11 about the baby shots. And so you can drill
12 down on that, I believe.

13 Also I will tell you, I hope that
14 you all can maybe - I was a visiting professor
15 at Cincinnati Children's Hospital, they have
16 two kind of panels of parents, parents of kids
17 who have that disease that they are making the
18 education for, and parents who don't. They
19 vet everything by both sets of parents. And
20 so there -- and so I think we need to vet
21 things by consumers, and then patients who
22 have got the disease.

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1 And then part of the drugs, if we
2 test certain things, it shouldn't just be
3 chronic disease. We need something like a
4 amoxicillin in there too that you just take
5 for a certain period of time if you can dose
6 it to kids.

7 DR. FISCHHOFF: Tim then Mona.

8 DR. LESAR: Yes, there's all kinds
9 of things rolling around in my head, so I will
10 try to straighten this out here a little bit
11 in terms of my thought processes, so stick
12 with me.

13 You asked for some practical ideas,
14 and I see -- I listened to a couple of things
15 today that kind of struck me, in listening to
16 one of the information publishers, was that
17 they were sending downstream fairly good
18 information that was being altered. To me
19 that seemed a fairly quick way, by at least
20 trying to have them, the vendors promote not
21 changing their format, that way you have some
22 control of the format. And that is being done

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1 at the purchaser level probably.

2 But because I think they are not
3 aware of how important the formatting might
4 be, and how important have that information in
5 a certain way. So some of that is not
6 malicious, it's simply lack of awareness. And
7 it seems to me that on all sides of working
8 with many of the larger chains, and many
9 societies representing independent pharmacists
10 could move some of that -- from that -- what
11 we saw, that 75 percent, and move that up
12 substantially simply by working on not
13 changing the formatting.

14 And also that would then push the
15 publishers to format their product more
16 according to the guidelines, even though we
17 agree that they are weak, in terms of knowing
18 what outcomes are.

19 And I think that we can work on
20 both ends there in the short term, and also in
21 the semi short term is utilizing information
22 that we get that you could obtain from

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1 evaluation of the MedGuides, and how that
2 occurs. I think there is a lot to be learned
3 there, and a lot to be learned from them in
4 terms of going forward with this process, how
5 we would further evaluate things.

6 So you have some things already in
7 process, we are evaluating these information
8 sources, that's really not completely
9 different. Maybe it is more focused than a
10 general medication guide. But it seems to me
11 that there is a lot of information that can be
12 gotten if it's done right and done
13 systematically and consistently between the
14 products that are -- those that are required.

15 I also believe that while delivery
16 of this is not an issue, that is, we look at
17 the 94 percent of patients getting this, it
18 will be an issue if the information interfaces
19 or ability to obtain data that even if we did
20 develop -- you did have this great
21 information, all consistent, make sure all the
22 pharmacy systems can obtain it and then print

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1 it out appropriately. So that is something
2 for the longer term. But certainly you could
3 say by such and such a date, pharmacy systems
4 should have this ability, give some time for
5 that to occur, and for that to be prepared.
6 And certainly in the longer term it is
7 developing strong research, understand how to
8 perform that research on outcomes from
9 information delivery. I am not an expert in
10 the area, but I'm sure there is a lot to learn
11 from other fields, and there is a lot to learn
12 from the people who are here about how to do
13 that research.

14 Are we creating the behaviors that
15 we want from the information that we are
16 providing, which I think is the outcome that
17 you need to measure. But I think there is a
18 lot that can be started right off from the
19 MedGuide information.

20 So I think we are looking for a
21 road to where we need to be, it will take some
22 time to get there, but I think there is a

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1 stepwise way to go there. It sounds like I
2 believe you could make some of your
3 improvements in what we evaluated for the
4 Florida study fairly quickly by simply working
5 with the societies and the chain drugstores.

6 DR. FISCHHOFF: Mona.

7 DR. KHANNA: I really like Dr.
8 Wolfe's example about, probably most patients
9 don't really need to know the pharmacokinetics
10 of a medication. And I think the testimony
11 that was in our packet by this consumer that I
12 mentioned before -- her name is Jenna Markle -
13 - I think she would agree with Dr. Wolfe. Her
14 example was a little different, about the
15 medication, Singulair. And she is saying that
16 Singulair's prescribing information did not
17 list a possible adverse psychiatric effect,
18 because it wasn't greater than 1 percent. AS
19 it turned out it was more frequent -- it
20 occurred more frequently than placebo, but
21 because it wasn't greater than 1 percent it
22 wasn't listed in the prescribing information.

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1 So those possible adverse psychiatric effects
2 affected her child, and as she is saying, the
3 children of other parents who took the same
4 medication.

5 So that is important information
6 that needs to be part of the basic information
7 that is provided.

8 One thing that we really haven't
9 touched on at all that Mr. Mehta brought up
10 that I just want to mention, and that is, we
11 should do the absolute best possible job using
12 the collective intellectual capital of this
13 committee and the FDA and from the public
14 response that we can to make sure that we
15 raise health literacy or we attempt to raise
16 health literacy with the best medication
17 information that we can accompanying
18 medications.

19 However, all we can do is produce
20 it. It's up to the consumer whether or not
21 they read it, whether or not they understand
22 it, whether or not they take it seriously.

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1 And I just have to mention that
2 because I think that when we look at outcomes,
3 and this group is mostly social scientists who
4 do a lot of the research, part of one of the
5 confounders may be that in some of the
6 research that you can lead a horse to water
7 but you can't make him drink. And I found
8 that oftentimes with viewer and reader
9 response to some of my stories, when they
10 would write in and ask for more information,
11 is that I could provide all the information in
12 the world about procedures and treatments and
13 resources and hospitals and physicians
14 involved in that particular medical condition,
15 but unless they wanted to understand it,
16 unless they wanted to act on it, I couldn't do
17 anything more than that, than provide the
18 information.

19 That doesn't mean we shouldn't do
20 our job as a committee and as the FDA to
21 provide it, but there is that confounder that
22 we all have to remember.

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