

1 DR. FISCHHOFF: Musa.

2 MS. MAYER: I'd like to respond to
3 that, because it's something I see too in
4 terms of it's like -- I would phrase it more
5 as receptiveness to bad news. And let's face
6 it, communicating risks about medications,
7 particularly the people who have seen ads
8 about that show sort of positive but fuzzy
9 outcomes, the bad news about rare or common
10 side effects is not going to be welcome, and
11 we know I think from some of the research that
12 patients tend not overestimate when language
13 is used to describe levels of risk, I mean way
14 overestimate. And I know from John Paling's
15 work perceptions of risk and numeracy and so
16 on is a big issue.

17 So what this is all leading me to
18 say is that I don't think you can create the
19 ideal tool that will work in a vacuum where
20 people are not receiving -- I mean I remember
21 an era where public health information was a
22 part of daily life, and where the government

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1 made investments in health literacy and health
2 understanding, not only through the schools
3 but throughout adult life.

4 And I think especially with the
5 most common conditions, with high blood
6 pressure, and arthritis, and well, many many
7 of the most common conditions, if there were
8 already a level of understanding about the
9 disease process, about the medications
10 collectively used to treat it, about the
11 limitations, then you create a more receptive
12 consumer. I mean I think patient use of the
13 internet to search for health information
14 shows that there is a great deal of hunger for
15 information.

16 So I think it's a question of
17 really providing a context in which that
18 information is seen as being important, and
19 sort of a part of the whole process of going
20 to the doctor and receiving a prescription
21 that, oh yes of course the next thing I do is
22 look to see what kinds of risks there are,

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1 take some time to sit down to look at
2 material, maybe have an opportunity to then
3 have a further conversation.

4 I mean it all has to occur within a
5 context. I don't think that the actual
6 instrument that is created can function
7 without that context, nor should we expect it
8 to really.

9 DR. FISCHHOFF: Sid.

10 DR. WOLFE: What you are bringing
11 to mind by what you just said is the surgeon-
12 general, this country has made enormous
13 strides in smoking largely because of a
14 surgeon-general, series of surgeon-general
15 reports starting in 1965.

16 We have estimated 100,000 deaths
17 from adverse drug reactions, a million and a
18 half hospitalizations, one of the leading
19 causes of death. I have never heard of a
20 surgeon-general's report on medications,
21 generally, what to look for. And I think that
22 that would be an example, maybe, of what you

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1 are talking about, the context of trying to
2 get people -- this is really important, you
3 might increase the chance that they are going
4 to look at this piece of paper and actually
5 think that they might prevent something from
6 either occurring at all or going too far down
7 the line like an Achilles tendon rupture.

8 I mean the whole function of the
9 surgeon-general has just been moribund the
10 last eight or 10 years or even possibly more
11 than that, and it's an example of the large --
12 as you said, we used to hear a lot more public
13 health things. We are just not hearing them.

14 This is a very major public health issue, and
15 it needs to be augmented and supported by
16 these other kinds of things.

17 DR. FISCHHOFF: Okay, Madeline and
18 then Mike.

19 MS. LAWSON: Yes, I would just
20 like to agree with Musa and Mona and Dr. Wolfe
21 as well. And certainly health literacy, I'm
22 an advocate for health literacy.

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1 I do think that we have to look --
2 I'm one who is pushing for collaborative
3 efforts, because I don't think that we can
4 address the issues if we are not pulling in
5 all the parties who have a vested interest.
6 And when you think many persons don't have
7 access to the internet, or even will think to
8 dial a 1-800 number, and maybe the only access
9 they have is going to a health clinic. And so
10 I think that we have to be fully aware that we
11 need to have all of these interested parties
12 involved as we go forward even with the
13 mandate, that we really are listening to all
14 the people, all the health providers and
15 consumers that have an interest.

16 DR. GOLDSTEIN: Just to pursue this
17 conversation a little bit about context,
18 because I think context and setting is very
19 important, and I would agree that we can't
20 expect information alone to be enough to
21 change behavior. It doesn't. It provides
22 information. Hopefully it increases

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1 comprehension. And then it's aligned,
2 hopefully, with what patients are hoping for
3 with their condition.

4 And there are times, as a clinician
5 -- I know we are going outside the bounds of
6 FDA -- I have a responsibility when patients
7 aren't on the same page as I am. And I think
8 it is important to try to understand where
9 they are coming from, and then try and help
10 them to see where I'm coming from.

11 So I think that is a role for the
12 collaborative relationship that is part of a
13 clinician-patient relationship, and certainly
14 in that setting I do want to have access to
15 the kind of tools that a blue sky kind of
16 approach might help me to help those patients
17 who have less receptiveness, that have less
18 understanding of the importance of making a
19 change, taking a medicine, than I would like
20 them to have.

21 And it reminds me, there is another
22 group, the Foundation for Informed Medical

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1 Decision Making, who many of you know, who
2 have done a lot of research about how people
3 make decisions that are tough decisions. And
4 how they respond very often to information
5 that is provided not only from their trusted
6 health care provider, but also from other
7 patients.

8 And that becomes a very important
9 source of information, and we want to remember
10 that, too, because part of helping our
11 patients make the right decision is giving
12 them access to other people who have similar
13 conditions who might help them to see the
14 value of some things that we as clinicians are
15 asking them to do.

16 And that may mean we want to
17 include that group in the testing that we do,
18 too, to use groups of peers to help assess
19 some of the tools so it helps them as well.

20 DR. FISCHHOFF: Terry and then
21 Baruch.

22 DR. DAVIS: This may be blue sky,

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1 but Sidney, I think you are so right. I think
2 there needs to be public awareness of how
3 important it is to pay attention to these
4 things. I think people sometimes are very
5 cavalier about taking drugs, and they don't
6 attend to the instructions enough.

7 And I mean we can give you all
8 guidelines I think for improving a one pager
9 and evaluate it, but then I don't know who
10 then says, can we get a surgeon-general --
11 well, we don't have a surgeon-general yet, but
12 this awareness is part of it, I think. And I
13 don't know if that is you all's role or who
14 wags that tail.

15 MS. HENDERSON: You're talking
16 about is it our -- a public awareness
17 campaign? It is probably -- we do some public
18 education as best we can. It is not -- it has
19 not traditionally been within a big part of
20 what the FDA does, nor are we appropriately
21 staff to do massive public education
22 campaigns. Places like the CDC, the Centers

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1 for Disease Control, do that kind of work. As
2 Sid points out the surgeon-general does that
3 kind of work.

4 Don't get me wrong, I don't think
5 there is anything with you guys going on the
6 record with any kind of recommendations about
7 the health care system that you wish to make.

8 And in fact I think it can only help.

9 DR. WOLFE: Or the FDA commissioner
10 in the past has intervened herself or himself
11 in some of these issues, and it gets on
12 national television and it serves an
13 educational purpose.

14 MS. HENDERSON: Oh, absolutely,
15 there is no question that having a
16 commissioner who goes out and makes -- look at
17 the impact David Kessler made around tobacco I
18 think.

19 So it's certainly the kind of
20 things that can be taken up by individuals, it
21 has not traditionally been a large part of --
22 public education campaigns are not a large

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1 part of the work that FDA does. We have not
2 been staffed for that or traditionally done
3 that. But feel free to make any of those
4 kinds of recommendations that you guys think
5 is appropriate.

6 DR. DAVIS: What I'm hearing is,
7 if you just improve the pamphlet it's a silo.

8 MS. HENDERSON: It's not enough,
9 absolutely. And we recognize, and I tried to
10 say earlier, we recognize that we work in a
11 system, in the health care system. And we are
12 a very big part of the problem, or the
13 solution to this problem, and certainly intend
14 -- I hear your cries for working with all the
15 stakeholders. We know we can't do this in
16 isolation.

17 So even where we don't control we
18 obviously have influence within the health
19 care system, so we are happy to hear your
20 discussion.

21 I just wanted to be sure you
22 weren't going to entirely recommend to us that

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1 doctors do better or something, which would be
2 great, but nothing we could do anything about.

3 DR. KHANNA: You know there
4 actually is an ad on TV. Do you all know what
5 I'm talking about? The set is a hospital,
6 inside a hospital, and it's all singing, and
7 there is someone -- all the health
8 professionals are in white coats. And someone
9 says, make sure you tell me your medicines
10 that you are on. And the other one says, make
11 sure you ask me why I'm giving you this
12 medicine. Does anyone know what I'm talking
13 about?

14 DR. GOLDSTEIN: It's the AHRQ, you
15 can go to their website.

16 DR. KHANNA: There you go. There
17 you go.

18 DR. GOLDSTEIN: Carolyn Clancy who
19 is their director developed with others this
20 ask-me-questions program.

21 DR. KHANNA: That's it, and that's
22 the kind of thing we need, because that will

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1 do what Dr. Wolfe said, which is raise the
2 importance of why you should find value in
3 knowing about your medications, and learning
4 about your medications, and why you are taking
5 them.

6 When I was on the front lines of
7 treating Hurricane Katrina evacuees, they
8 would come in to our tents, and they'd say, oh
9 my God, I haven't taken my medicine for three
10 days, I had to leave them in the house when I
11 ran out. And we'd say, what medications were
12 you taking? I don't know; it was a blue pill.

13 Well, I shouldn't use a bad example. I don't
14 know, it was a round pink pill. Oh my god,
15 and I would say, well, what were you taking it
16 for? I don't know. So I mean we have to
17 create that awareness of, we are all on the
18 same page here, why it is important to avoid
19 all these medication errors and these
20 unnecessary deaths and find value in learning
21 about medication. It's just good medical
22 care. It's just good paying attention to your

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1 health.

2 MS. DeSALVA: Okay, since I raised
3 this whole blue sky thing, I just wanted to
4 clarify real quick that it was not my
5 intention to boil the ocean and I actually
6 didn't mean the health system broadly, but
7 really as Musa said probably more effectively,
8 context, and as others have said that one of
9 the questions that we are being asked is the
10 very first one, is a single tool the answer.

11 And I think what is coming out is,
12 it can be a valuable tool in the context of
13 other forms of communication and other points
14 in time.

15 And one of my concerns is, let's
16 take diabetes as an example, and I'm not a
17 category expert, but if you have a patient who
18 is type 2 diabetic and has been in treatment
19 for a year and the research shows that that
20 person is susceptible to a lack of adherence,
21 and there is another communications
22 intervention that is going to help that

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1 patient adhere, will this have a chilling
2 effect on that? Will this sort of rule the
3 day, and will it be more difficult to move
4 other forms of communication into the system
5 that won't confound or won't make all this
6 indiscriminate communication worse.

7 DR. BRUHN: It's really been a
8 great discussion. Just a couple of points.
9 Oops, I think my chair is giving out here.

10 I am excited about all the things
11 that were presented. I just wanted to add a
12 couple of thoughts.

13 Research does need to be done. I
14 encourage that FDA not do it, and that is
15 primarily because of the huge bureaucracy you
16 face in getting anything done that involves,
17 what was it, more than five people or nine
18 people. I have a colleague at the University
19 of Maryland who has been waiting -- well, by
20 now it's been almost two years -- for a
21 research project to be gone through all of the
22 approval steps that are required by your

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1 bureaucracy.

2 So whereas we are looking at others
3 to join in partnership and help move forward
4 communicating about various things, if the FDA
5 has a mechanism for encouraging others to
6 provide this type of data based upon some of
7 the criteria for reliability and
8 appropriateness and sample selection and so
9 forth, that would be so much faster, so much
10 more efficient, and you can still evaluate its
11 appropriateness, but don't get tied up in that
12 research yourself.

13 And similarly in the idea of
14 sharing things like ask me questions. That is
15 the ad I recall. And others who come forth to
16 share with the public, you have a
17 responsibility for managing your own care.
18 Partner with groups like health organizations
19 we have here, like support groups we have
20 represented here, so that it's not everything
21 on FDA's head, but it's all of us working
22 together to enhance health.

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1 DR. FISCHHOFF: Just to pick up on
2 the process, it seems to me FDA has the -- the
3 thing that you can do nobody else can do. I
4 mean FDA has this one vital piece, and if that
5 piece were stabilized, a whole lot of other
6 good things would follow from it, that people
7 would be more likely to go to information if
8 they knew where to find decent authoritative
9 information, and now you can't find it, I mean
10 it's essentially impossible to find
11 information about -- I mean to make a
12 reasonable choice I need to know how big the
13 risks and benefits are of the thing I am
14 considering taking, and what the alternatives
15 are, whether people are numerate or not, they
16 are making some assessments of how big these
17 effects are, and that information is currently
18 unavailable, so people can't conceivably make
19 reasonable choices either about what to take
20 or what not to take, or if they have taken
21 something, to see whether or not it's working.

22 So if I am taking a drug I need to

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1 know whether these Achilles tendon problems
2 occur in 1 percent or 5 percent or 50 percent,
3 so I can't fulfill the obligation of taking
4 the drugs in a safe way unless I have that.

5 So that piece is currently missing.

6 I think it in some sense kind of threatens
7 the whole system, because as several people
8 have said, the communications are inseparable
9 from the drug. I mean the effects that we get
10 in the clinical trial are in part due to the
11 information that is given to people in the
12 clinical trial, where they are under close
13 surveillance, they get their things -- I mean
14 it's a Cadillac -- staying American here --
15 it's a Cadillac information, and the drug that
16 is on the market is probably not as effective
17 and it's probably riskier than the drug that
18 was tested, just because it doesn't have the
19 same quality of information.

20 And I think if FDA could get that
21 right, it would get market share, people would
22 be spinning -- people who can reach other

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1 audiences would do that.

2 So I think that -- it's not
3 everything, but it's absolutely vital, and it
4 won't get done unless FDA does it.

5 So then I'm thinking, and maybe you
6 can -- you know, the FDA people can inform us
7 -- so how does -- imagine that we wanted to
8 get this done, to have kind of a standard
9 format, mandatory or not, how would one do
10 that?

11 So one of the nice things about FDA
12 from what I've learned is that it is a highly
13 consultative organization. But that also
14 means that the bad thing about a consultative
15 organization is that things come out of a
16 committee, and they may not have any coherence
17 at all.

18 So I would say -- I mean I can
19 imagine a process where people know the
20 research on -- you know, that -- you know, the
21 process knows that as several people said if
22 you give people verbal quantifiers, they are

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1 all -- they can't guess what the size of the
2 information is. So you don't have numbers, or
3 ranges, or whatever, the whole thing is
4 defeated.

5 But I can imagine a process where
6 somebody in a position of authority at the
7 final decision said, public, they can't handle
8 the truth. They are so innumerate, or
9 predictably irrational, and they just can't
10 handle it. And then it goes out the door.

11 So what is the process by which FDA
12 can produce something where the end product
13 takes advantage -- it is consistent with the
14 science.

15 So I had two thoughts. One thought
16 is that you have a consultative process which
17 I think is the typical one. Second, somebody
18 suggested -- I forget who it was -- suggested
19 a competition. And so conceivably what FDA
20 could do would be to set up the -- you know,
21 so FDA does technical standards. Thou shalt
22 use this font, do this and so on. FDA could

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1 make this a performance standard, which would
2 say, you know, that 50 percent of the
3 population needs to understand the probability
4 of dying from this drug, you know, within 1
5 percent of the actual number, or whatever it
6 is. And then have a competition whereby
7 people submit coherent designs, and you see
8 who comes the closest to doing that, and FDA
9 adopts a design rather than tries to create
10 its own standard.

11 And that in terms of the
12 cumbersomeness, in defense of FDA I would say,
13 this is not a bureaucracy that is entirely of
14 their making. It's the paperwork reduction
15 act, and so on. So but I think -- I could
16 imagine that a performance standard might be
17 something that one could get through that
18 would have some kind of coherence, and that
19 would be what -- and then you are testing to
20 that standard, and the work is done
21 externally.

22 So is this -- does this sort of

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1 make sense? Do either of you have some
2 comments?

3 DR. OSTROVE: I don't think we'd
4 ever thought about that before. But certainly
5 performance standards are things that we have
6 considered in the past, and I think it's
7 something that we -- again, we are asking you
8 for advice, and we are taking lots of notes.
9 Lee is taking notes, Betty is taking notes,
10 and I'm taking notes. And I think obviously
11 we need to get buy in regardless of what we
12 decide to do.

13 But all of this is going to be
14 taken back and put into the process that we
15 are going to be following. Again I -- have we
16 ever thought about a competition?

17 MS. HENDERSON: I'm not sure we've
18 ever thought about a contest-like competition,
19 but it's not unlike -- I could envision that's
20 not a lot unlike letting a contract, where
21 often we set up guidance for what we want a
22 contractor to come in with, and you advertise

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1 that the FDA is willing to pay X number of
2 dollars for a piece of work that looks like
3 this, and then you select a contractor who
4 produces work for you.

5 I don't know if this fits that or
6 not, and the concept as Nancy said is
7 certainly not foreign to us. Much of how the
8 sponsors currently do business is by
9 guidelines that are set out by the FDA for how
10 one performs premarket clinical trials, and
11 what standards we expect sponsors, that they
12 know what they are going to be held to when
13 they bring their trials in and look for
14 approval of their drug product for example.

15 So it is certainly not a foreign
16 concept. And it's very interesting.

17 DR. DAVIS: What's the deal on the
18 OTC drug facts? You all did that, you
19 standardized that. What evidence do you have
20 that that is helpful? Is that published
21 literature? I don't know how that went down,
22 and is it helpful?

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1 DR. OSTROVE: Are you talking about
2 the drug facts, kind of the whole system, or
3 specific labels?

4 DR. DAVIS: The labels changed on
5 OTCs.

6 DR. OSTROVE: Right.

7 DR. DAVIS: And did you all say --

8 DR. OSTROVE: You mean when we
9 were going through that process?

10 DR. DAVIS: Yes, did y'all mandate
11 that?

12 DR. OSTROVE: Yes, that was
13 mandated, absolutely. That's in the
14 regulations. All the specifications are set
15 out, and we did some research on that. But
16 the -- even the research that was done was
17 considered. But the thing that we need to
18 keep reminding the public is that the research
19 is only a piece of it, and that there are
20 other considerations as well.

21 So that for instance, I mean let's
22 just take something right out of the blue, the

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1 research would demonstrate that for elderly
2 individuals who are reading something you
3 ought to have a type size, a font size, of at
4 least 12, so 12 points. Yet in the medication
5 guide requirements, we had a font -- we
6 specified a font size of 10 points. And there
7 were reasons for that, beyond the -- so there
8 are other issues. There are cost-benefit
9 issues that need to be taken into account.
10 There is the burden on the manufacturers.
11 There are other things that need to be taken
12 into account.

13 So as much from my perspective as a
14 social psychologist, I would want to have the
15 research be the primary factor. It's only one
16 of the factors. And that's even been true of
17 the food label.

18 DR. DAVIS: I was just wondering if
19 that could help shape us to answer our
20 questions. You know, is that a model at all
21 for us was I guess my question.

22 DR. OSTROVE: The OTC? Well, I'm

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1 not sure.

2 DR. FISCHHOFF: Let me -- since
3 we are -- let me thank everybody for their
4 contributions, invite everybody back here at
5 8:00 o'clock tomorrow morning.

6 Don't miss Lee's reading of the
7 conflict of interest statement. And again,
8 let me thank our presenters, thank the members
9 of the public who spoke, thank the panel, and
10 we will see you tomorrow.

11 (Whereupon, the above-entitled matter
12 concluded at 5:01 p.m.)

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