

1 the medical field and also the environmental  
2 field is that we in the U.S.A. tend to be more  
3 insular in the level of respect that we give  
4 to the research findings in the work from  
5 other countries.

6 Now because from England and the  
7 other countries with whom you collaborate  
8 there's usually a smaller base of researchers  
9 doing comparable work, my guess is that  
10 subjectively only there is an opinion about  
11 how progressive, how possibly inadequate the  
12 U.S.A. is in its own methods of managing risks  
13 and benefits when it comes to medications.  
14 Since no one can throw a shoe effectively at  
15 you, would you enlighten us please by saying  
16 whether in general there is an impression that  
17 the U.S.A. might improve its risk  
18 communication and benefits communication and,  
19 from your experience, collaborating with other  
20 countries in what way might that be?

21 DR. RAYNOR: Okay. Nowhere is  
22 doing CMI perfectly. We've got the issue in

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1 the U.K. of the fact that there are package  
2 inserts and we've got the issue in Australia  
3 where the pharmacies won't give the things  
4 out. And the key problem I suspect within the  
5 U.S. is the fact that you have maybe four or  
6 five different types of information that  
7 people might get.

8           And my perception of the computer-  
9 generated leaflets that come in pharmacies, I  
10 mean I particularly dislike the fact that on  
11 the reverse side you might have an  
12 advertisement for toothpaste or some other  
13 offer that was going on. I think that any  
14 sort of distracting information like that is,  
15 you know, surely not appropriate.

16           It's not for me to say what you  
17 should do. I hope that in my presentation  
18 there have been a number of clues as to what I  
19 think you might do. But clearly you have your  
20 particular context there, and I hope you will  
21 be able to go forward with all the advice  
22 you're going to be getting yesterday and

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1 today.

2 DR. FISCHHOFF: Thank you very much  
3 and thank you for your presentation and for  
4 also for making, let me recommend the  
5 materials that Dr. Raynor made available to  
6 the panel are really a recommended reading.  
7 You can find them at our website along with  
8 many other goodies. So I recommend reading  
9 them.

10 Our next speaker is a former member  
11 of the Committee, Dr. David Moxley from the  
12 University of Oklahoma. By way of context, a  
13 strong commitment in the composition of this  
14 Committee and in the nature of our  
15 deliberations has been that this system needs  
16 to work for all Americans. And, whatever the  
17 best system available for broadband  
18 communication it will not reach everybody for  
19 one reason or another. And David Moxley has  
20 done some remarkable work in ensuring that  
21 healthcare services are made accessible, or as  
22 accessible as possible, to some of our most

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1 needy citizens. And we thought that it was  
2 important that he had an important  
3 contribution to help us to think about how do  
4 we make, how do we go beyond the best general  
5 method to ensure that everyone else -- that  
6 everyone is served. So, please.

7 DR. MOXLEY: Thank you. Can you  
8 hear me? Okay.

9 Three disclaimers this morning.  
10 One is I come with an example from  
11 homelessness, but particularly with  
12 homelessness or about homelessness among older  
13 African-American women which is a long-term  
14 project I've been working on with a colleague  
15 in Detroit, Michigan through Wayne State  
16 University. The second disclaimer is anything  
17 I say today is not meant to be pejorative  
18 toward Detroit, Michigan. It's realizing a  
19 lot of challenges, not just during this  
20 economic period, but it has been for 30 years,  
21 and some of what I will share with you today  
22 is a product of the last 30 years that in a

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1 sense the institutionalization of homelessness  
2 as a way of life among certain groups in  
3 Detroit. And my third disclaimer is I hope  
4 that I won't come off as sounding negative  
5 toward any healthcare provider.

6                   The           Leaving           Homelessness  
7 Intervention Research Project has been going  
8 on for about eight years. A couple of those  
9 years my colleague, Olivia Washington, and I  
10 took to warm up and get to know the issue from  
11 the perspective of the women we've been  
12 working with. When we say older African-  
13 American women, we're referring to women who  
14 are over the age of 50 who may come into  
15 homelessness suddenly, typically suddenly,  
16 will have been homeless for three months or  
17 longer, and oftentimes thought that they were  
18 well prepared to prevent homelessness before  
19 they found themselves tipping into this  
20 serious kind of situation.

21                   We incorporate multiple levels of  
22 helping into the project through what we

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1 consider to be a community-based,  
2 participatory action research design where we  
3 work closely with the participants, and our  
4 principal research and development aim has  
5 been to get to know homelessness from the  
6 perspective of the women themselves. To date,  
7 about 530 women have participated in some  
8 aspect of the project. And I underscore  
9 research and development because we have not  
10 tested thoroughly the combined synergies of  
11 the interventions that we've been developing,  
12 and we're about ready to do that, and as you  
13 will see that itself is a challenge.

14 Another thing about the project is  
15 that it tests or integrates, I should say,  
16 health science ideas with social science  
17 ideas, but most of all content taken from the  
18 humanities. We pride ourselves in being a  
19 project that fosters humanistic thinking and  
20 humanistic involvement between who we refer to  
21 as the researchers and who we refer to as the  
22 participants.

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1           Our principal aim is to really  
2           develop a useful and a practical knowledge  
3           that will first of all decrease the  
4           debilitating effects of homelessness. As you  
5           can imagine, those are multiple. But then  
6           really helping participants get out of  
7           homelessness, stay out of homelessness, and  
8           then improve the quality of their life.

9           Many of the participants we work  
10          with are very wobbly relative to getting out  
11          of homelessness. Once they're out of  
12          homelessness, they can tip quickly back into  
13          homelessness, and there's a variety of reasons  
14          for that as you'll see as I move ahead.

15          We've operated over the past five  
16          years through a number of different  
17          subprojects. One we refer to as Telling My  
18          Story which is a methodology we've designed in  
19          order to help women talk about their homeless  
20          experience. And that's actually tied to a  
21          communication kind of process where we try to  
22          match the intervention to the kind of issues

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1 that they're dealing with.

2 We've developed a multi-method  
3 assessment which we refer to as the GOHI,  
4 getting out of homelessness interview. We've  
5 invested a great deal of energy in group work  
6 for mobilizing protective factors to help  
7 women take care of themselves while they're  
8 homeless. We have developed an advocacy  
9 intervention that's actually tied to the group  
10 work intervention that's designed to help  
11 quicken the process of helping women leave  
12 homelessness. And we're moving into the  
13 development of what we refer to as an  
14 intentional community that helps sustain  
15 participants once they are out of  
16 homelessness, but yet they're not out of  
17 harm's way.

18 What does all this have to do with  
19 risk communication? Well, we do a lot of work  
20 in communicating around health in highly risky  
21 situations, so the participants are dealing  
22 with risks daily. And the risks come in

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1 multiple forms.

2                   From a paradigm kind of  
3 perspective, we're really trying to figure out  
4 how does one move from a reactive kind of  
5 paradigm where one reacts to these multiple  
6 issues that women accumulate, not only while  
7 they're homeless, but also during the life  
8 course. And then how do you move from that  
9 reactive kind of approach to a more proactive  
10 kind of approach? And if you can imagine, if  
11 you think about all the paradigms we work with  
12 in health and human services, we tend to favor  
13 a reactive kind of approach.

14                   A lot of this culminates in  
15 increasing public awareness through social  
16 action. We actually have with the  
17 participants created a museum quality social  
18 installation that moves around Detroit and  
19 other areas to educate the public about the  
20 health consequences of homelessness.

21                   Health within the project means  
22 that the participants possess adaptive

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1 resources to function effectively in the face  
2 of the exigencies and challenges they face  
3 daily. Of course, health status is degraded  
4 during the homeless process and before a  
5 person becomes homeless. And we do recognize  
6 that homelessness itself is a state of ill  
7 health. It drains the adaptation of the  
8 participants. It wears down adaptation,  
9 flexibility, and functioning. It stimulates  
10 the onset of serious health problems like  
11 arthritis. It can exacerbate serious health  
12 problems like homelessness and is a major  
13 threat to health and well being.

14 We consider diminished status to be  
15 reflective of the kind of situations in which  
16 the women find themselves where their inherent  
17 value as human beings is degraded. That can  
18 happen in health services. That happens in  
19 human services. That happens in interaction  
20 with the police. It happens in interaction  
21 with potential employers or in vocational or  
22 educational kinds of settings. And we're

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1 deeply concerned about how this degradation  
2 sets in motion serious consequences that  
3 threaten health. We may refer to that as  
4 depression, but it's actually a form of  
5 depletion, and the depletion of vitality of  
6 the participants at the point we connect with  
7 them, communication is seriously at risk, and  
8 their receptivity to messages concerning  
9 health and well being is severely compromised.

10 One set of consequences is the  
11 adaptation a person makes to homelessness in  
12 order to cope with her situation. Diminished  
13 status weakens host resistance. It increases  
14 risk for very serious and negative outcomes.  
15 It situates people in degraded environments,  
16 and it fosters susceptibility to trigger  
17 factors.

18 One of the areas that we have  
19 become aware of and that we're concerned about  
20 but we don't have the competence to address  
21 right now is that period of preparation for  
22 homelessness in which a person experiences

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1 substantial social issues that weakens their  
2 resistance and begins to prepare them to  
3 become homeless which is something we tend not  
4 to want to think about because we focus really  
5 on the trigger events that moves a person into  
6 the homeless situation.

7 We operate at the front end of the  
8 project with a dense kind of narrative  
9 approach. We listen attentively to the  
10 stories that the participants share with us  
11 about their homelessness. And the kind of  
12 trigger factors we identify are accidents,  
13 health issues, marital disruption, job loss,  
14 maybe substance use, maybe criminal activity,  
15 domestic violence, and serious mental illness.

16 The dominant triggers that move a  
17 person into homelessness we found in our  
18 project is either accidents which accounts for  
19 a substantial amount of the reasons why people  
20 would end up homeless; serious health issues  
21 that prevent them from working. Now these are  
22 women who have to continue their work life if

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1 they're actually going to be able to handle  
2 their situations, and if their employment  
3 status is threatened by ill health, that often  
4 is an onset through substantial stress. That,  
5 too, prepares them for homelessness. And  
6 marital disruption, typically the loss or  
7 death of a -- I should say the death of a  
8 spouse. Job loss also figures substantially  
9 into that.

10 We incorporate the use of  
11 photography among the participants so they can  
12 document the environmental situations that  
13 they experience. This is one of the typical  
14 photographs. So far we've involved eight  
15 women, each of whom represent the different  
16 pathways into homelessness in a Photovoice  
17 activity where they've produced somewhere  
18 around 400 photographs that document their  
19 immediate area, geographic area of  
20 homelessness. You can see 80 percent of the  
21 photographs have some form of serious  
22 environmental degradation, typically rubble,

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1 the destruction of property, the misuse of --  
2 or the loss of utilization in housing  
3 structures, and what we refer to as the  
4 negative aesthetic in which homelessness is  
5 embedded.

6 We also see substantial decay in  
7 the sacred that the participants document.  
8 This is a church located in one of the areas  
9 of Detroit that had made a substantial impact  
10 in the civil rights movement. In fact,  
11 located close to this church is another church  
12 where Martin Luther King rehearsed the "I Have  
13 A Dream" speech before going on to Washington,  
14 D.C., and south of this church is substantial  
15 civil rights history, substantial civil rights  
16 memories.

17 Help. I just demonstrated learned  
18 helplessness.

19 (Laughter.)

20 Also, that church is probably two  
21 blocks away from the terminus of the  
22 Underground Railroad before it moves from

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1 Detroit into Windsor. So it's a fairly  
2 important area in American history, yet from  
3 the kind of photographs that the participants  
4 -- you see from the photographs, you wouldn't  
5 recognize the importance that the women  
6 attribute to the areas that they frequent in  
7 this part of Detroit.

8 I'll defer to the expert.

9 (Pause.)

10 Through Photovoice, participants  
11 identify the places they trust. And trust is  
12 a very big factor. It's an important variable  
13 within the project. You'll see from these  
14 places of trust they often have a sacred or  
15 religious kind of meaning assigned to them.  
16 This is an important area in Detroit because  
17 this is the area in which participants can get  
18 food. One of the things we know from our  
19 assessment process is that almost 80 percent  
20 of the participants in the first interview  
21 will describe food inadequacy, nutritional  
22 inadequacy, inadequate calories, and often no

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1 place to store the food that they actually  
2 have access to. Food quality is also a  
3 serious kind of issue.

4 This is -- now all of these were  
5 taken by the women themselves with black and  
6 white throw-away cameras, so these are scans  
7 of the picture. Unfortunately, this trusted  
8 place was destroyed by the Health Science  
9 campus right behind it. A specialty clinic  
10 was developed for the suburbs and treating a  
11 certain kind of ailment that isn't prevalent  
12 among homeless women. And this option called  
13 Crossroads no longer exists here, but was  
14 often seen as a place for the resolution of  
15 the food issues that many of the participants  
16 face.

17 Through Photovoice, they can  
18 identify the places they do not trust. Most  
19 of the places they do not trust are healthcare  
20 providers. Some 60 percent of the photographs  
21 represent some aspect of healthcare provision  
22 and that typically means a place that they're

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1 abruptly treated, a place where their  
2 homelessness is not taken in consideration, a  
3 place where their disease state and  
4 interaction with their nutritional status is  
5 not considered because a full history of their  
6 situation is never taken into consideration.

7 In this case, in this one  
8 photograph, one of our participants needed a  
9 \$500 pair of shoes that was prescribed by the  
10 physician, and when she brought up her  
11 homelessness, he told her that she shouldn't  
12 be walking frequently, but she walks as much  
13 as three or four miles a day in the pursuit of  
14 nutrition and in the pursuit of the things  
15 that she needs to maintain her health.

16 I won't go through all of these,  
17 this list, but these are the characteristics  
18 of the kinds of issues. At the front end,  
19 most participants will identify anywhere from  
20 five to eight serious issues. It could be  
21 damaged credit. It could be exposure to  
22 predatory lending. It could be an outstanding

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1 bench warrant. It could be disqualification  
2 from Social Security benefits. There are many  
3 kinds of practical issues.

4 Now what we mean by vulnerability  
5 is when a participant identifies at least four  
6 serious issues. That seems to be the cutting  
7 point. They assign to each issue a high level  
8 of distress, and the fact that the issue has  
9 not been resolved. They also assign to the  
10 issue a level of frustration that they've  
11 experienced that's generated by the hassles  
12 they experience when they try to resolve the  
13 issue.

14 So the stress burden that the women  
15 are carrying is very high. And since stress  
16 is often a self-perceived kind of variable, it  
17 has a lot -- it enters into the picture  
18 relative to the receipt of communication  
19 because a number of the women will be so  
20 distressed their system either closes down or  
21 they just can't hear things and they can't  
22 listen attentively.

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1           Now we are selecting women who do  
2 well on the mini-mental status interview.  
3 They have rich backgrounds of competence and  
4 of coping. In fact, my colleague, Olivia  
5 Washington, will often speak to the strong  
6 black woman stereotype, the kind of  
7 performance that the women have engaged in has  
8 been really high in their past lives and their  
9 appreciation for their own self-care ability  
10 is very strong, but it gets actually worn down  
11 during the preparation process and the tipping  
12 in process and then the process of being  
13 homeless.

14           This idea of the production of  
15 numerous hassles and hassles as being dominant  
16 in a person's day-to-day life and that they  
17 set out every morning in order to survive,  
18 literally erodes their allostasis, the  
19 equilibrium within their body to maintain good  
20 health, and often we see demoralization that  
21 will be diagnosed as depression.

22           The consequences of the issues,

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1 personal health consequences. Arthritis is a  
2 major issue. Cardiovascular problems figure  
3 in very importantly. Mental health issues as  
4 a consequence of unresolved trauma that either  
5 brought them into the homeless situation or  
6 have accumulated during the life course,  
7 figure in in a very important way. But  
8 there's pronounced deprivation.

9 So what helpers should prepare for?

10 Serious depravation, depravation of basic  
11 living needs, demoralization, complex health  
12 issues, high levels of dependency on the  
13 helper, considerable emotion, high levels of  
14 emotionality, and a lot of unresolved life  
15 experiences, particularly the exposure to  
16 violence.

17 What helpers will come to see  
18 paradoxically considerable resilience, hope in  
19 the future, aspirations for self and the other  
20 women that they get to know during their  
21 homeless process, concern and compassion for  
22 other homeless people which stands out as a

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1 big issue. Faith and spirituality figures in  
2 in a very important way. We did a study a  
3 couple of years ago on the prayer life of the  
4 participants and you'll see themes of  
5 restoration of health, desire for better  
6 healthcare, desire for better functioning, but  
7 also sort of a realism that that's something  
8 that's not readily available to them.

9 We focus on two types of  
10 narratives, a narrative of plight and a  
11 narrative of efficacy. They stand side by  
12 side. You'll hear both of them. The plight  
13 summarizes the homeless kind of situation.  
14 The narrative of efficacy is the mastery  
15 activities they use, their strategies for  
16 trying to master and overcome homelessness or,  
17 worse, to try to adapt to homelessness. And  
18 consider homelessness as their principal  
19 vehicle of existence. So there's a very  
20 strong existential component relative to some  
21 women will think about trying to get out of  
22 homelessness.

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1           A number of women, anywhere from  
2 around 40 to 50 percent, will have been so  
3 worn down they pretty much are asking  
4 questions about how they're going to survive  
5 homelessness. They'll ask questions like can  
6 I get shoes or boots to stand out on a corner  
7 to wait for a bus? I need a coat in order to  
8 -- a heavy coat. I need somewhere where I can  
9 at least get one meal a day.

10           There are three types of  
11 intervention that have proven useful so far.  
12 Now we blend or what we call threefold these  
13 interventions sort of together and our more  
14 componential design that we're moving toward  
15 we're going to, of course, separate those.  
16 But in the development stage we've taken some  
17 liberty in actual testing them. Group work  
18 figures in as a very important aspect of  
19 addressing the personal consequences with the  
20 participants.

21           We've been blending cognitive kinds  
22 of approaches with what we refer to as

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1 experiential and supportive approaches in the  
2 context that don't exceed anywhere from eight  
3 to ten women. The women learn about how  
4 they're thinking about homelessness and how  
5 homelessness influences their actual thoughts,  
6 experiential approaches in which they learn  
7 about how to take action to resolve their  
8 homelessness and a mutual support option in  
9 which they learn to support one another.

10 Now all of this is driven by a  
11 communication strategy where we prepare, we  
12 use the group work to help the participants to  
13 move into a plan of action that will help  
14 strengthen their health status at the same  
15 time deals with the actions that they have to  
16 take to resolve these issues. Now we refer to  
17 that as the reactive paradigm because it's  
18 reacting to the issues that the women have  
19 accumulated.

20 We assemble four sources of what we  
21 refer to as self-efficacy, mapping those  
22 against what Bandura would consider the

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1 sources of self-efficacy. We go through a  
2 period of emotional arousal that's followed by  
3 exposure to powerful role models of women who  
4 have overcome homelessness. We move into a  
5 period in which there is persuasion around how  
6 to get out of homelessness. Then we move into  
7 a performance period where we ask the women to  
8 collaborate with us in the production of a  
9 plan that they feel is useful in helping them  
10 get out of homelessness. That plan evolves  
11 around their strengths, but it also deals with  
12 the realities that the issues that they  
13 prioritize as most important need to get  
14 resolved.

15 We match with that plan of action  
16 what we refer to as effective sources of  
17 technical assistance. We don't really use  
18 terms like psychotherapy, but we have  
19 developed technical assistance relationships  
20 with people who have expertise to help them  
21 resolve the issues that they face. And if  
22 we're successful in doing that, we begin to

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1 see a decrease in the actual stress level that  
2 the women experience and more susceptibility  
3 to positive communication about direction.

4 The control group work which  
5 actually has had two replications on a quasi-  
6 experimental basis and then two replications  
7 on a true experimental design, although the  
8 effect sizes are moderate, it does begin to  
9 help women mobilize their energy and begin to  
10 direct their motivation to the process of  
11 looking forward and beginning to think about  
12 this plan of action that we refer to as ALH.

13 ALH is Advocacy for Leaving  
14 Homelessness which is a modularized 15-session  
15 meeting with someone who will mobilize the  
16 technical assistance to help them resolve the  
17 issues they need to get out of homelessness,  
18 not stay out of homelessness, get out of  
19 homelessness as we consider that to be a  
20 significant tipping point for the  
21 intervention.

22 This advocacy intervention, of

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1 course, is reactive. It comes into play late  
2 in the homeless experience. The assistance  
3 comes into play when the issue reaches a  
4 crisis point, but it's not difficult to  
5 anticipate the issues. The anticipation of  
6 the issues, an early alert system in the  
7 community to be able to handle this are some  
8 of the things that we're moving toward, would  
9 begin to shift us from a reactive kind of  
10 paradigm to a more proactive kind of paradigm.

11 And of course, we know what the  
12 gold standard is. The gold standard is a  
13 suitable supply of housing. Of course, in the  
14 United States we're 3.6 million housing units  
15 short, and that basically reflects the  
16 magnitude of homelessness in the United  
17 States. In another project, we've  
18 demonstrated that we can build a house for --  
19 under 1,000 square feet for \$8,500. So  
20 there's a solution -- and the solution is what  
21 we refer to as microhousing.

22 The proactive advocacy, of course,

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1 the early alert system, easily triggered by  
2 the person; considerable information, exchange  
3 of information about the well being of  
4 individuals, so we know what's going on for  
5 them; an abundant and relevant education about  
6 rights that helps people understand their  
7 health and how to protect their health, and  
8 about how to navigate difficult situations in  
9 an empowered way, but without being alone and  
10 isolated. One of our vulnerability indicators  
11 is that the person basically says they have no  
12 one to rely on and we have a social network  
13 method for being able to discern that.

14 The third practice is intentional  
15 community development, access to these  
16 technical experts who can help resolve issues.

17 Small and personalized helping resources that  
18 truly represent the person. This is very  
19 important, short links between the person and  
20 the sources of help. On the average,  
21 participants without this kind of community  
22 support will face somewhere between five to

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1 eight steps in order to get an issue resolved,  
2 and after those steps if the issue isn't  
3 resolved, the demoralization begins to get  
4 more -- becomes more of a serious issue.

5 Quick resolution of serious issues  
6 that can disrupt the living situation,  
7 hopefully within a week, once it's actually  
8 framed and understood. A sense of community  
9 and belonging and avenues for personal  
10 fulfillment. We do know that one of the  
11 principal indicators of a restoration of  
12 health is that a woman will begin to talk  
13 about employment and vocational development.  
14 Now the issue there is is how to create  
15 employment that actually adapts to the health  
16 issues that a participant faces, and we're  
17 developing a process to sort of -- we're  
18 developing a process to address that.

19 What does this have to do with  
20 communicating? Practical issues with  
21 medication management, we have to expect the  
22 potential for limited access to food. If the

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1 stipulation is to take medication with food,  
2 we're in a difficult kind of situation if a  
3 person doesn't have a consistent food supply.

4 Loss of medication while on the  
5 streets or moving around, actual degradation  
6 of the containers or the theft of the  
7 medication. At points of transition, the  
8 person may lose control of the medication,  
9 particularly when entering jail. We've had  
10 incidents where women will actually go to jail  
11 for petty issues or petty concerns. I do  
12 believe now in Detroit it's a crime to be  
13 homeless. It's called vagrancy. The jail,  
14 the county jail is sort of a holding point for  
15 many of the women facing these kinds of  
16 issues, but they oftentimes lose their  
17 medication when they enter the jail or it's  
18 misadministered or even so when they're  
19 entering a shelter.

20 Inadequate storage or heroic  
21 efforts to store medication. We actually have  
22 a case where four women got together who have

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1 diabetes who bought a refrigerator and rented  
2 space in someone's apartment so they could  
3 store their medication. Of course, access to  
4 that is a big issue and raises all sorts of  
5 other kinds of concerns.

6 Then the influence or control of  
7 caregivers, particularly non-family ones who  
8 are not likely health professionals. Case  
9 managers often figure in as important  
10 communicators and managers of the medication.

11 Mental health personnel, particularly shelter  
12 personnel or even more competent -- people who  
13 are perceived as more competent homeless  
14 individuals may actually help individuals  
15 manage their medication.

16 All of these possibilities are  
17 consistent with the person's loss of control  
18 over their personhood and environment. And  
19 one of the things we're trying to demonstrate  
20 is the extent to which you have to engage in  
21 order to restore the control the person feels  
22 they exercise over their actual living

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1 situation, and if medication is part of that  
2 living situation, facilitating that control  
3 becomes an important part of the self efficacy  
4 aims of the project.

5 The adaptation the person makes to  
6 homelessness can influence communication. The  
7 person communicating medication expectations  
8 or requirements may not possess credibility,  
9 so trust is a big issue, and it may be a  
10 physician who actually isn't trusted. And the  
11 lack of trust may influence limited listening  
12 or a reduction of communication.

13 Helplessness can dampen receptivity  
14 to communication. Focusing attention can be a  
15 challenge because of stress and nutritional  
16 inadequacy. The best way to communicate with  
17 someone who is homeless in a medication  
18 interaction is to offer them food. And do so  
19 in a very dignified and respectful manner  
20 which means that the healthcare provider  
21 probably should share the food with the  
22 person. And it's a ritual process that begins

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1 to establish a context in which there is a  
2 higher quality of communication between a  
3 person who has pretty much experienced  
4 considerable victimization and a person who is  
5 considered to be privileged. And in that kind  
6 of interaction we have a situation where  
7 communication could actually break down or  
8 communication, the person may be so vigilant,  
9 they'll believe everything the person has to  
10 share with them or what the person shares with  
11 them.

12           There can be a loss of energy and  
13 vitality that reduces cognitive vigilance and  
14 therefore receptivity to information provision  
15 is reduced. And the person may not be a  
16 direct recipient of the communication because  
17 they're dependent on others. Oftentimes we  
18 find -- not oftentimes, we find people in a  
19 minority of cases who may have a guardian,  
20 probably out of the 550 have had guardians or  
21 case management personnel or shelter personnel  
22 who will work vigilantly with the person to

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1 address the medication and the role of  
2 medication in their life. Oftentimes family  
3 members do not figure in to that process for a  
4 number of reasons.

5 Important health practices, assist  
6 the person to secure medication on their  
7 person or in a trusted place. Help the person  
8 fulfill nutritional needs in conjunction with  
9 medication if that's what's required. Do an  
10 inventory of the medication and address the  
11 person's understanding of each medication and  
12 it's role in their self care. That usually  
13 should be done verbally.

14 Strengthening the self efficacy may  
15 improve receptivity to communication about  
16 self care. The process of going through what  
17 we refer to as our self efficacy groups or our  
18 workshops, as a person moves to the tail end  
19 of that process, it's probably easier and more  
20 productive to have health care messages toward  
21 the tail end when we're talking about  
22 performance or persuasion and performance.

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1 Before that, they would have gone through this  
2 emotional arousal. They would have been  
3 exposed to powerful role models and their  
4 receptivity is increasing.

5 Discuss medication management under  
6 supportive group conditions. Support is a  
7 very, very important element here. The  
8 person's perception that they're in a safe,  
9 kind, compassionate environment is -- and  
10 creating those kinds of settings enriches the  
11 communication experience. And understand the  
12 context in which the person uses and stores  
13 the medication.

14 I know there's been at least ten  
15 situations where people have experienced  
16 rebound effects because they've discontinued  
17 abruptly medication they probably shouldn't  
18 have discontinued and they couldn't access a  
19 physician because they didn't have a medical  
20 home. And so they're moving about the  
21 community, accessing healthcare under very  
22 wobbly clinical kinds of conditions, and my

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1 hope is that the movement, the medical home  
2 movement is going to sort of help facilitate  
3 people connecting with physicians with  
4 continuity of care.

5 Thank you. I could share with you  
6 a lot more, but that's the project in a  
7 nutshell.

8 DR. FISCHHOFF: David, thank you  
9 very much. If you could stay up there just  
10 for one second. I think we have time for one  
11 question, and maybe I'll ask it. I mean I  
12 think that, you know, I think you've shown  
13 sort of the level of detail that one needs to  
14 understand people's context in order to think  
15 about -- to come up with any sort of  
16 meaningful solution, and on some level I've  
17 been thinking about what can we do with this  
18 piece of paper that we've been, that we're  
19 talking about here.

20 And so let me just offer you a  
21 couple of speculations is that the  
22 standardization which -- let me say -- that

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1 standardization could -- of the information --  
2 a succinct standardization of the information  
3 could help in this situation so that people  
4 are all reading off the same page. So if I'm  
5 trying to help somebody, you know that I'm  
6 likely to have the same information that  
7 they've received in other cases.

8 DR. MOXLEY: Right.

9 DR. FISCHHOFF: And that the women  
10 that you've been working with are women who at  
11 an earlier, happier stage in their lives  
12 probably could have -- you know, the  
13 broadband, general communication would have  
14 worked for them. They were coping. They  
15 could have been the interpreters for other  
16 people, so it's not so much the content would  
17 be the challenge, as making it meaningless --  
18 meaningful, rather, in a situation where  
19 they're trying to reestablish control.

20 DR. MOXLEY: Can I say something  
21 real quickly?

22 DR. FISCHHOFF: Please.

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1 DR. MOXLEY: Eighty percent of the  
2 participants will have a cell phone. Eighty  
3 percent of the participants will have an email  
4 address, and they'll access their email  
5 usually at a university location because they  
6 can get to computers in a library or in a  
7 public kind of -- they're computer literate.

8 People will say, you know, like  
9 Rita will say I may be homeless, but I'm  
10 computer literate, and she's the same one who  
11 will say I have three strikes against me.  
12 She's our three strikes theme, where she'll  
13 say I'm black, I'm a woman, I'm poor. But I'm  
14 computer literate.

15 She also represents someone who has  
16 a very strong work ethic and sees her  
17 medication as supporting her ability to work.

18 So that's an important nuance in the whole --  
19 in fact, many of the participants -- I know  
20 how you feel about these kinds of descriptors,  
21 so I'm trying to quantify them, but a majority  
22 of the women have

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1 -- will score 90 percent on our work ethic  
2 measure. It's very, very strong. And work is  
3 central. Thank you.

4 DR. FISCHHOFF: Thank you. So  
5 we'll take a break now, and we'll start again  
6 at 10:30 with the public, open public hearing  
7 portion of our program.

8 (Whereupon the above-entitled  
9 matter went off the record at 10:25 a.m. and  
10 resumed at 10:33 a.m.)

11 DR. FISCHHOFF: Okay, I'm now about  
12 to start the open public hearing part of our  
13 meeting. This will be the Agency-recommended  
14 introduction.

15 Both the Food and Drug  
16 Administration, FDA, and the public believe in  
17 a transparent process for information  
18 gathering and decision making. To ensure such  
19 transparency at the open public hearing  
20 session of the Advisory Committee meeting, FDA  
21 believes that it is important to understand  
22 the context of an individual's presentation.

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1 For this reason, FDA encourages you, the open  
2 public hearing speaker, at the beginning of  
3 your written or oral statement, to advise the  
4 Committee of any financial relationship that  
5 you may have with any company or group that  
6 may be affected by the topic of the meeting.  
7 For example, the financial information may  
8 include a company's or a group's payment of  
9 your travel, lodging, or other expenses in  
10 connection with your attendance at the  
11 meeting.

12 Likewise, FDA encourages you at the  
13 beginning of your statement to advise the  
14 Committee if you have any financial  
15 relationships. If you choose not to address  
16 this issue of financial relationships at the  
17 beginning of your statement, it will not  
18 preclude you from speaking.

19 In addition, I should note, in  
20 addition to the speakers, we have received  
21 several communications in writing, and they  
22 have been made available to the members of the

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1 Committee. We have six people who have asked  
2 to speak at the open public hearing. We're  
3 going to be very pressed for time since we  
4 have a hard stop at 11:30, so let me encourage  
5 the speakers to feel as welcome as possible,  
6 but if you could abbreviate in any way, then  
7 we would, of course, appreciate that. As I  
8 hope you saw yesterday, the input from the  
9 public is vital to the members of the  
10 Committee.

11 So our first speaker will be Claire  
12 DeMatteis from Catalina Health Resources.  
13 Please.

14 MS. DeMATTEIS: Thank you, Dr.  
15 Fischhoff. Is the microphone on? Super.

16 Thank you for giving me the  
17 opportunity to be here today. My name is  
18 Claire DeMatteis, and I'm Executive Vice  
19 President and General Counsel to Catalina  
20 Marketing Corporation which is the parent  
21 company of Catalina Health Resource, and I'm  
22 speaking today on behalf of Catalina Health

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1 Resource known as CHR.

2 CHR commends FDA for seeking the  
3 advice of this expert Committee on how to  
4 better communicate useful information about  
5 prescription drugs to patients in the pharmacy  
6 environment. We can all agree that the  
7 current system could do a better, more  
8 efficient job of delivering meaningful  
9 information to patients, and we welcome the  
10 opportunity to present our view today.

11 CHR fills a unique niche in the  
12 process by which a patient becomes informed  
13 about prescription drugs in the pharmacy. We  
14 participated in the original Keystone process  
15 and have been working diligently ever since  
16 with the FDA, pharmacies, and manufacturers to  
17 improve the quality of prescription drug  
18 information patients receive in the pharmacy.

19 Because we operate at the intersections  
20 between patient and pharmacy, education and  
21 promotion, the voluntary and the mandated, and  
22 because we've been doing this for 15 years, we

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1 offer a unique perspective on the state of  
2 pharmacy-based prescription drug  
3 communications to patients.

4 At CHR, we focus upon written  
5 communications about prescription drugs. CHR  
6 is responsible for Patient Link. Patient Link  
7 is a newsletter printed in 17,500 pharmacies  
8 nationwide. In 2008, over 110 million  
9 patients received a Patient Link newsletter  
10 with over 1.2 billion prescriptions. Since  
11 1994, we have distributed over 10 billion  
12 Patient Links to patients.

13 The Patient Link newsletter  
14 includes several components. First, it  
15 typically has the pharmacy-provided CMI for  
16 the drug dispensed to the patient, and we have  
17 some examples here just to show you the actual  
18 visual, what it looks like. This is what  
19 actually is attached to the prescription drug  
20 package.

21 On the other page, the Patient Link  
22 newsletter may contain additional information

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1 for the patient. Since 2005, Patient Link has  
2 carried 500 million FDA public service  
3 messages a year about health and drug safety.

4 Patient Link may also help pharmacies  
5 communicate to their patients about generic  
6 drug availability, cost assistance, and other  
7 programs.

8 Patient Link may contain a message  
9 sponsored by a drug manufacturer that provides  
10 more information about the drug dispensed to  
11 the patient or the condition and the medical  
12 threats. The message may be a refill  
13 reminder. It may provide compliance advice,  
14 additional risk and effectiveness information  
15 about the dispensed drug, or it may advise  
16 about support programs for patients taking the  
17 manufacturer's drug. Patient Link may also  
18 provide information about alternative or  
19 adjunctive prescription or OTC therapies or  
20 information related health conditions that the  
21 patient may be at risk for.

22 The Patient Link newsletter is a

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1 short document, usually two to three legal  
2 sized pages. It is written for the patient in  
3 plain, understandable language. Yet, despite  
4 its brevity and because it can provide so many  
5 different pieces of information, the Patient  
6 Link newsletter can trigger a multitude of  
7 laws, regulations, and draft and final  
8 guidances involving several different FDA  
9 divisions.

10 We wish to emphasize this point  
11 strongly. There is no single office in FDA  
12 with responsibility for all pharmacy  
13 communications to patients, nor is there a  
14 single guidance or regulation that pulls  
15 together all the different ways by which FDA,  
16 pharmacies, and manufacturers wish to or must  
17 communicate with patients in the pharmacy. It  
18 is a very complex and quite honestly it can be  
19 a very frustrating patchwork.

20 To illustrate these challenges, I'd  
21 like to give you a very real example. Let's  
22 assume that a patient receives a first time

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1 prescription for an antidepressant. It is  
2 conceivable that with that prescription, a  
3 patient could receive the following at the  
4 pharmacy: the drug with usual stickers and  
5 receipts attached; a CMI for the drug, here's  
6 the CMI; then a medication guide that is part  
7 of the CMI, and remember that a Keystone  
8 compliant CMI should have all the risk  
9 information contained in the medication guide,  
10 even if it does not repeat the medication  
11 guide verbatim; an additional medication guide  
12 the pharmacy may provide via a tear-off pad,  
13 attached label printout, or some other means.

14 If the drug is dispensed in a unit of use  
15 dosage form provided by the manufacturer, it  
16 may include the full prescribing information  
17 or PI which will include the medication guide,  
18 and if the drug has one, a patient package  
19 insert.

20 These PPIs are much shorter and far  
21 more consumer friendly than the PPIs for oral  
22 contraceptives and estrogens. Manufacturers

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1 frequently use these FDA, consumer friendly  
2 PPIs with patient education materials and in  
3 direct-to-consumer prescription drug print  
4 advertising to satisfy FDA brief summary  
5 requirements.

6 If the drug is accompanied by a  
7 message from the drug's manufacturer informing  
8 the patient about assistance available for  
9 patients taking the drug, current, informal  
10 interpretation of FDA requirements would  
11 mandate that the message be accompanied by the  
12 drug's full PI in easily readable, negative .2  
13 type.

14 This is true even though the  
15 message is intended for the patient, and even  
16 though the patient has already received the  
17 CMI, the medication guide, and possibly a PI  
18 with a medication guide and a PPI. If the  
19 patient receives a refill reminder for a drug  
20 from the pharmacy and the manufacturer pays  
21 for the reminder, that message must be  
22 accompanied by that drug's PI under current

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1 FDA interpretations.

2           So we have a CMI, medication  
3 guides, PPIs, PIs, and in the educational and  
4 promotional arena brief summaries of the PIs  
5 which can be a PPI or yet another document, a  
6 consumer-friendly version of the highlights of  
7 the PI. These documents arise in part from  
8 FDA regulatory distinctions between drug  
9 advertising and labeling and are governed by  
10 different divisions and different offices  
11 within FDA.

12           What has resulted is a patchwork of  
13 repetitive, voluminous and even contradictory  
14 documents all intended to inform the patient  
15 about her prescription drug therapy and yet  
16 none wholly succeeding.

17           We believe it simply makes no sense  
18 to continue this fragmented approach. It  
19 doesn't work. And the data before this  
20 Committee conclusively shows this. Patients  
21 need, want, and deserve a single, simple,  
22 straightforward document written for them in

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1 plain language and that they can have  
2 confidence in. We need to find one document  
3 that works and get everyone in the habit of  
4 using it.

5 To that end, CHR is proud to have  
6 joined with seven other stakeholders to  
7 petition FDA for a solution. On July 1, 2008,  
8 we joined in a citizen petition with the  
9 National Consumers League, the National  
10 Alliance for Care Giving, the National  
11 Association of Chain Drug Stores, the National  
12 Community Pharmacists Association, the Food  
13 Marketing Institute, the National Alliance for  
14 Hispanic Health, and the Healthcare  
15 Distribution Management Association. This  
16 diverse coalition has asked FDA to create a  
17 concise, plain language document that would  
18 combine and simplify the many documents  
19 patients currently receive in a pharmacy about  
20 prescription drugs.

21 This FDA-approved single patient  
22 document, let me say that again, we want this

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1 to be an FDA-approved single patient document.

2 And it could be used in lieu of the CMI and  
3 the medication guide, if the drug has one, and  
4 in lieu of a drug's full PI with patient-  
5 directed labeling like refill reminders and  
6 compliance aids.

7 We would also hope to see this  
8 patient document replace the many other used  
9 in prescription drug promotion and in other  
10 patient communication materials. CHR and its  
11 coalition partners do not urge creation of yet  
12 another required document for pharmacies to  
13 distribute to patients. Rather, we ask that  
14 FDA look to the many excellent existing models  
15 it already has such as the facts box that are  
16 included on the labeling for foods, OTC drugs,  
17 and dietary supplements. We will provide the  
18 one document solution petition to the  
19 Committee. We hope that you will agree with  
20 the petition's reasoning, and we ask that you  
21 recommend FDA's swift implementation of it.

22 Last, we want to raise a

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1 longstanding problem that is very detrimental  
2 to patients. As I've mentioned, under current  
3 FDA interpretations, a prescription drug print  
4 advertisement must be accompanied by the so-  
5 called brief summary of the drug's  
6 effectiveness and risk information. FDA and  
7 manufacturer advertisers have significantly  
8 improved the brief summary and today it is  
9 much less common than it once was to see a DTC  
10 print advertisement accompanied by all or most  
11 of the drug's PI verbatim. FDA and industry  
12 are to be commended for this effort.

13           However, these reforms have reached  
14 only to consumer-directed advertising, not  
15 patient-directed labeling. Under FDA  
16 interpretations, compliance information,  
17 refill reminders, and the many other things  
18 that can help patients to get and stay on  
19 therapy are deemed to be labeling. And even  
20 if directed to patients, should be accompanied  
21 by the drug's full PI.

22           No one believes that patients

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1 should be receiving PIs with their compliance  
2 materials and refill reminders, especially  
3 when there are better risk documents available  
4 and already in use that are written for  
5 patients. Yet, the interpretation remains  
6 causing patient confusion, a lot of wasted  
7 trees, and higher costs.

8 FDA has acknowledged for nearly 20  
9 years that the PI is not useful to patients  
10 and recently vowed to fix by guidance. We ask  
11 that this Committee urge FDA to resolve this  
12 inequity as quickly as possible. This  
13 concludes my remarks. CHR thanks the  
14 Committee for this time and attention, and I  
15 welcome any questions.

16 DR. FISCHHOFF: Thank you very  
17 much. Our format is that there isn't  
18 typically a question and answer, and we're out  
19 of time today. So thank you.

20 Okay, our next speaker is Michael  
21 Miller from the University of Oklahoma.  
22 Please, welcome.

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1 DR. MILLER: Good morning,  
2 honorable members of the FDA Risk  
3 Communication Advisory Committee. It is  
4 indeed an honor to be here and this is an  
5 incredible experience for me and I just want  
6 you to know that.

7 My name is Michael Miller. I'm a  
8 pharmacist and an associate professor of  
9 clinical and administrative sciences at the  
10 University of Oklahoma College of Pharmacy and  
11 on behalf of my colleagues from the University  
12 of Oklahoma, Dr. Michael Schmitt and then my  
13 colleagues from UAB Deep South Musculoskeletal  
14 CERTs, Drs. Jeroan Allison, Kiefe, Saag,  
15 Funkhouser and Ms. Ray, and my colleagues at  
16 ASHP Research Foundation, Dr. Dan Cobaugh and  
17 Dr. Cynthia LaCivita.

18 I'm pleased to present the results  
19 of two studies that we recently completed, and  
20 I also want to acknowledge that this research  
21 has been supported by the Agency for  
22 Healthcare Research and Quality Centers for

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1 Education Research on Therapeutics Cooperative  
2 Agreement.

3 This has all been discussed  
4 already, and so I won't go into detail. We've  
5 already talked about the problems with written  
6 medicine information. Health literacy  
7 concerns, just to note that approximately,  
8 there have been studies that have been done at  
9 the national level, as well as in sub-  
10 populations, that about a third of adult  
11 Americans function at the lowest levels of  
12 health literacy and to mention here, there are  
13 risks associated with nonsteroidal anti-  
14 inflammatory drug use that have warranted the  
15 creation of FDA-sponsored medication guides.  
16 Unfortunately, people that don't have the  
17 ability to read, comprehend and act on that  
18 information if they have poor health literacy.

19 The objectives of this project that  
20 I'm going to present are simply to estimate  
21 the multivariable associations among key  
22 socio- demographic factors health literacy,

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1 the reading of written medication information  
2 and nonsteroidal anti-inflammatory drug risk  
3 awareness.

4 And then finally, I'll estimate  
5 some path models for reading written  
6 medication information as well as NSAID risk  
7 awareness.

8 It's important to note that the  
9 data that I'm going to be using are cross  
10 sectional follow-up data from the Alabama  
11 NSAID Patient Safety Study. The parent  
12 project, the Alabama NSAID Patient Safety  
13 Study randomized physician practices to  
14 intervention and control groups.

15 Physicians in both groups received  
16 four different continuing medical education  
17 programs to improve safe prescribing of NSAIDs  
18 and as well, they received NSAID monographs  
19 written in layman's terms for distribution to  
20 their patients. In addition, the patients of  
21 intervention practices received a patient  
22 activation kit that promoted self assessment

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1 of NSAID risk and subsequent discussion with  
2 their physician.

3 In terms of patient recruitment,  
4 patients were recruited from 39 private  
5 community-based general family and internal  
6 medicine physician practices in Alabama.  
7 Patient eligibility criteria included the  
8 following: being established patient at one  
9 of the primary care physicians, currently  
10 taking prescription NSAIDs, 50 years of age  
11 and older, and their willingness to provide  
12 contact information consent and complete a 30-  
13 minute telephone survey.

14 In terms of implementation, an in-  
15 depth survey was administered using computer-  
16 assisted telephone interview protocols.  
17 Computer software contained checks for logical  
18 consistency and out of range errors. Patients  
19 taking part in the survey received a \$20 gift  
20 card. Interviewers underwent formal training  
21 with certification of competency before  
22 beginning data collection.

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1           Data were collected between June  
2           2006 and February 2007. Among the eligible  
3           patients, 73.1 percent completed the telephone  
4           interview, and although the sample design was  
5           intended to be race inclusive, one patient  
6           was excluded because they were not white or  
7           African-American which precluded them from any  
8           viable planned analyses.

9           These are some of the measures that  
10          we used. The primary dependent measure in  
11          this study was NSAID risk awareness, and NSAID  
12          risk awareness score was based on correct  
13          answers to four questions related to important  
14          cardiovascular, renal, and gastrointestinal  
15          risks. Each question began with the stem,  
16          "How do you think taking NSAIDs affects the  
17          risk of blank" and used the five category  
18          response set that included decreases risk,  
19          increases risk, does not affect risk, not  
20          sure, or refused.

21          The correct answer to all questions  
22          was increases risk with the remaining

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1 responses classified as incorrect. An index  
2 of known risks was computed creating an  
3 ordinal variable of zero to four known risks.

4 Reading written medicine  
5 information concerning NSAIDs was established  
6 by a single question as follows: "Often a  
7 drug store gives you written information such  
8 as pamphlets or handouts, along with your  
9 prescription. Have you read about the risks  
10 of NSAIDs in this written material provided by  
11 the drug store?" The response set included  
12 yes, no, not sure, don't know or refused.  
13 Patients with a response other than yes were  
14 categorized as not having read the written  
15 medicine information.

16 We also collected a set of  
17 demographic characteristics and we established  
18 health literacy using some screening questions  
19 that have been published in prior literature.  
20 One item health screening literacy questions  
21 listed have been identified as a top three  
22 single item predictors of functional health

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1 literacy from a pool of 16 different screening  
2 questions.

3           And these questions have been  
4 validated against two standard measures of  
5 health literacy, the short test of functional  
6 health literacy in adults and the rapid  
7 estimate of adult literacy in medicine and  
8 have areas under the receiver operating  
9 characteristic curves from .66 to .84 for  
10 inadequate functional health literacy,  
11 depending on the question.

12           Each question uses a five item  
13 response set that can be collapsed into  
14 dichotomous groupings using optimal cut-points  
15 identified in previous research. And of the  
16 three screening questions, screening question  
17 two, "how confident are you in filling our  
18 medical forms by yourself?" typically  
19 performed the best invalidation studies.

20           I'll shorten this section. We  
21 obviously did some descriptive statistics for  
22 the sample. Some bivariate relationships were

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1 assessed using chi-square. Because these data  
2 were nested in a randomized clinical trial and  
3 it wasn't the primary study, we did use the  
4 Mantel Haenszel chi-square and some other  
5 techniques to rule out confounding an effect  
6 modification from the parent study  
7 intervention.

8 We used some generalized linear  
9 late and mixed model techniques, known as  
10 gllamm. And to account for clustering of  
11 patients within physician practices and path  
12 models were estimated to simultaneously test  
13 relationships among variables from the gllamm.

14 As you can see the study group  
15 characteristics here. Risk awareness on that  
16 scale index as zero to four was two. About  
17 two thirds of the people read written medicine  
18 information provided at the pharmacy. A  
19 little over a third were greater than 65 years  
20 of age and on through there. Importantly, the  
21 estimates of health literacy, about three  
22 quarters of the people were actually

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1 identified to be having adequate literacy  
2 based on their responses to those questions.

3 In the multi-variable analysis,  
4 looking at the prediction of reading written  
5 medicine information, we found three  
6 significant predictors: being female, being  
7 associated with reading written medicine  
8 information. If you were older, greater than  
9 65, you were less likely to read written  
10 medicine information and the estimate of  
11 having adequate health literacy was associated  
12 with reading written information.

13 And we used three separate  
14 predictors of health literacy, three separate  
15 questions, and you see a consistent  
16 relationship.

17 From that data, we then estimated a  
18 path model and we didn't want to eliminate  
19 education from this equation because of its  
20 relationship with health literacy. So we  
21 created this path model and we found a  
22 relationship between education and health

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1 literacy. But interestingly, education didn't  
2 predict reading the information, reading  
3 written medicine information.

4 It was the health literacy estimate  
5 that was important. We saw the same  
6 consistent relationships, if you're older,  
7 less likely to read written information; and  
8 being female, you're more likely to read  
9 written information.

10 We then estimated--now that we did  
11 that analysis--we added in as the dependent  
12 measure risk awareness and what we saw here  
13 was being older, you're less likely to have  
14 NSAID risk awareness. Once again, the health  
15 literacy estimates were predictors of risk  
16 awareness, positive predictors of risk  
17 awareness. And if you substituted education  
18 in this particular case for health literacy,  
19 you saw education was a predictor of NSAID  
20 risk awareness.

21 And this is the path model, it  
22 looks like the Starship Enterprise from that

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1 particular gllamm model. And you saw a very  
2 similar pattern emerging with age and the  
3 health literacy estimate predicting risk  
4 awareness. You saw education related to  
5 health literacy. Interestingly, literacy was  
6 related to reading both written information  
7 and risk awareness. What you did see though  
8 is the reading of the written information was  
9 not a significant predictor of NSAID risk  
10 awareness.

11 There are study limitations here.  
12 The data were derived from self report, so  
13 there is some potential recall bias and some  
14 socially desirable responses. People have  
15 talked about that yesterday. We do  
16 acknowledge that. The study used secondary  
17 data nested within a randomized clinical  
18 trial, but we did everything we could to rule  
19 out the interference of the intervention  
20 variable. The one item health risk screening  
21 questions only provide estimates of health  
22 literacy and may be influenced by personal

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1 experience of a patient. And only awareness  
2 of NSAID risk is assessed and may not be  
3 representative of other drug classes.

4 Now in terms of the summary and  
5 conclusions, I would just like to say from our  
6 findings we saw that reading written medicine  
7 information was not associated with NSAID risk  
8 awareness in this study. The elderly, and  
9 those with less than adequate health literacy  
10 should be targeted as special populations for  
11 intervention to improve NSAID risk awareness.

12 As a policy consideration, I would  
13 say that the one item health literacy  
14 screening question, while it still needs  
15 development may serve as a practical way of  
16 assisting, in identifying or triaging patients  
17 at risk for not reading written information  
18 and decreased NSAID risk awareness. It's a  
19 simple, unobtrusive measure that does not give  
20 you any sense of being tested. And so if it  
21 can predict that maybe we could use that as a  
22 triage mechanism.

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1           And finally, future research should  
2 focus on methods to facilitate the use of  
3 written medicine information and to promote  
4 the translation of information into patient  
5 understanding and action. What I want to  
6 reinforce--what I've heard thus far--is that  
7 you can't just give somebody a piece of paper.

8       As a pharmacist, as a caretaker, a former  
9 caretaker of elderly parents, you can't just  
10 hand people a piece of paper. It has to be  
11 facilitated by providers and we need to be  
12 able in these busy practice settings to triage  
13 people out, identify them and do extra  
14 intervention on those folks.

15           Thank you very much for your time.  
16 I can't believe I made it on time.

17           There are also references, if I  
18 might add.

19           DR. FISCHHOFF: Thanks very much.  
20 We have oxygen bottles out in the lobby.

21           (Laughter.)

22           Thank you very much. I'm sorry

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1 that we're all so rushed. Wait until you see  
2 how rushed we're going to be after lunch.

3 Our next speaker is Cassie Plummer  
4 of iGUARD.

5 Thank you and welcome.

6 DR. PLUMMER: Hi. Is it working  
7 now? Okay.

8 Hi. My name is Cassie Plummer.  
9 I'm a drug information pharmacist from iGUARD.

10 I'd like to thank the Committee for allowing  
11 me to speak today. I have no financial  
12 disclosures other than iGUARD is a subsidiary  
13 of Quintiles.

14 Today, I'm going to speak about a  
15 medication guide survey that we conducted with  
16 our membership.

17 First, a little bit about iGUARD.  
18 We are a web-based medication monitoring  
19 service for patients. Patients complete an  
20 on-line medication profile and that allows  
21 them to have medication safety checks for drug  
22 and disease interactions. They also receive

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1 personalized drug safety alerts as new  
2 medication arises from the FDA MedWatch Safety  
3 Alert Program and manufacturer recall and Dear  
4 Doctor letters.

5 Patients also receive printable  
6 medication records that they can put in their  
7 wallet and they do also have access to  
8 medication reviews that are administered  
9 through an on-line patient drug review format.

10 Currently, we are monitoring  
11 medications and emailing out safety alerts to  
12 over one million patients in the United  
13 States. Our membership gives us a unique  
14 opportunity to collect feedback on the  
15 preferences of patients who actively seek  
16 medication information through the internet.

17 We conducted a study about  
18 medication guides. We chose to look at  
19 medication guides because medication, excuse  
20 me, consumer medication information leaflets  
21 have been studied extensively, and there's  
22 also a lot of variety amongst the different

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1 information leaflets that are dispensed  
2 through pharmacies. And also, medication  
3 guides are one of the newest methods or  
4 mechanisms for delivery of medication safety  
5 information and it appears that they are  
6 increasing in prevalence since post REMS.

7 In fact, 10 of 22 new molecular entities that  
8 have been approved in the year since REMS  
9 begun, 10 of 22 have had medication guides.

10 We initiated a survey of our  
11 membership, of our patients taking  
12 antidepressants to obtain feedback about the  
13 medication guide. This presentation  
14 summarizes top line findings and a more  
15 complete analysis will be submitted to the  
16 docket.

17 We administered a web-based survey  
18 to our patients taking antidepressants within  
19 the class of SSRIs, SNRIs or Wellbutrin. We  
20 sampled to have 50 respondents in two age  
21 groups, 18 to 64 and 65 years and older. We  
22 showed the patient the medication guide and

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1 then we administered questions that measured  
2 the frequency that patients received and read  
3 the antidepressant medication guide that  
4 measured the difficulty of the information in  
5 the medication guide, as well as the  
6 preferences for medication guide delivery in  
7 terms of method and frequency.

8 And finally, we asked how often  
9 patients discussed suicidality, the primary  
10 focus of the medication guide; how often they  
11 discussed this with their physician and their  
12 pharmacist. Patients received a \$10  
13 honorarium for their time and we received IRB  
14 waiver.

15 This is just a quick summary of the  
16 demographics. We did not see a large  
17 difference in answers between the age groups  
18 and due to the limited time of this  
19 presentation we combined the two age groups to  
20 report the results. Sixty-nine percent of our  
21 respondents were female with a mean age of 59  
22 years. Most of the respondents had some

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1 college or a college graduate degree. Our  
2 population for this survey was largely white  
3 and non-Hispanic. And 66 percent were not  
4 working and 74 percent were long-time  
5 antidepressant users of two years or more.

6 We did not conduct a statistical  
7 analysis for this data, so we can only comment  
8 on the data trends that we see and not on the  
9 statistical significance.

10 For frequency of receipt and  
11 reading of the medication guide for  
12 antidepressants, two thirds of study  
13 respondents received the medication guide with  
14 each antidepressant prescription filled. Of  
15 the 80 patients who had received the  
16 medication guide for their antidepressant,  
17 almost 98 percent had read the medication  
18 guide, one or more times.

19 The graph at the right shows the  
20 distribution of that -- of how often they read  
21 the medication guide. Forty-one percent read  
22 the medication guide once. Almost 44 percent

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1 read the medication guide sometimes. And 12.5  
2 percent read the medication guide every time  
3 they received their prescription refill.

4 When we asked patients about the  
5 ease or difficulty of the information  
6 contained in the medication guide less than 20  
7 percent of patients found the medication guide  
8 difficult, very difficult, or extremely  
9 difficult to understand.

10 To look at the preferred method of  
11 delivery, we asked a series of yes/no  
12 questions in the format "if you were to  
13 receive a new prescription with a medication  
14 guide, would you like to receive the copy from  
15 your doctor, yes or no?" A second question,  
16 "would you like to receive a copy from your  
17 pharmacy, yes or no?" et cetera continuing on  
18 with a question about receiving it from the  
19 mail and receiving it by email.

20 Eighty-six percent of patients  
21 indicated that yes, they would like to receive  
22 a copy of the medication guide from their

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1 pharmacy, versus 50 percent that indicated  
2 they would like to receive it from their  
3 doctor. Interestingly, we can also look at  
4 the number of patients who answered yes, to  
5 receiving it from their doctor, and yes, from  
6 receiving it from their pharmacy and we  
7 received 46 of the 100 respondents said they  
8 would like to receive it from both places.

9 In essence, nearly half of patients  
10 want to receive medication safety information,  
11 excuse me, half of patients want to receive  
12 medication information, both at the point of  
13 prescribing and at the point of dispensing.

14 Also, interesting to note in this group of  
15 patients who are active internet users, only  
16 53 percent would like to receive the  
17 medication guide by email.

18 We then asked patients how often  
19 they would prefer to receive the medication  
20 guide and 67 percent indicated they only  
21 wanted to receive it once with a new  
22 prescription and then if the information

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1 changed versus 30 percent of patients who  
2 wanted to receive it with every prescription.

3 Finally, we asked patients how  
4 often they discussed the potential risk of  
5 suicidal thoughts or actions associated with  
6 their antidepressant with their doctor or  
7 their pharmacist. And 54 percent of patients  
8 indicated that they never had discussed this  
9 risk with their physician versus 75 percent  
10 who had never discussed the risk of suicide  
11 thoughts and actions with their pharmacist.

12 So in conclusion, patients are  
13 receiving -- patients in this population are  
14 receiving and reading the medication guide for  
15 antidepressants. Although patients were  
16 provided with a sample of the medication guide  
17 for the antidepressants with the survey, it's  
18 still unclear if patients are able to  
19 differentiate between the medication guide or  
20 the consumer medication information leaflet.  
21 And this may introduce some recall bias into  
22 our results. Are patients actually able to

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1 determine or remember what they actually  
2 received in their pharmacy.

3 We also note that we might have  
4 some attention bias where patients are aware  
5 that they're in the study, so they may answer  
6 positively to the questions about how often  
7 they read the medication guide.

8 Most patients wished to receive the  
9 medication guide from their pharmacy, but only  
10 with new prescriptions and when they're  
11 updated. I found our results interesting,  
12 indicating that in this active group of  
13 internet users, patients would still rather  
14 receive this information from their pharmacy  
15 than by email.

16 And finally, there was a discussion  
17 yesterday focusing on considering the greater  
18 question of improving the system of  
19 communication and I think our last data point  
20 shows that there's limited healthcare  
21 professional support of this medication guide  
22 program and with doctors and pharmacists not

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1 discussing the risk of suicidality with their  
2 patients taking antidepressants. And  
3 definitely, this can be improved upon.

4 So that concludes my presentation.

5 And I would be happy to answer questions  
6 later if there's time.

7 DR. FISCHHOFF: Thanks. I think  
8 there probably won't be time in the plenary  
9 session, but I hope you'll be available and as  
10 you know, we have inquiring minds around the  
11 table. Thank you very much.

12 Our next guest or public speaker is  
13 Ellen Hoenig Carlson from AdvanceMarketWoRx.

14 MS. CARLSON: Okay, can you hear  
15 me? Thank you very much. I really don't have  
16 to report any financial disclosure. I am here  
17 on my own. But I have been in the industry  
18 doing direct-to-consumer patient marketing  
19 since the FDA changed the regs. So since 1997  
20 for Bristol-Myers and now on my own. So I do  
21 consult for the pharmaceutical industry, but  
22 I'm not here on behalf of them.

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1 I'm going to try to go fast, since  
2 I know we have time. I think the questions  
3 that have been raised have been great and I  
4 think I'm not going to go over them, except  
5 for I think what I'm trying to bring forward  
6 as a lot -- supporting a lot of the different  
7 pieces that you've heard, but kind of bringing  
8 them together in a slightly different way.

9 And the way we want to really think  
10 about it is really enticing consumers to  
11 really want to read it, to want to learn, to  
12 want to really ask questions. And what's  
13 useful to the consumer, what's useful to the  
14 FDA, and unfortunately, I'm a big believer in  
15 less is more. And I think that as we go  
16 through this, the human mind cannot learn all  
17 those things, so I think it may be better for  
18 us to be able to focus on the few important  
19 things and make sure those are communicated  
20 and think about how all the different  
21 communications to the consumer with the  
22 pharmacist, with the physician, with TV ad, a

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1 printout, how do they all work together.

2 And so that's really one of the  
3 important places.

4 And so the issue like from a  
5 consumer standpoint is that they are  
6 incredibly rushed. They are incredibly  
7 overwhelmed. I think somebody spoke about  
8 people who are living on the streets and when  
9 you're living on the streets, it's hard to  
10 kind of pay attention. Well, that's also  
11 happening now with all the financial issues  
12 that are happening. So people are really  
13 worried. People are losing their jobs.  
14 People aren't paying attention. And then if  
15 you have a disease like a depression or ADHD  
16 and having trouble paying attention is going  
17 to make it even harder.

18 So I think that the complicated and  
19 kind of that long and boring, what I see in  
20 research having been in probably one million  
21 different qualitative sessions with all  
22 different kinds of diseases, is they just skip

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1 right over it and don't even read. So either  
2 they're not reading it or -- sorry, they're  
3 either not reading it or they're not reading  
4 it in its entirety. They're not understanding  
5 it.

6 And I think one of the places that  
7 we've talked about is, there was a lot of  
8 talking about trying to make headlines color.

9 And I think that that will help, but that is  
10 still just one medium and that's just the  
11 written. And I think what I'm going to try to  
12 bring forward is that it needs visuals. And  
13 it needs aural.

14 And it is not about one medium. So  
15 it doesn't matter how much those words are put  
16 in how many pretty this and that, it will not  
17 communicate. If you don't want them to think  
18 that it's bad for their stomach, then put a  
19 stomach on there with an X and they will  
20 understand not to. And so I think that's kind  
21 of what I'm going to try to quickly do. I  
22 know there's only a few minutes.

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1           The thoughts where I'm coming from  
2 is obviously a lot of consumer markets we do a  
3 lot of testing. We are always talking to  
4 consumers. We are always revising. We talked  
5 about that. It's a constant flow, and I  
6 absolutely, everyone who is working with the  
7 consumer ought to be doing that. And  
8 absolutely once it's in the market, going  
9 back. In the DTC world what we try to do  
10 sometimes is what we call match-back studies,  
11 so we actually look at a prescription and see  
12 is this working, are they staying on the drug?  
13 I think you had asked that question. So I  
14 would definitely, it's not just doing the  
15 research before, but after.

16           I'm going to talk about some work  
17 from Dr. John Medina. It's from Neuroscience.

18 A lot of people have published a lot of  
19 things. I happen to think that he has some  
20 really interesting ways of talking about it.  
21 He also teamed up with Garr Reynolds who is an  
22 expert in presentation. So should you ever

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1 really want to think about how you do  
2 presentations, somebody like him I hope would  
3 be brought in, because he has nothing to do  
4 with Pharam, but he really understands how you  
5 communicate.

6 So I borrowed from him. There's a  
7 lot of rules. I picked four. And I'm going  
8 to go through these really quickly. Consumers  
9 don't pay attention to boring things. We have  
10 to repeat to remember. We need to stimulate  
11 more than once sense and if you only have one  
12 visual, usually trumps all others.

13 So I'm going to use again borrowing  
14 from their presentation, but maybe add a  
15 little fun. So you're kind of thinking what  
16 does he have to do with it? Well, there's  
17 three reasons. He has these big eyes which  
18 remind you that vision is the most dominant  
19 sense that humans have in terms of learning.  
20 His remarkable coloring and shape remind you  
21 that we are wired to notice differences and  
22 patterns.

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1           So I think some of the work  
2 yesterday with the box of benefits and risk  
3 that is going to be a good way to communicate  
4 because that starts to become a pattern. And  
5 so that would work. It might even be better  
6 if we add some visuals to those things.

7           So that's really what he's talking  
8 about. Again, structuring the presentation  
9 around the meaning, so that's why I think that  
10 benefits and risks, that's the big picture  
11 meaning and then you're having some sub-points  
12 to talk about it.

13           We cannot communicate that many  
14 things to a consumer at one time. So we  
15 really do have to get to the big picture.  
16 What is it we really want to communicate?

17           The use of patterns, I think that  
18 that work with the box is going to be very,  
19 could go over really well and be very  
20 impactful. This is just a quote from Dr.  
21 Medina, but just that the brain is attention  
22 to patterns, and so we start to remember

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1 things that are in patterns and quicksand is  
2 obviously a useful evolutionary trait.

3 Not to pick on anybody's brief  
4 summary, but just too much information and  
5 there's just not enough time devoted to kind  
6 of connecting the dots for the consumer. And  
7 so I don't think there's anybody who is  
8 reading that whole thing unless it's once in a  
9 while and they really have a question.

10 Repeat to remember. The capacity  
11 of the working memory is like less than 30  
12 seconds. So if we really want people to know  
13 something, we have to tell them a few times.  
14 There's a reason if you've ever gone to Disney  
15 and get on the bus that they tell you three  
16 times within 30 seconds what place you're in  
17 so you can remember where your car is parked,  
18 because the consumer has to hear it three or  
19 four times or they're not going to remember  
20 it.

21 More of the sense is a lot of data  
22 here, but reading only with the words really

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1 doesn't have a lot of memory stability. And  
2 so when you add the voice, hearing, or even  
3 combining hearing and seeing with visuals, you  
4 get the best results. So again, we have  
5 better recall with visual and I think that  
6 that's an area that's not really been brought  
7 in enough yet, the use of visuals and  
8 pictures, because that's what people remember.

9 Hear a piece of information. Three days  
10 later, you'll remember 10 percent of it. But  
11 with a picture, you may remember 65 percent.

12 So just that the pictures really  
13 help, and I think that's really something that  
14 as you go forward with the process to really  
15 try to integrate that. I know we have to go  
16 fast, so I think in terms of my experience of  
17 working with consumers for over 12 years in  
18 this arena is to really focus on what is the  
19 key idea that we need to communicate because  
20 we can't get through all the pieces. They  
21 just will not read it. And so go for the big  
22 one and connect the dots, less is more. And

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1 then to repeat, if it's important, then you've  
2 got to repeat it a few times if we really  
3 expect them to remember and digest it. If we  
4 can add some real visuals, I think that would  
5 be a big help to it and maybe even start to  
6 have consumers know that this visual means  
7 benefit, this one means risk, or stomach or  
8 food or whatever the issues are. And then  
9 just the idea of really showing consumers a  
10 pattern really helps. So I think the idea of  
11 the box of benefit and risk is -- would be a  
12 very big benefit to really being able to  
13 communicate.

14 So with that I think we would get  
15 the objective of what everybody wants which is  
16 really more balance between benefit and risk,  
17 more understanding, more education, and more  
18 engaged consumers. So thank you very much. I  
19 appreciate the time.

20 DR. FISCHHOFF: Okay, thank you  
21 very much. Our next speaker is Ellen  
22 Liversidge.

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1 MS. LIVERSIDGE: Good morning and  
2 thank you for pronouncing my name correctly.  
3 I don't have any financial conflict to report.

4 In fact, I hardly have any finances at this  
5 point.

6 My name is Ellen Bleaker  
7 Liversidge, and I'm a Board Member of the  
8 Alliance for Human Research Protection. I've  
9 spoken before the FDA various committees over  
10 the last several years, and I appreciate very  
11 much being given the opportunity to speak  
12 today. I called in late.

13 My remarks are not directed at this  
14 Committee which I have spoken to before, and I  
15 believe this Committee carries out its tasks  
16 with both humility and diligence.

17 My topic is atypical  
18 antipsychotics, an example of how the FDA is  
19 asleep. Two years ago, in June of 2007, I  
20 spoke before a committee of the FDA, perhaps  
21 this one, with as much passion as I could  
22 muster, asking that this lethal class of

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1 drugs, the atypical antipsychotics be given  
2 med. guides. I was shocked that there were no  
3 med. guides for these drugs which have been  
4 out three years. I must conclude since  
5 nothing happened, unless I missed it, that the  
6 FDA either does not take the med. guide  
7 seriously or is purposefully choosing not to  
8 have med. guides for this class of seriously  
9 lethal drugs.

10 And then I have to wonder who else  
11 takes med. guides seriously? I believe the  
12 FDA pays little attention to drug safety,  
13 unlike food safety. I agree that food safety  
14 is extremely important, but given where the  
15 vast number of deaths occur versus the  
16 attention paid to one area over the other, it  
17 just doesn't look right.

18 Recently, The New England Journal  
19 of Medicine had an article citing the risks of  
20 atypical antipsychotics and I'll read one  
21 brief paragraph. "Should the use of  
22 antipsychotic medications be restricted on the

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1 basis of these data" -- the data are in your  
2 packet, I think -- "much of their use is in  
3 vulnerable populations and outside the labeled  
4 indications including the use in children and  
5 in the elderly with dementia. And there is  
6 much less evidence of efficacy in these  
7 populations.

8 In the absence of clearly,  
9 established benefits for many of these  
10 patients, the risk of a fatal side effect is  
11 not likely to be acceptable. For these  
12 patients, the use of antipsychotic medications  
13 should be reduced sharply, perhaps by  
14 requiring an age-dependent justification for  
15 their use." This is from The New England  
16 Journal of Medicine. I believe the article  
17 was in January.

18 We learn this from The New England  
19 Journal, but there's nothing coming from the  
20 FDA. As a matter of fact, well, 15,000  
21 individuals are currently suing AstraZeneca  
22 over diabetes and other side effects from

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1 seroquel and a Court battle is going on, maybe  
2 it's over, about proprietary information,  
3 whether or not it should be released showing  
4 that the company knew of the risks, just as  
5 was the case with Zyprexa. The FDA is  
6 preparing to consider approval of the drug for  
7 extended use and is being approached and  
8 approved for extended use, including for  
9 children by the other manufacturers of this  
10 lethal class of drugs.

11 I simply cannot understand why the  
12 FDA gives these drugs a pass as thousands die  
13 and there are basically no serious warnings,  
14 no black box warnings except for seniors with  
15 dementia, no revisiting of drugs whose  
16 clinical trials are turning out to be highly  
17 suspicious, if not bogus.

18 There were 30,000 people maimed and  
19 killed in the Lily Ziprexa mass tort  
20 settlement and there will be 15,000 or so in  
21 the AstraZeneca seroquel trials. I find it  
22 astonishing that there is total silence from

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1 the FDA in these instances, especially when  
2 there is now clear evidence from internal  
3 documents that lethal side effects were known  
4 by the company, yet hidden. For information  
5 about this, you can look on the blog site  
6 called Curious Seasons because it has lengthy  
7 internal Lily documents for Zyprexa.

8 Surely you have heard of a recent  
9 case in California where the medical director,  
10 head nurse, and chief pharmacist were arrested  
11 for injecting repeated shots of atypicals in  
12 their elderly nursing home population. Three  
13 died and most did not have dementia. Has the  
14 FDA gone to investigate this travesty, I don't  
15 know. I'm being told my time is almost up, so  
16 I will just tell you that my only son Rob died  
17 from profound hyperglycemia due to Zyprexa in  
18 the year 2002.

19 And the FDA knew that there was a  
20 problem and months and months and months later  
21 they did nothing about it in terms of warning.

22 I urge those on this Committee to push the

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1 FDA to act. As the Dalai Lama said "it's not  
2 enough to have compassion. One must act."

3 Those of us who have lost family  
4 members have never been invited to speak to  
5 the FDA. Well, who better to discuss ultimate  
6 risk communication failure than us. On the  
7 contrary, we are usually treated as pariahs by  
8 the Agency, and I hope to God that this  
9 changes under the Obama Administration. Thank  
10 you very much.

11 DR. FISCHHOFF: Thank you for  
12 coming to speak to us. If I speak about the  
13 division of responsibility with FDA, our  
14 Committee as you may know is just an advisory.

15 Other people make those decisions. I think  
16 the role that we play is in helping FDA to  
17 identify what is the information that ought to  
18 be there so that people can make appropriate -  
19 - to be available to consumers so that they  
20 can make appropriate decisions and then  
21 whether that information has  
22 -- whether the communication has met the

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1 standard of adequacy. So that's our piece.  
2 And if we accomplish our job there will be  
3 better and more useable information available.

4 MS. LIVERSIDGE: May I just make  
5 one comment to that?

6 DR. FISCHHOFF: Yes.

7 MS. LIVERSIDGE: If you would just  
8 take my suggestion that you had a consumer who  
9 lost someone to an atypical antipsychotic who  
10 has never been invited by the FDA nor has  
11 anyone I know ever been invited to speak to  
12 the FDA about the failure of risk  
13 communication in our case.

14 DR. FISCHHOFF: Thank you. Thank  
15 you for speaking to us.

16 Our final public speaker is Kala  
17 Paul.

18 DR. PAUL: My name is Kala Paul and  
19 I'm a physician. I'm a neurologist and I'm  
20 president of the Corvallis Group. It's a  
21 company providing consulting in risk  
22 management and risk communication. And I

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1 thank the panel for allowing me to have these  
2 few minutes to speak on behalf of consumers.

3 I am a consultant to the  
4 pharmaceutical industry in writing literature  
5 such as the health information that we've been  
6 talking about. And I feel that right now I'm  
7 sort of in the position of the CMI. I have  
8 two minutes to grab your attention and convey  
9 an important message.

10 I also need to do some full  
11 disclosure. I am not here on behalf of anyone  
12 in the industry. I'm speaking for myself on  
13 behalf of my experience working with patients  
14 and iterative testing of medical information  
15 and product information and I have paid all my  
16 taxes.

17 What we have seen when we write and  
18 test this material and we do it as it was  
19 suggested by Dr. Raynor, we do it in an  
20 iterative fashion. We do it across all kinds  
21 of platforms, medication guides, patient  
22 package inserts, instructions for use. We do

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1 it across a variety of therapeutic areas and  
2 what we see is so important to see in the  
3 people who have problems with health literacy.

4 I don't think anybody can  
5 overestimate how difficult it is for some  
6 people to understand the information that you  
7 put in front of them. They don't read if the  
8 sentences are too long. They don't understand  
9 if the words are too big. And if you've got  
10 words in sentences that go across the whole  
11 page, they simply skip it.

12 The issue for what you have to do  
13 as a Committee is not just make changes in  
14 that, but make changes where you look and see  
15 what the result is with these patients when  
16 you make those changes. And I'm speaking  
17 particularly for things like numeracy, which  
18 is so fraught with problems where you think  
19 you are making a difference by putting in a  
20 number and all you've done is opened a  
21 different can of worms. With signage, where  
22 you think that you've made something clear and

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1 people misinterpret it, particularly those  
2 with low literacy.

3           So what I'm asking you when you  
4 consider coming together to make a decision  
5 that one piece of information written one way  
6 with the FDA's approval is possibly the best  
7 way to go, there's my bias, that you be very  
8 careful about making suggestions that do  
9 something, but you don't know what they do  
10 until you've tested them, specifically in  
11 patients -- low-literacy patients and in the  
12 elderly to see if what you've done has  
13 actually improved and made a difference in  
14 that document.

15           Again, the answer is as was  
16 mentioned before, you can make a beautiful  
17 document. It's getting it out there too  
18 that's going to make a bigger difference if  
19 that's the way we are choosing to communicate  
20 health information.

21           Thank you again for the opportunity  
22 to speak.

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1 DR. FISCHHOFF: Thank you again for  
2 joining us. We now have a short video from  
3 one of our guest members. We have on the  
4 panel today members of the Risk Communication  
5 Advisory Committee, as well as members of  
6 other FDA, several members of other FDA  
7 Advisory Committees who are doing double duty  
8 and Terry is one of them.

9 DR. DAVIS: These are two-minute  
10 clips and I wanted to bring them to illustrate  
11 problems people have understanding  
12 prescription and over-the-counter drug  
13 information. And the first clip people are  
14 all reading below ninth grade and in the  
15 second clip, they have all literacy levels,  
16 but they're still struggling to understand the  
17 information.

18 DR. ZWANZIGER: Terry, I'm not  
19 sure. There's one called "Easy To Make  
20 Mistakes" --

21 DR. DAVIS: That's the second one.  
22 So the second one shows that it's easy to

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1 make a mistake.

2 (The following video was played and  
3 was transcribed as follows:)

4 "MALE VOICE: It says take one  
5 capsule.

6 FEMALE VOICE: That's right, one  
7 capsule.

8 MALE VOICE: One capsule. I don't  
9 know --

10 FEMALE VOICE: Twice.

11 MALE VOICE: Twice daily.

12 FEMALE VOICE: Okay, so how would  
13 you take this?

14 MALE VOICE: Well, it's not on  
15 there to tell you how to take it. They say  
16 take it twice daily, but it don't say what  
17 time to take it. Do not take with --

18 FEMALE VOICE: Dairy.

19 MALE VOICE: Dairy prod --

20 FEMALE VOICE: Products.

21 MALE VOICE: Products, okay.

22 FEMALE VOICE: Do not take dairy

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1 products --

2 MALE VOICE: On a case --

3 FEMALE VOICE: Antacids.

4 MALE VOICE: Antacids.

5 FEMALE VOICE: Or iron --

6 MALE VOICE: I can't see without my  
7 glasses on. Iron.

8 FEMALE VOICE: Iron preparation.

9 MALE VOICE: Preparation.

10 FEMALE VOICE: What are iron  
11 preparations?

12 MALE VOICE: I don't know.

13 FEMALE VOICE: I don't either.

14 FEMALE VOICE: I had chlamydia  
15 which I didn't treat right away and it led to  
16 my PID. Really painful. I was in the  
17 hospital like for four or five days.

18 FEMALE VOICE: You were seen and  
19 diagnosed with it?

20 FEMALE VOICE: Right.

21 FEMALE VOICE: But then you didn't  
22 take the medicine?

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1 FEMALE VOICE: I didn't take all of  
2 it.

3 FEMALE VOICE: You took some of it?

4 FEMALE VOICE: Some. I ain't  
5 finished it.

6 FEMALE VOICE: Didn't finish it.  
7 Why was that?

8 FEMALE VOICE: I just felt better.

9 FEMALE VOICE: You were feeling  
10 better, so you didn't take it.

11 FEMALE VOICE: No pain or nothing  
12 like that.

13 FEMALE VOICE: Did you understand  
14 that you needed to take more of than you had  
15 and you just didn't do it?

16 FEMALE VOICE: No. I ain't know I  
17 needed to take all of it.

18 FEMALE VOICE: It says three-  
19 fourths tablespoon three times a day until all  
20 taken, so I guess I'm -- I don't know if I'm  
21 supposed to get it by the mouth, ear or what.  
22 And I don't know if I'm supposed to shake it.

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1       So I'm just going to fill it up and give one  
2       dose and then another dose. I don't know how  
3       I'm supposed to give this to her."

4                       (End of video transcription.)

5               DR. DAVIS: So all these people had  
6       low literacy. Now this next group, people  
7       have all literacy levels, but they're still  
8       struggling with the information we're  
9       currently giving them.

10                   (The following video was played and  
11       was transcribed as follows:)

12               FEMALE VOICE: So what you do, you  
13       come out of that room, that examination room  
14       with this intelligent woman or man thinking,  
15       God, I hope I don't make a mistake with my  
16       medicine because I did not understand anything  
17       he or she is saying to me.

18               FEMALE VOICE: When your children  
19       have fever, what do you usually give them?

20               FEMALE VOICE: Motrin or Tylenol.  
21       Only Motrin because that's what my doctor  
22       recommended.

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1 FEMALE VOICE: How old is your  
2 daughter?

3 FEMALE VOICE: She is four.

4 FEMALE VOICE: She's four.

5 FEMALE VOICE: I would give her the  
6 four to five -- a tablespoon and a half.

7 FEMALE VOICE: You gave her a  
8 tablespoon and a half. Can you find where it  
9 tells you how many you take, the dosage?

10 MALE VOICE: Three a day?

11 FEMALE VOICE: Take three to two  
12 milliliters and there's something I want to  
13 point out. I don't actually read this because  
14 I know what it says now, so if I had to sound  
15 it out, if it was before I knew it, because  
16 I've heard it so many times, I would not be  
17 able to read that.

18 FEMALE VOICE: Okay.

19 FEMALE VOICE: Every three to four  
20 hours as needed for pain.

21 FEMALE VOICE: What's a milliliter?

22 FEMALE VOICE: I don't know.

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1 FEMALE VOICE: The medication that  
2 was given to her was not explained. Well, we  
3 didn't use it.

4 FEMALE VOICE: In fact, she ran out  
5 of her high blood pressure medicine, so she  
6 didn't take it. She didn't call me to tell me  
7 to fill it. So finally I found out that she  
8 had not been taking it. I said mother, you  
9 can't do that. You have to keep taking that  
10 high blood pressure medicine.

11 MALE VOICE: When you get your  
12 prescription you get all this stuff and just  
13 throw it away because my eyes are not that  
14 good.

15 FEMALE VOICE: And then it says  
16 discontinue. What does that mean?

17 FEMALE VOICE: I don't know.

18 MALE VOICE: How many times do you  
19 take these thyroid pills?

20 FEMALE VOICE: Once a day.

21 MALE VOICE: Okay, do you take one  
22 of each of these?

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