

1 signed up to speak. If there is anybody else,
2 we'd ask each of you to restrict yourselves to
3 no more than 10 or 12 minutes. If there are
4 additional people who would like to speak,
5 there is a little confusion with the sign-in
6 list, come up and let Lee know and we will
7 find the time to work you in.

8 So the speakers are in this order:
9 Dennis Weaver from the National Association of
10 Chain Drugstores, Paul Johnson from Wolters
11 Kluwer Health Clinical Solutions, Tony Lee
12 from the National Community Pharmacists
13 Association, Marcie Bough from the American
14 Pharmacists Association, Gerald McEvoy of the
15 American Society of Health Systems Pharmacists
16 - some of these people wear more than one hat,
17 so I'm just giving you one, Diana Zuckerman,
18 president of the National Research Council for
19 Women and Families, Saul Shiffman, and Jeffrey
20 Fetterman from ParagonRx, and Pam Bundy of Eli
21 Lilly.

22 So if there is anybody else, come

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1 up and see Lee, and let me invite to the
2 podium - to the mike I guess, okay - Dennis
3 Wiesner from the National Associations of
4 Chain Drugstores. So we welcome you all and
5 look forward to your comments.

6 MR. WIESNER: Thank you.

7 Members of the Risk Communications
8 Advisory Committee, good afternoon. And first
9 off, towards your first comments, I'm not
10 receiving any type of financial remuneration
11 for my comments today.

12 I'm Dennis Wiesner, senior director
13 of privacy, pharmacy, government industry
14 affairs, at HEB, the regional food-drug chain
15 located in Texas with a little over 300 retail
16 stores.

17 I'm here on behalf of the National
18 Association of Chain Drugstores, representing
19 the views of the chain pharmacy community, and
20 appreciate this opportunity to share our
21 experiences in our stores as it relates to
22 written information for our patients.

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1 We've been pleased to work with the
2 FDA over the years to address the issues
3 related to written prescription information
4 that is distributed by pharmacies to our
5 patients.

6 We thank you for the opportunity to
7 offer our suggestions as the committee works
8 with the FDA to consider next steps to improve
9 the communication and content of information
10 around prescription drugs for our patients.

11 As a pharmacist, I understand that
12 many patients rely on written information
13 distributed to them with their prescriptions.

14 At the same time many of these patients
15 discard this information they receive without
16 ever reading it or in many cases, after only
17 reading portions of that.

18 The written materials are obviously
19 intended to provide patients with information
20 about their medications, such as why are they
21 on the medication? What should they expect?
22 Potential adverse side effects. And of course

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1 how to use it properly to adhere to their
2 physician's instructions.

3 These are the typical questions
4 that most patients ask and information they
5 seek when they pick up a prescription from the
6 pharmacy or the pharmacist.

7 Pharmacists are trained to convey
8 this information in a succinct manner, using
9 layman's terms when at all possible. Any
10 written prescription information provided to
11 patients should complement that verbal
12 communication and be presented in a very
13 similar manner to achieve the optimum
14 understanding by the patient or, in many
15 cases, their caregivers.

16 Pharmacists instruct the patients
17 to read the information and to call back if
18 there are any additional questions.
19 Unfortunately the current system does not
20 afford patients with succinct easily
21 comprehensible information, and that
22 unintentionally creates barriers to the proper

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1 use of this information received.

2 First, many times there is just too
3 much information. Consider as an example a
4 patient that may be receiving a prescription
5 for an antidepressant, and we are only talking
6 about one medication. In the current system
7 they may receive the following: they may get
8 consumer medication information, the CMI, they
9 may get a patient package insert, a PPI, and
10 they may get a MedGuide. And there may be
11 other additional information that may be
12 provided at that time.

13 I actually went to one of my stores
14 to print out some of this information, and
15 just on an antidepressant, because of the
16 printout that came out, it ended up being nine
17 letter-sized pages, plus the accompany patient
18 package insert.

19 In more extreme cases some of the
20 medication guides that we actually print, the
21 Medguides, actually go as long as 15 or more
22 pages.

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1 Furthermore there are other
2 documents a patient could receive in addition
3 to these, such as messaging from the
4 manufacturer that may accompany the drug
5 product, how to use the product.

6 The amount of written prescription
7 information handed to the patient is just
8 frequently quite overwhelming. The patient
9 could easily leave the pharmacy with a
10 multitude of different information from
11 different sources that vary very much in
12 content and complexity.

13 Patients routinely question the
14 amount of paper they actually receive, with
15 the end result, again, of either more
16 confusion, or a failure to really read the
17 information properly.

18 Even if there is critical
19 information to be conveyed, such as adverse
20 side effects, repeated presentation of that
21 information in multiple documents
22 unnecessarily discourages the patient from

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1 taking the drug sometimes or reading the
2 documents.

3 Even if they - especially of the
4 documents do not highlight to the same degree
5 the reasons why the medication is being taken.

6 The problems created by the volume
7 and the length of the information are only the
8 very first challenges to patient acceptance.
9 As the CMI survey results point out the
10 difficulty in comprehending CMIs continues to
11 hinder this program and contributes to the
12 issues we are experiencing with the patients
13 and their understanding.

14 The complexity is also a problem
15 with the other written information that may
16 additionally be provided.

17 Another challenge is that the type
18 of information that must be communicated is
19 inherently very difficult to convey. It's
20 very complex. Complex clinical information is
21 not easily transmitted to simple layman's
22 terms. Clinical knowledge about drugs, or

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1 therapy, expands, and this is added to the
2 various written documents, and they are
3 updated for this new information.

4 And under the current system it's
5 often difficult to sometimes really strike
6 that balance between the information the
7 patient finds useful, and then
8 correspondingly, the information that is
9 useful to the practitioner or the clinical
10 community, but not necessarily the patient.

11 The committee should keep in mind
12 that whether patients retain documents once
13 they leave the pharmacy depends largely on
14 consumer behavior and past experiences. Many
15 patients may not hold on to their written
16 information for future review primarily
17 because it is difficult for them to sort out
18 which documents are actually important.

19 This can occur increasingly with
20 the more medication a person takes. And
21 again, we come back to the term of being a
22 little bit overwhelmed by the actual paper.

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1 In many cases any impression in a
2 consumer's mind about the need to retain these
3 documents for future reference is diminished
4 as they receive the same documents over and
5 over with each refill of the medication.

6 In focus group discussions at my
7 company among daily prescription drug users,
8 and feedback that is received by our
9 pharmacists in our pharmacies, patients voice
10 dissatisfaction or are confused about the
11 amount and content of information they
12 currently receive, and many times they refer
13 to it as the amount of paper is actually very
14 wasteful.

15 One thing I haven't mentioned, and
16 I want to just say for a quick moment, is the
17 point is the simple logistics in our
18 pharmacies of how we manage all this material
19 and the processes necessary to ensure delivery
20 to the patient.

21 It generally involves a combination
22 of automatically printing the materials

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1 coupled with manufacturer supplied documents.

2 It is a real challenge for this information
3 to be aggregated and distributed each and
4 every time to our patients.

5 As the committee considers way to
6 improve these efforts, some basic questions
7 must be answered. What is the ultimate goal?

8 Is it to improve patient adherence and
9 understanding of the risks their drugs may
10 pose? And several others of a similar nature.

11 If so, then the FDA must seriously
12 consider whether providing patients and
13 caregivers with a multitude of duplicative
14 information as required currently truly
15 achieves that goal.

16 Pharmacies want to provide useful
17 information to patients to help them take
18 their medications appropriately. But in
19 addition to outstanding questions concerning
20 the utility of CMI as revealed by the recent
21 survey results, FDA's current policies for the
22 distribution of MedGuides continues to stifle

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1 our goal to ensure that patients receive
2 concise and easy to understand information.

3 As we discussed during the 2007
4 hearing on MedGuides, as more and more drugs
5 require MedGuides, the program is expanding in
6 a manner that is inconsistent with the purpose
7 of the program when it was created.

8 Every if these efforts were
9 improved individually, there are still the
10 issues of redundancy and complexity.

11 Therefore the FDA should move
12 towards addressing common issues raised by all
13 of the current initiatives, and help create a
14 solution that would help achieve the ultimate
15 goal of enhancing patient care.

16 There is a consensus in the
17 pharmacy and patient communities that a short,
18 simple, easy to understand document should
19 replace all written prescription information
20 patients currently receive with their
21 prescriptions.

22 NACDS recently joined our pharmacy

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1 and patient care partners on a citizens'
2 petition urging the FDA to issue guidance
3 permitting pharmacies to distribute a concise,
4 plain language, FDA-approved single page
5 document to replace the current written
6 information provided to patients.

7 Pharmacies should be permitted to
8 distribute the single-page document in lieu of
9 CMIs, MedGuides, and other labeling that are
10 currently being distributed.

11 Such a document should be one page,
12 except in rare circumstances, and should focus
13 on the most important information for the
14 consumer to use the drug safely and
15 effectively, and most importantly,
16 instructions on where the patient may obtain
17 more detailed information about that drug.

18 The pharmacist is always available,
19 but it is important that they have another
20 reference to go to.

21 The citizens' petition, which we
22 incorporate into our comments by reference,

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1 provides further detail about our proposal for
2 a one-document solution.

3 We urge the Risk Communication
4 Advisory Committee to consider our petition,
5 and recommend the FDA to move toward a single-
6 document solution.

7 We would like to underscore our
8 pharmacies' commitment to partnering with the
9 FDA on this critical issue. We are prepared
10 to serve as your eyes and ears to evaluate
11 whether any reforms made to current efforts
12 are achieving their desired outcomes.

13 In that regard it would be
14 beneficial for this already distinguished
15 committee to enlist a community pharmacist as
16 a committee member. As the final point of
17 contact with the patient at the time of
18 dispensing and delivering prescriptions, a
19 community pharmacist would be able to provide
20 insights that otherwise might be missed.

21 I appreciate this opportunity to
22 speak before you, and pleased to take any

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1 questions.

2 DR. FISCHHOFF: Thank you very
3 much.

4 The protocol here is that we hear
5 from the speakers, and then if there is time
6 then perhaps there is an option for having
7 some comments to all of them.

8 So I think we'd be very happy to
9 speak with you, but the protocol is just we
10 hear from people.

11 So thank you for the very useful
12 comments. Thank you.

13 MR. WIESNER: Thank you.

14 DR. FISCHHOFF: Our next speaker
15 is Paul Johnson from Wolters Kluwer Health
16 Clinical Solutions.

17 MR. JOHNSON: Good afternoon. I'm
18 a senior clinical manager for Wolters Kluwer
19 Health. So I certainly hope they pay for my
20 expenses here today.

21 But I'd like to thank the committee
22 for the opportunity to speak. And I heard a

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1 lot of things today that I would very much
2 like to comment on, but 10 minutes is nowhere
3 near enough time to do that. So in my
4 prepared comments, I basically just wanted to
5 talk at a high level about the results of the
6 final report, and to talk about some of the
7 efforts that Wolters Kluwer Health has done to
8 further the CMI initiative as it has been, and
9 will continue to do as things move forward.

10 In 2001 there was 89 percent rate
11 of distribution, and 56 percent of those met
12 at the time the action plan criteria which was
13 being used as the standard to meet for CMI.
14 And in 2008 we met a goal of 94 percent
15 distribution with about 70 or 75 percent
16 usefulness, depending on the number used. And
17 with the print size, line spacing, ease of
18 reading being the most negative rated areas.
19 But yet there was a significant improvement in
20 the usefulness of the information, meaning
21 there was a significant improvement in the
22 content of that information.

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1 And so I think that some say these
2 results indicate that the private sector has
3 failed in providing information to the public,
4 but I believe that given the similar nature of
5 the two studies, and in comparison of the two,
6 these results actually should demonstrate a
7 significant further positive trend on the part
8 of the private sector over the last several
9 years. So although these results fall short
10 of the stated numerical goal of the action
11 plan, I think we need to recognize the
12 improvement and realize how and why it
13 occurred.

14 And I think as far back as 2002 and
15 after the results of the first survey, and
16 then 2002 when we had these meetings, data
17 providers kind of took all this information to
18 heart, and took efforts to improve the content
19 of their legacy CMI leaflets so that they
20 would at least contain the relevant clinical
21 information as outlined in the action plan,
22 and as has been asked here today, what are the

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1 standards for the criteria, and how are things
2 selected?

3 The information in the CMI leaflets
4 is derived directly from FDA information,
5 including the package inserts, patient package
6 inserts, medication guides, and whatever
7 pieces of information would be available. And
8 we believe we were successful in the effort,
9 and that it contributed to the content
10 improvement scoring in the survey.

11 But the problem that we have had is
12 that the users of our data, the pharmacy
13 software vendors, the self programmers, the
14 pharmacy end users, ultimately end up
15 controlling the formatting of the leaflets in
16 regard to the font size, the line spacing, and
17 these factors.

18 So since the older systems remain
19 largely in place, unchanged from the time of
20 the initial survey, and to date, and due to
21 the technical inability of many of these
22 pharmacy systems to format this data with

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1 bullets and bolding, we were not surprised by
2 the results of the formatting criteria result.

3 These unfortunately are the type of
4 leaflets that still represent the majority of
5 content found in the marketplace today and
6 that were evaluated in the survey.

7 Now although the content improved,
8 WK Health understood that this would not meet
9 action plan goals. So Wolters Kluwer Health
10 produced a new CMI database product
11 specifically designed to meet both - or to
12 meet the action plan content and format
13 criteria.

14 The action plan compliant CMI
15 database has been available in the
16 marketplace, and available, for pharmacies to
17 implement, for approximately 2-1/2 years, yet
18 we have expended significant effort to help
19 develop this project in order to get the type
20 of action plan compliant CMI into the hands of
21 the public. But despite its availability
22 there has been a lack of widespread adoption

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1 by pharmacies and system vendors.

2 We surmise that very little if any
3 CMI of this type was actually sampled in the
4 survey, and I provided examples of the
5 lisinopril and the metformin monographs from
6 this database that were in place at the time
7 of the survey along with the evaluation sheets
8 used in the assessment.

9 Although the adoption of this CMI
10 database product has been limited, there are
11 pharmacies that are distributing this CMI to
12 patients in the marketplace today as we speak,
13 and I believe that had more of this type of
14 CMI been distributed by pharmacies for this
15 survey it very likely would have been
16 successful in regards to both content and
17 format, and we wouldn't probably be here
18 today.

19 So given the results nonetheless,
20 we all now find ourselves entertaining the
21 same questions and concerns that we had
22 originally hoped that the action plan would

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1 answer, and we are trying to determine where
2 to go from here.

3 I think as has been said today, we
4 can pretty much all agree that as health
5 professionals charged with caring for
6 patients, we have a responsibility to work
7 with them in order to obtain the best possible
8 outcome in their health care.

9 I think we all agree that this
10 requires patients to be adequately informed
11 regarding their therapy, be it medical or
12 medicinal therapy, so that they can work
13 together with their doctor or pharmacist to
14 choose courses of therapy that are right for
15 them. But it seems that where the differences
16 of opinion tend to lie is how to best make
17 that happen.

18 In 1996 the private sector put
19 together plan for what it believed to be
20 useful information for patients. The
21 secretary of health and human services agreed
22 with the criteria that were set forth, and

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1 agreed with that plan, and based on the
2 references associated with some of the
3 announcements and some of the articles
4 associated in the communications from FDA
5 regarding this meeting, there is obviously now
6 renewed interest in completely reevaluating
7 ore redefining these criteria, as well as
8 conducting further research to see what
9 patients really want in their CMI.

10 Prior to coming to the meeting I
11 took a look at the transcript of the Drug
12 Safety and Risk Management Advisory Committee
13 meeting from July of 2002 regarding CMI. At
14 that time there was discussion over topics
15 such as the need to conduct further research
16 to determine what truly constitutes useful
17 information for consumers. Should it be
18 customized? How much information is too much?
19 How much information is too little? What can
20 a consumer understand? Should the CMI be a
21 synopsis of selected key information to be
22 used in addition to verbal patient counseling?

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1 Or should it be the single document that
2 patients can rely on for all the drug
3 information they need to know in the absence
4 of patient counseling?

5 And again as we just heard do
6 patients even use the information?

7 Although the survey results did not
8 meet the goal, I emphatically reject the
9 notion that the private sector initiative was
10 a failure. I think all the things that we are
11 talking about here today really just
12 demonstrate the need for really just
13 determining what it is that we want for
14 patients to have.

15 It's been demonstrated that once
16 criteria are defined as they were in the
17 action plan data providers definitely stepped
18 up to develop enhanced content to meet that
19 criteria, as was definitely noted in the
20 survey results.

21 I think that the results also
22 demonstrate a very efficient distribution

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1 system for patient information that has been
2 built collectively by the data providers, by
3 pharmacy software vendors and self
4 programmers, and there has been at least one
5 successful effort on the part of a data
6 provider, although not reflected in the
7 survey, to develop CMI that was compliant with
8 the standards that were at least in place at
9 the time that that information was developed.

10 So given the success I think it is
11 definitely reasonable to research and evaluate
12 how we can continue to improve the information
13 that patients get, just as it was reasonable
14 to do that in 2002. However, we absolutely
15 should not throw the baby out with the
16 bathwater. I think it would be a huge mistake
17 to ignore all the positive progress that has
18 been made in favor of the public as a result
19 of the action plan initiative based just on
20 the results of this study.

21 There have been significant strides
22 made by the private sector, and the effort

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1 continues still today. We need to build on
2 the successes that currently exist, and I
3 encourage FDA to continue to closely work with
4 the stakeholders on this, even more closely
5 than they have in the past.

6 We have been, and remain, as
7 committed as ever to the provision of useful
8 drug information for patients.

9 Thank you very much.

10 DR. FISCHHOFF: Thank you as well.

11 Thank you for your comments.

12 Our next speaker is Tony Lee from
13 the National Community Pharmacists
14 Association.

15 Welcome.

16 MR. LEE: Thank you very much.

17 My name is Tony Lee. I'm director
18 of public policy at the National Community
19 Pharmacists Association.

20 I am an attorney, but I am
21 definitely not a pharmacist, and I don't even
22 play one at our association.

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1 We represent 23,000 independent
2 pharmacies, small community pharmacies in the
3 U.S. We have about 55,000 pharmacists and
4 300,000 employees.

5 We thank the committee for this
6 opportunity to testify before you, and we
7 would definitely welcome working with you more
8 in the future.

9 I was not able to be here this
10 morning, but I do understand from the
11 discussions that apparently not much of the
12 discussion was focused exactly on what the
13 patient wants or needs, and that is the focus
14 that we have now. I am going to be echoing a
15 lot of the comments made by the gentleman with
16 NACDS. We didn't consult together, but we did
17 of course work with NACDS to present the one
18 document petition along with other groups. So
19 naturally that is our punch line: we believe
20 in the efficacy of that one document solution.

21 We believe that patients want to
22 know at least four simple things, maybe only

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1 four simple things: what the drug is and what
2 it does; how to take the drug effectively; the
3 potential side effects; and then just a number
4 to contact for any questions besides the
5 pharmacy or the pharmacist or the physician.

6 The problem we see is just despite
7 all the best intentions, it's a systematic
8 problem. The guides, the patient package
9 inserts, and CMI's, are just too technical,
10 long and not user friendly, and they just
11 cannot effectively present the information
12 that patients are seeking.

13 Particularly with the CMI, or first
14 with the CMI, it's too length, and you know
15 that often in the pharmacy it is stapled onto
16 the pharmacy bag with the prescription, and
17 the information is too technical.

18 This is a lot of verbiage, but what
19 it boils down to is, we do appreciate the
20 attempts to pare down the CMI, but even there
21 when you are making your policy choices, we
22 feel that the current version of the CMI and

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1 this was done in the CDR report of 2008, you
2 see the site there, it showed that the
3 emphasis or the amount of time submitted on
4 safety and effectiveness notices did serve to
5 take away from emphasizing and enforcing
6 adherence which we believe is the most
7 important part of the information.

8 And we believe that CMI is simply
9 just not readable and comprehensible enough
10 for the patient. We just have heard too many
11 and seen too many reports of consumers just
12 throwing away the information, or even if they
13 take it home not reading it. We want it to be
14 concise and readable enough so that it
15 encourages communications with the pharmacist
16 and the physician, and so you can have the
17 effective counseling and care that would help
18 the patient most.

19 In terms of practical matters, we
20 do have an issue about our - especially with
21 independents on being able to print out all
22 the information that is on the CMI. Our

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1 information software templates are programmed
2 to print out only one page of information, and
3 oftentimes the CMI is longer than that, and
4 sometimes our pharmacies do not have the
5 necessary equipment to print our the necessary
6 information. So we do have some costs and
7 practical concerns there.

8 Now we understand that these
9 medication guides are going to be much more
10 specific and technical, and so there is even
11 more of a problem there. They are supposed to
12 be - have specific information on the safe and
13 effective use of the medicine, but they are
14 just clinical highly technical descriptions of
15 the chemical content of the medications. And
16 as FDA has heard, they are often duplicative
17 with the CMI.

18 We understand the reliability
19 concerns, but this document in particular has
20 become something that is just a legal document
21 as opposed to something that really helps the
22 patients and consumers.

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1 Also we believe that PPIs are not
2 effective. The font is often quite small, and
3 the information is likewise not user friendly.

4 Our punch line again is the
5 solution we are supporting is the one document
6 solution, the citizens' petition. Which calls
7 for the voluntary use of the standardized
8 document in lieu of other drug information
9 documents.

10 The second bullet - this is not
11 prescriptive; this is just one idea that has
12 been talked about, so I don't mean to
13 overemphasize that and I urge you to consider
14 the one document petition in its entirety.
15 But one example, one possibility is a document
16 on one double-sided piece of paper in three
17 columns to contain the information - there
18 could be other forms too - and in certain
19 cases it could expand beyond that. But we
20 believe that would be the correct basic
21 format.

22 Again we believe that clear and

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1 less is more, and those are the terms that I
2 start off with in the beginning that we
3 believe are necessary: what the drug does, how
4 to take it, the potential side effects, and
5 then a number of questions beyond just the
6 pharmacist and pharmacy, and the physician.

7 So again we believe that just
8 systematically it's just near impossible to
9 get the medication guides, PPIs, and CMIs to
10 work together in a nonredundant way to get the
11 patient the information that is really
12 effective. It is just not going to be clear
13 and concise enough.

14 We believe that MedGuides, PPI and
15 CMI, they have too much - they have TMI. And
16 you know it's an example, a real life example,
17 not to be flip, but when you do have all those
18 documents, there is an example, a patient who
19 may not really understand, or even one that is
20 quite informed will be overwhelmed by the
21 information. And if you are talking about an
22 anti-depressant drug, you see over and over

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1 again that there are risks on suicide, that is
2 going to affect the patient, maybe affect
3 adherence inappropriately.

4 And sometimes the material is not
5 only duplicative but sometimes it is
6 conflicting because the emphasis in each
7 document.

8 Again we do appreciate that the FDA
9 has addressed this issue on these documents
10 many times in the past, but we just believe
11 that systematically that there is a problem
12 with that.

13 And thank you for your time.

14 DR. FISCHHOFF: Thank you very
15 much.

16 Our next speaker is Marcie Bough
17 from the American Pharmacists Association.
18 Thank you.

19 MS. BOUGH: Good afternoon.

20 Again, my name is Marcie Bough. I
21 am a pharmacist with the American Pharmacists
22 Association where I serve as director of

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1 federal regulatory affairs.

2 APhA is the first established and
3 largest professional pharmacists organization
4 and we represent over 62,000 pharmacists
5 providing care in all different practice
6 settings.

7 I have no conflict of interest for
8 this meeting.

9 APhA appreciates that the committee
10 is focusing on the different types of
11 communications that patients receive at the
12 pharmacy, including medication guides, PPIs,
13 and CMIs.

14 We support the agency's ongoing
15 efforts to reevaluate and improve the patient
16 communication and information system.

17 Pharmacists are committed to
18 improving patient health through the
19 appropriate use of both prescription and over
20 the counter medications. Pharmacists help
21 patients manage their medications through
22 patient education activities such as written

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1 information, oral consultation and medication
2 therapy management.

3 In addition to counseling patients,
4 medication guides, patient package inserts and
5 CMIs, are tools that pharmacists use to
6 provide patients with information. Ideally
7 patients would use these tools to learn more
8 about the medications they are taking.
9 Unfortunately, we know that these three
10 documents, patients are getting too much
11 information on too many pages that often is
12 overwhelming to them, rather than helping them
13 educate about their medications.

14 As a result much of the information
15 may be stapled to a prescription bag that goes
16 unread or is thrown away without notice or
17 review.

18 In addition the ineffective system
19 is burdensome on the pharmacist's time,
20 workflow, and ability to provide patient care.

21 As an example of what can be stapled to the
22 prescription bag when they leave the pharmacy,

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1 here is an example of a CMI document on the
2 professional package labeling, and a two-page
3 medication guide that would be stapled with
4 that.

5 Another example is, again, the CMI
6 information printed out with labeling, but
7 then a 13-page medication guide that goes
8 along with that.

9 This varies because these don't
10 even include some of the patient package
11 inserts that could go with that. But as an
12 example, there is wide variation in the amount
13 of information that patients may receive.

14 I will leave this with FDA staff
15 for your review.

16 The ultimate goal with our meeting
17 here and in discussions with all of this
18 information is to make the system more
19 effective through reengineering and
20 streamlining, possibly through a one-document
21 communication tool.

22 However this change would take time

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1 to develop. In the meantime we suggest some
2 steps to improve the current system in the
3 near future.

4 First focusing on MedGuides, as
5 stated in the FDA's June 2009 medication guide
6 hearing, APhA continues to be concerned with
7 increasing number of MedGuides. Yesterday the
8 number of medication guides listed on the
9 FDA's website is 152 or so, and that may not
10 even capture all of them that are out there.

11 Lack of standardization, logistical
12 challenges in the pharmacy supply chain, and
13 in the pharmacy, impact on distribution and
14 pharmacy workflow, cost shift to pharmacy for
15 printing the pharmacy labeling and dispensing
16 system, readability and patient understanding;
17 and lack of evidence that they are useful in
18 achieving the intended outcomes. As we
19 described at the 2007 hearing and in 2008
20 comments to the Office of Management and
21 Budget on current estimates and burdens for
22 MedGuides, we asked that you consider the

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1 following recommendations to improve the
2 existing program.

3 One, remove the requirement to
4 provide MedGuides with every fill, and reduce
5 the distribution to the first fill per year of
6 a prescription at a pharmacy; better enforce
7 the requirement for manufacturers to supply
8 pharmacies with an adequate number of
9 medication guides.

10 Three, streamline the alternate
11 reorder system so pharmacies could call one
12 number or go to one website to reorder all
13 medication guides.

14 Four, streamline the program to
15 allow pharmacy software vendors more
16 flexibility to integrate the information into
17 CMI, or through an electronic communications
18 avenue. However, the agency must address how
19 printing expenses would shift from
20 manufacturers to pharmacies.

21 Scientifically evaluate the
22 usefulness and effectiveness of the program to

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1 see if it is achieving intended outcomes, and
2 if patients understand why they are receiving
3 medication guides.

4 Limit the burdens to the health
5 care system. This is especially important as
6 MedGuides and other tools to help manage risk
7 are being included as part of the risk
8 evaluation and mitigation strategies, or REMS,
9 that are part of the FDA process.

10 Seven, consider ways that
11 prescribers could be better informed about
12 medications that require MedGuides, and
13 explore opportunities for prescribers to
14 provide them the information to patients at
15 the point of prescribing.

16 Second, focusing on CMI, CMI is the
17 patient information that is voluntarily
18 developed by private entities and third party
19 vendors and provided by pharmacists as written
20 information processed through the
21 functionality of the pharmacy's computer
22 software system and printed as part of the

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1 computer generated prescription label.

2 Based on today's marketplace
3 pharmacies can choose with whom they contract
4 out of a small number of CMI vendors.

5 It is important to note that
6 pharmacists generally do not have much control
7 or flexibility in changing the content of CMI
8 from the vendors. Changes are generally
9 limited to font size, number of page
10 printouts, and the amount of information
11 printed when the prescription is dispensed.

12 Pharmacists continue to hear from
13 their patients that they get too much
14 information; the material is hard to read or
15 understand; and that the font size is too
16 small, and formatting is confusing.

17 And we have seen from examples that
18 there is a wide variety of the amount of CMI
19 that is printed.

20 The feedback from FDA's December
21 2008 CMI study showing that 94 percent of the
22 patients are receiving the information, but

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1 only 75 percent was useful. Unfortunately,
2 that 75 percent result certainly does not meet
3 the 95 percent goal set in place by Congress
4 in '96 and outlined in the FDA guidance in
5 2006 to pharmacies.

6 We agree with the study finding
7 that some areas need more improvement;
8 specifically the consistency and format length
9 and the amount of information provided in CMI.

10 Because pharmacists have little
11 flexibility in adjusting the CMI, the burden
12 falls on vendors to improve. Therefore, APhA
13 recommends that the agency meet directly with
14 the small number of CMI vendors to improve the
15 content design by, one, further defining areas
16 of the existing guidance that have not been
17 met; two, clarifying that all eight of the
18 criteria for defining useful information be
19 printed in CMI; three, specify that areas may
20 or may not be customized or altered; four,
21 specifying a more user-friendly format and
22 font and literacy standards that must be met

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1 in CMI.

2 In addition we recommend FDA
3 clarify the types and amounts of marketing
4 and/or targeted messaging information that can
5 be included in CMI. Again, there is a wide
6 variety of the amount of information that gets
7 added to CMI.

8 We also recommend that the agency
9 explore the possibility of creating a system
10 that verifies which CMI vendors meet the FDA
11 recommended guidelines for producing useful
12 CMI. Such a system could serve as a tool to
13 assist pharmacies when choosing a CMI vendor
14 for a third party contractor.

15 Third, regarding patient package
16 inserts with the part of the approved product
17 labeling that are generally attached to the
18 prescription packaging itself.

19 However some products require the
20 pharmacists to remove or cut the PPI from the
21 professional labeling in order to dispense
22 that information to the patient.

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1 This lack of standardization for
2 the products that have PPIs creates workflow
3 challenges and burdens for pharmacy staff.
4 While we appreciate the importance of PPIs, we
5 feel that the information that they include
6 could be blended into a stream blind patient
7 communication tool.

8 Fourth, looking prospectively
9 towards a monumental change, one of the most
10 important concepts that the advisory committee
11 and FDA could address is ways to standardize
12 the system so that all patient information for
13 a specific medication could be integrated into
14 one document when they pick up their
15 prescription.

16 The information should be concise,
17 bulleted, easy to read, and maintain a balance
18 of benefit and risk information.

19 Moving in this direction would help
20 streamline the logistics and workflow within a
21 pharmacy practice setting, and allow more time
22 for patient care.

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1 Such a document would also need to
2 include additional sections on risk management
3 for information of those medications that
4 require a MedGuide or other risk management
5 tool. They would need to include a reference
6 for talking to the health care provider or
7 pharmacist of any questions that they may
8 have, and include reference to an online set
9 of materials or area for additional
10 information.

11 However, as supportive of this
12 concept as we are, it must not be implemented
13 without addressing the potential cost shift to
14 pharmacy due to printing costs. And as a
15 point of clarification with discussion of the
16 citizen petition, while we support the concept
17 of that citizen petition, AphA itself did not
18 actually sign on as a petitioner.

19 Finally in response to the several
20 discussion topics proposed to the committee,
21 APHA offers the following suggestions:

22 Consider building upon the success

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1 of the drug facts label, a nonprescription
2 products as a way to reformat patient
3 information for prescription medications in an
4 easy-to-read standardized format.

5 Consult with researchers and
6 writers within FDA's own office of women's
7 health who have created easy to read health
8 information pamphlets that include an overview
9 of what patients need to know about the
10 medications for certain conditions.

11 The information is developed from
12 FDA approved product labeling, is written to a
13 fourth to sixth grade reading level for easy
14 patient understanding; and is well formatted
15 and focused on safe medication use.

16 For the committee's benefit, I have
17 left two folders of materials from the Office
18 of Women's Health with FDA staff for your
19 review.

20 Ensure the effectiveness of patient
21 information in evaluating, so that efforts
22 used to create information is equally matched

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1 by efforts to evaluate the effectiveness and
2 level of patient understanding.

3 Again, we need to see some outcomes
4 from the process of all of this to show we are
5 actually meeting intended outcomes.

6 Again, we need to recognize that
7 pharmacists use written information as an
8 adjunct to oral communication with the
9 patient, not as a replacement to direct
10 pharmacist provided patient care.

11 Finally recognizing the data shows
12 pharmacists are often considered by patients
13 to be one of the most trusted health care
14 providers. Studies show that patients working
15 with pharmacists as a coach through programs
16 such as the diabetes 10-city challenge, have
17 improved medication adherence and decreased
18 adverse events.

19 Medication therapy management is
20 one of the most important and evolving
21 initiatives within our profession, and serves
22 as a way for patients to manage their

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1 medications.

2 As the role of the pharmacist is
3 further integrated into direct patient care,
4 medical home models and health care reform
5 activities, we feel that pharmacists, as
6 medication experts on health care teams, are
7 well positioned to provide patient education,
8 risk benefit information, and improved
9 medication use and outcomes to help reduce
10 overall health care costs.

11 In conclusion we believe that FDA
12 could make changes to the existing program
13 right now. However we strongly urge the
14 agency to consider how it can reengineer the
15 entire written prescription drug patient
16 information system, and the requirements, to
17 achieve one document for each medication.

18 Thank you.

19 DR. FISCHHOFF: Thank you.

20 Our next speaker is Gerald McEvoy
21 from the American Society of Health System
22 Pharmacists. Welcome.

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1 DR. McEVOY: Good afternoon.

2 I am Gerald McEvoy. I am the
3 assistant vice president of drug information
4 at the American Society of Health System
5 Pharmacists. And there I also serve as
6 editor-in-chief of both our professional drug
7 information, which was actually one of the
8 compendia that was used in the study, HFS drug
9 information, as well as our consumer
10 medication information.

11 So as part of disclosure I want to
12 make that clear.

13 The consumer medication information
14 that we provide unlikely was part of the
15 evaluation--in fact, I'm fairly confident that
16 it was not, because it is principally deployed
17 electronically, as opposed to in print, in
18 pharmacies.

19 ASHP is a 35,000 member
20 professional and scientific society, and we
21 have long had as one of our principal missions
22 helping people make the best use of their

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1 medicines.

2 We also have a very long record of
3 evidence based drug information publishing,
4 and safety issues with medications are very
5 strongly aligned to our best practices and
6 other initiatives within the organization.

7 We also have a very long history of
8 participating in the process of trying to
9 determine goals and other issues regarding
10 CMI. We've been publishing CMI for almost 30
11 years. Our CMI is principally accessible
12 through the National Library of Medicines,
13 MedLine Plus consumer website, Consumer
14 Reports health website, and our own safe
15 medication website, and our information is in
16 a format that really provides all of the
17 opportunities for best practices in terms of
18 formatting of the content, bulleted points,
19 the use of actual black boxes to indicate
20 warnings, and so forth; and they also include
21 hyperlinks to documents like MedGuides,
22 because again, they are accessible

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1 electronically as opposed to depending on
2 print deployment.

3 If they are printed the URLs for
4 those websites do appear. So it's a
5 combination of print and electronic
6 information.

7 We also have a very long history
8 participating in this process. We were part
9 of the Keystone group, and I think it's
10 important for this committee to recognize that
11 the Keystone group really was a consensus
12 building activity. There wasn't a whole lot
13 of science or evidence that was part of that
14 process; there was some, but at the end of the
15 day it was a group of experts that were
16 convened, and they put together their best
17 thoughts in terms of a guidance document then
18 that publishers attempted to comply and adhere
19 to.

20 We did make comments in 2002
21 regarding the 2001 evaluation, and we also
22 provided a very detailed evaluation to FDA

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1 analyzing the specific sub-criteria in that
2 analysis, and showing that in fact a lot of it
3 was really based on the opinion of the
4 committee. There was a disparity between what
5 was required by Keystone and what was really
6 open to interpretation.

7 I think that is one of the messages
8 that I want to bring across today is, there is
9 really a lot of interpretation still, as you
10 will see in the criteria that were used,
11 versus what the guidance document for Keystone
12 actually spell out. And then other activities
13 of the group.

14 We too believe that substantial
15 improvement has been made between the previous
16 evaluation and the 2008 evaluation. And the
17 principal areas where the failure exists. One
18 is content assessment criteria that really
19 were beyond the scope of previously defined
20 standards. I think that criterion three, for
21 example, the directions of use, were not
22 clearly - are not clearly spelled out in the -

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1 in those documents in terms of what was
2 actually developed as sub-criteria.

3 And then clearly the formatting
4 issues that you saw in the samples earlier, at
5 the point of service.

6 The guidance document in Keystone
7 clearly recommend that the content providers
8 depend on the PI as the basis of the
9 information. Researchers identify that they
10 use additional sources, and that is certainly
11 appropriate in creating CMI, and enhancing the
12 quality of the information.

13 But in terms of meeting the
14 standard that exists that raises some
15 questions.

16 Some of the new examples of sub-
17 criteria were the requirement for a physical
18 description of the drug or imprint code.
19 Those are not outlined in either Keystone or
20 in the guidance document. Personal dosing
21 instructions, specificity and frequency of lab
22 tests, monitoring schedules, and then what is

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1 commented here today and is also commented in
2 the study is, there is really a challenge
3 between being comprehensive and meeting the
4 guidance from those documents, and creating a
5 document that is comprehensible.

6 So the printing and formatting
7 issues, a high percentage of those criteria
8 were not being met, and they continue to have
9 the lowest scores between 2001 and 2008.
10 Those things that you saw earlier in the
11 samples really extend beyond the control of
12 the content provider. And you heard previous
13 speakers mentioning that.

14 The fact that they varied between
15 content providers on the identical piece of
16 information clearly indicates that there are
17 downstream effects that the publisher has no
18 control over.

19 And some of those things include
20 content that is actually eliminated at some
21 point downstream from the document, from the
22 data that is provided, as well as the font

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1 characteristics.

2 We had encouraged FDA to do a
3 separate evaluation of the actual content that
4 the providers provided as part of this 2008
5 evaluation, so that they can actually
6 determine to what extent the content as
7 intended to be distributed met the criteria,
8 versus what actually was given to the patient
9 downstream, because that is necessary to truly
10 and clearly identify where the problems
11 reside.

12 There are certainly strong
13 indicators that those problems are downstream.

14 The numbers were described earlier where for
15 example a first aid leaflet, exact same one,
16 varied from 760 words to almost 2,500 words,
17 and the adherence varied from 30 percent to 88
18 percent for that same leaflet. And again
19 those things are out of the control of the
20 providers.

21 We have heard about the multiple
22 types of information that are out there right

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1 now, and the fact that there is very little
2 information demonstrating what effect they
3 have on consumer behaviors and outcomes. And
4 that's a very clear need we think in moving
5 forward.

6 There certainly is information
7 overload in what they receive, and despite
8 what we describe as evaluation of usefulness
9 in 2001 and 2008, from the perspective of
10 consumers and their safety and health I really
11 don't think that we are evaluating the
12 usefulness of the information with the current
13 mechanism.

14 MedGuide problems, we've heard
15 about those, I won't repeat those. But it
16 certainly contributes greatly because of the
17 length and the lack of standards and content
18 for what appears in those documents.

19 There's issues with MedGuides from
20 the consumer perspective that mainly gravitate
21 around the length of those documents. FDA's
22 original goal was a two-page goal. In 2007

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1 when we looked at everything that was
2 available, they averaged eight pages long,
3 with a range of 2 to 31 pages. The emphasis
4 in those documents is on risk, and oftentimes
5 it's on a single risk associated with the
6 drug.

7 Recommendations: the first
8 recommendation is, we believe we clearly have
9 to conduct well designed research to determine
10 optimal content and format of CMI, and that
11 research must be patient and consumer centric.

12 The research that we've done in
13 2001 and that we did in 2008 did not have the
14 consumer as the center of the research.

15 The goal should be a single
16 comprehensive yet comprehensible document.
17 Testing can be performed initially with
18 existing CMI and MedGuide integration that is
19 available from the publishers. They currently
20 summarize and integrate MedGuides into their
21 CMI. Additional testing of prototypes.

22 We do not believe that the highlight

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1 section should be used as the basis of that,
2 because if you look at what the intent of
3 highlights is, it really doesn't serve this
4 purpose well. It is really intended to direct
5 health professionals to more detailed
6 information in the professional labeling.

7 Yes, it provides summary, but it
8 has a half page limit, and it doesn't provide
9 instructions that you would give to the
10 patient to monitor things, and a variety of
11 other issues.

12 We heard one of the committee
13 members earlier saying that we should look at
14 two different levels of information, and that
15 I think is something that also can be looked
16 at.

17 A highlights type of information
18 that highlights what's most important to the
19 patient as well as the detailed information
20 for those who are interested in it and what to
21 refer to it.

22 I think it would be a mistake, as

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1 somebody just said, to throw out the baby with
2 the bath water. I think we should make our
3 best efforts to use current, well established
4 infrastructure for content development and
5 deployment, and we should use good science to
6 come up with criteria that the publishers can
7 adopt, and that are very clear in terms of
8 what they are going to be measured against in
9 terms of standards.

10 We have to ensure that those
11 guidance documents are specifically detailed
12 as any assessment criteria.

13 And we saw earlier the criterion
14 three on directions from use, the publishers
15 performed worse than they did in 2001, and
16 there is a good reason for that. The guidance
17 document states that you should describe
18 treatment effects when it's a physical
19 reaction, when it is something that the
20 patient themselves can detect. Yet over half
21 of the things that are in the lisinopril
22 monograph for example are lab tests; the

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1 patient would have no idea in terms of. And
2 they were very specific, how often they should
3 get a lab test. And again the guidance
4 documents that the publishers were working
5 against did not provide that direction, yet
6 that is what they were assessed against.

7 We need to fully engage
8 stakeholders and continue to do that. We
9 clearly need to establish what is most
10 important to communicate to the patient, and
11 how to best do that. It may be print; it may
12 be electronic; it may be a combination. We
13 know that we have to talk better about risk
14 benefit. We have to weigh carefully how much
15 safety information we provide. And how much
16 information goes into CMI, on how to use the
17 medication versus other means of doing that,
18 including oral counseling.

19 What are the best times to
20 communicate each of those? We've been talking
21 principally about distributing that
22 information at the point of dispensing in

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1 pharmacies. Well, that is too late to make a
2 decision about risk benefit. The drug has
3 been prescribed; the physician may or may not
4 have described the risk and benefits to the
5 patient. And allowing them to participate in
6 the decision of whether or not they want to
7 take the risk that might be associated with
8 that drug in order to achieve the benefits.

9 And tomorrow you are going to hear
10 from a speaker on the drug facts box
11 prototype. Perhaps that is something that
12 could be used in that venue by physicians
13 because the intent of that is to provide a
14 concise well structured summary of risk
15 benefit.

16 Should CMI be provided with the
17 first prescription as well as all additional
18 prescriptions, we have to ensure downstream
19 adoption of the content and format. We have
20 to improve stakeholder involvement, improve
21 boards of pharmacy engagement to ensure that
22 that occurs; and we have to consider the

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1 economic impact of anything we decide to do.

2 And then finally, my strongest
3 point is, do not do anything again without
4 good evidence to support it. We have already
5 had a Keystone guidance document. We have had
6 an FDA guidance document that were all
7 challenged with interpreting and implementing.

8 And we heard questions to the committee
9 earlier, or from the committee earlier, for
10 example in something like how do you define
11 what adverse effects to include. And we saw
12 that the FDA staffers couldn't even tell you
13 that. And I can tell you that the documents
14 themselves do not clearly define that.

15 Thank you very much.

16 DR. FISCHHOFF: Thank you as well.

17 Our next speaker, I'm not sure if
18 she is here, Dr. Diana Zuckerman from the
19 National Research Center for Women and
20 Families. Is Dr. Zuckerman here?

21 Okay, our next speaker is Saul
22 Shiffman from Pinney Associates.

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1 DR. SHIFFMAN: Good afternoon,
2 members of the panel and of the audience.

3 In my spare time I am a professor
4 of health psychology and pharmaceutical
5 sciences at the University of Pittsburgh,
6 another institution across from our chair's
7 home base.

8 But I appear here today under the
9 auspices and sponsorship of Pinney Associates,
10 which is a consultancy that consults the
11 industry on issues of risk management and OTC
12 switches.

13 And that coincidence of domains of
14 work is not coincidental. In fact we
15 encounter the issues of patient comprehension,
16 of medical information, in both of those
17 contexts, and part of what you will see in my
18 talk is our attempt to put the practices and
19 lessons of those two areas together.

20 So we have heard this morning calls
21 for empirical evaluation not of the materials
22 but rather of patients and consumers and how

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1 well they understand such materials. And that
2 is exactly what I intend to present to you.

3 We have covered this well, but it
4 bears repeating, which is that the safety and
5 effectiveness of medicines and devices depends
6 not only on pharmacology but on the patient's
7 behavior, which in turn depends on their
8 understanding of the relevant information.

9 And obviously many stakeholders
10 have been working diligently to accomplish
11 that, and as a result of the history we have
12 heard, there are a variety of materials -
13 package inserts, medication guides, CMI - that
14 patients get. And the question is, are these
15 effective, particularly I'm going to focus on
16 in terms of their communication objectives.

17 And I would argue that
18 comprehension is not sufficient to assure
19 appropriate behavior. In the end it is the
20 behavior that matters. But it certainly is
21 necessary as a component of assuring
22 appropriate behavior.

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1 And importantly as we have heard,
2 it is amenable to scientific evaluation rather
3 than simply projection from qualities of the
4 material.

5 The interesting thing is that in
6 another part of the Food & Drug Administration
7 there are standards of long standing for
8 evaluating the consumer comprehension of
9 materials, and in particular for non-
10 prescription OTC drugs a label comprehension
11 study is actually required for - particularly
12 for a drug to be switched from prescription
13 only to over the counter; and the evaluation
14 of comprehension is governed by standards
15 enforced by the agency and adhered to by
16 sponsors.

17 So what I am going to be presenting
18 is a study essentially using those methods
19 that have generally been applied to OTC labels
20 to evaluate what I'm going to call patient
21 information materials, which are the materials
22 that we have heard of.

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1 This is not meant to be the be-all
2 and end-all study. It is really a very small
3 demonstration study simply to show how this
4 could be done.

5 We evaluated only one set of
6 materials, so it's not a comparative study,
7 and the procedures are really quite simple.
8 We enrolled people - I will describe who they
9 were in a moment. They reviewed these
10 materials. We tested their comprehension, and
11 then also tested their knowledge of some of
12 the vocabulary in that material, and then we
13 also tested their literacy.

14 In terms of participants, we did
15 not look at patients who were using a
16 particular medication, so it is a kind of
17 general population. We looked for adults, and
18 we limited it to people who had not been to
19 college, which constitutes roughly half of the
20 U.S. adult population, and almost two-thirds
21 of people 65 and older. So very important and
22 numerous sub group for patient communication.

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1 You can see there was some
2 diversity in the group. Those of you who know
3 Pittsburgh know that we do not have a lot of
4 Hispanic or Asian communities, so those are
5 underrepresented.

6 And we did test them using the
7 REALM, which is a measure developed by Dr.
8 Davis, and about 29 percent were considered
9 low literacy by the standards FDA and the
10 nonprescription office sets for considering
11 someone to be low literacy.

12 Here you see - oops, it seems to
13 have shifted, but I'm sure you can see it
14 anyway - the materials, and the - these were
15 printed two sided, so there is actually twice
16 as much information as you see displayed.

17 You can see the package insert was
18 the longest, the medication guide was the
19 shortest. These were actual materials for a
20 marketed drug. We picked one product as our
21 example. The name of the product and sponsor
22 was masked. This isn't really about the

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1 product, but about these materials.

2 You actually can't see the reading
3 ease scores, which are from Flesch, but it's
4 15 for the package insert, and essentially 40
5 for the CMI and 42 for the MedGuide. Just to
6 give you some frame of reference the State of
7 Florida - oh, and Higher scores mean more
8 readable - the state of Florida requires that
9 materials such as insurance contracts and
10 policies have a reading level of at least 45,
11 which is to say none of these materials would
12 qualify in Florida as consumer friendly
13 material.

14 The participants were presented
15 with the materials, and the set that we gave
16 them was to review the materials as you
17 normally would when you get a new medicine.
18 So notice, new medicine, which we assumed
19 would evoke a more vigilant set. They were
20 allowed to review the materials privately, but
21 with their consent they were videotaped so
22 that we could determine how much time they

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1 spent on the various materials.

2 The median time spent was 30
3 minutes, and that is three times more than the
4 participants said they normally spent, so in
5 fact this is a best case test in some ways.
6 They knew they were going to be tested. They
7 knew they were being watched, literally, so
8 again, kind of a best case test.

9 After they indicated they were
10 done, we tested their comprehension. We did
11 not try to test all of the materials. We
12 picked seven communication objectives. You
13 will see what they are as I review the
14 results. And it was an open book test, just
15 as at home you might have the materials with
16 you, the materials were in front of them.

17 The assessment was a scenario based
18 assessment; that is, it was action oriented,
19 and it presented consumers with a plausible
20 situation that was directly addressed by the
21 materials, and asked them what was to be done.

22 So there was nothing complicated or

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1 inferential. Everything that was tested was
2 directly addressed in the materials. And then
3 they were coded by two judges for correctness,
4 and importantly, it had to show some actual
5 knowledge from the materials. We saw a
6 tendency for respondents to use, I would speak
7 to my doctor, as a sort of get-out-of-jail-
8 free card. And in fact you had to show you
9 had some awareness of what the issues were.

10 So let me go through what the
11 performance was. And I struggled for a way to
12 frame the performance, and I thought there was
13 one system of grading performance that we are
14 all familiar with from school. So we have
15 assigned these by grades. The best grade was
16 A minus, and that was actually for the
17 information covered in all three pieces of
18 material that the medication should not be
19 stopped abruptly. So respondents did very
20 well on that.

21 Fewer actually got the product
22 name, but that is not of much concern, because

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1 it is probably not as important.

2 It then dropped down rather rapidly
3 to what by grading standards would be a D
4 minus, so less than two-thirds were able to
5 give account of the indication for the
6 product, and unfortunately a failing grade was
7 assigned to the sole focus of the medication
8 guide which was the concern about suicidality
9 in teens, and less than 60 percent were able
10 to give account of that, even though it was
11 not only the sole focus of the medication
12 guide, but was a black box warning on the
13 package insert.

14 Finally we actually I felt I needed
15 to invent a grade lower than F for the
16 remainder of the material. So if you were
17 getting an F minus, the materials warned about
18 the importance of informing your provider and
19 your prescriber if you were dehydrated. A
20 quarter got that. We asked a permissive
21 question, that is, in fact pain medications
22 were not contraindicated, and only one out of

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1 five got that.

2 And finally the most distressing
3 was that the materials described a syndrome of
4 potentially fatal symptoms which required
5 immediate medical attention and this was
6 identified correctly by 13 percent.

7 So if we are in the school context,
8 this is not just a failure, but a cause to be
9 remanded for remedial education.

10 Finally, broadly, the participants
11 who tested as low literacy in fact did worse
12 across the board which has been the consistent
13 finding in Dr. Davis' research and other
14 research.

15 I won't spend too much on this,
16 because actually everyone has been saying
17 exactly the same thing, that there is too much
18 information, inadequate focus, and
19 prioritizing. We are really presenting people
20 with a very difficult cognitive task, not even
21 just requiring medical understanding, but
22 requiring the juggling of all this

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1 information, deciding what's important and
2 how to translate it into action.

3 In terms of the study, obviously
4 the study has many limitations. It's a small
5 study. In some ways it's best case; in other
6 cases you could say it's worst case. Our
7 purpose wasn't really to settle the issue, but
8 more to demonstrate that one could evaluate
9 comprehension of these materials, and although
10 we didn't know what the outcomes were starting
11 out, certainly they indicate that
12 comprehension is very very problematic.

13 So clearly the conclusions that the
14 study can support is at least with this set of
15 materials that comprehension is not adequate,
16 and importantly, that even critical life and
17 death information that requires immediate
18 action and is highlighted is not being
19 communicated to consumers, and that these
20 materials need to be improved.

21 Now the Food & Drug Administration
22 is admirably a data-driven agency. And so I

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1 think the metapoint is that these decisions
2 also need to be data driven, and just as we
3 wouldn't release a medication or a device onto
4 the American public without pre-market
5 empirical evaluation of its effectiveness, and
6 then following it in the market, we similarly
7 shouldn't release educational materials
8 without pre-market evaluation and end market
9 evaluation.

10 And I notice that a lot of the way
11 the guidelines are written for REMS--it talks
12 about the 18-month period for the first
13 evaluation. But clearly just as with a drug,
14 before you put it out there, you want some
15 empirical assurance that it is likely to
16 perform well when you then follow up in 18
17 months. You don't want to learn 18 months in
18 that the materials have had no effect.

19 So let me stop there. Thank you
20 for your attention. And if there is time I
21 look forward to comments and questions.

22 DR. FISCHHOFF: Very nice.

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1 Our next speaker is Jeffrey
2 Fetterman from ParagonRx.

3 MR. FETTERMAN: Good afternoon.
4 I'm Jeff Fetterman. I'm president and CEO of
5 ParagonRx. By means of disclosure let me say
6 that we are a company that consults with the
7 pharmaceutical industry on matters of risk
8 management programs and risk communications.

9 But that role also provides an
10 opportunity to have access to data and some
11 observations that when brought together may
12 provide some useful insights for the
13 committee.

14 First observation is that the FDA
15 amendment act sets the bar higher as it
16 relates to medication guides. And I'm
17 starting with medication guides and
18 recognizing that this actually extends to
19 other communications as well.

20 So in what way does it set the bar
21 higher? Well, it sets the bar higher in the
22 sense of the point of compliance, and so in

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1 the past, the compliance of many of our
2 clients, pharmaceutical companies, has been
3 the documentation and content of the
4 medication guides.

5 Well, the point of compliance in
6 the world of REMS now in which there is an
7 assessment as was just pointed out, 18 months,
8 three years and seven years, has to be
9 understanding of the material. And so now
10 it's a more performance based compliance.

11 So there was a bit of discussion
12 earlier about the somewhat pejorative
13 speculation about the intentions of
14 pharmaceutical companies.

15 I would suggest that the intention
16 is to comply, and the point of compliance is
17 dependent upon what some of the expectations
18 are.

19 So in that spirit, are the
20 medication guides sufficiently effective? So
21 I've got three data points that may
22 triangulate to provide a few insights.

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1 The first is, a comprehension study
2 of a medication guide that we conducted.

3 A second is a study of drug facts box to
4 communicate medication benefits; I will spend
5 very little time on that, because I see it's
6 actually highlighted tomorrow; but very
7 important.

8 And thirdly literature defining
9 adult learning principles.

10 So on the first one, comprehension
11 study of the medication guide, in this case
12 the objective was to look at the medication
13 guide to understand, to pretest it to
14 understand whether patients can actually
15 comprehend the safety message.

16 This is very interesting, again
17 getting to the motivations that I talked about
18 earlier, given that there is a need to
19 demonstrate effectiveness at 18 months, there
20 is a growing awareness and need to say, should
21 we test this before it is issued.

22 And so these were interviews

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1 conducted with patients. The cohort were
2 patients who were diagnosed with a condition
3 that was similar to the indication for the
4 drug of study, or the product which was
5 indicated, and the assessment was, the
6 patients were given the opportunity to review
7 the medication guide. They were then
8 administered a written test. And then they
9 were interviewed by a research associate.

10 This shows the answers to the
11 written portion of the test. Four of the
12 questions were about risk communications, and
13 you will see the responses vary from 13 out of
14 the 23 respondents getting a correct answer on
15 one of the four, risk oriented questions; and
16 then on two of the risk-oriented questions, a
17 full 23 out of 23 recorded the correct answer.

18 So it demonstrates some degree of
19 comprehension, but also some degree of not
20 sufficient comprehension.

21 That is further demonstrated by in
22 the interview process when the interviewer

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1 asked, tell me what you think is the most
2 important information you should know about
3 this product. And what was reported was that
4 in about -- in 12 out of the 23 patients what
5 they found was that they were able to report
6 the most important safety information was the
7 most important. In four additional patients
8 they were able to report the right information
9 upon prompting.

10 The others reported information
11 that interestingly was about how to use the
12 medication, which to them was most important.

13 So it also points out the need to really
14 construct the surveys in the right way as you
15 are going forward. And I agree with taking an
16 evidence based approach to all of this.

17 Perhaps most interesting from your
18 perspective is what did the patients
19 themselves say about what needed to be
20 improved in the guide? They just read it,
21 they just took a test. And now they were
22 saying, this is what I would do if I were you

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1 to make this more effective.

2 Most importantly they said, start
3 by telling me what the medication is for, what
4 its benefit is, and why I would use it,
5 because that is a context for me to understand
6 the risk that you are about to tell me.

7 If you just start telling me the
8 risk I really don't understand the
9 information.

10 Secondly they asked to place the
11 risk statements in a summarized box at the
12 front end of all the literature. In other
13 words to call it out and to summarize it
14 before you tell me more detail. In some ways
15 this gets to a recommendation that was made
16 earlier about tiering the information that is
17 provided.

18 And then finally they recommended
19 the use of call out boxes and other formats to
20 highlight information, really draw their eye
21 in, because there is too much there to follow.

22 The second point of evidence is the

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1 study that you will be reviewing tomorrow, so
2 I will spend very little time on this. But
3 it's recently published, and it is very
4 important because what it shows is, the
5 comment made by the patients, which is, pull
6 out that information to the front and share it
7 with me. They actually demonstrated in this
8 study that it improved comprehension and
9 decisions.

10 So it took a DTC ad, it actually
11 took four different DTC ads, and then replaced
12 the brief summary with a drug summary box that
13 had both product benefit and product risk
14 listed, and then assess whether patients
15 really understood the information and what
16 kind of choices they made.

17 And so the results again at a very
18 high level, and you will have a much better
19 view of this tomorrow, is that the drug fact
20 box actually improves patient knowledge,
21 again, consistent with what the patients
22 themselves ask for. It helps them to make

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1 better choices related to the symptoms they
2 were experiencing, and it corrected some
3 overestimation as it applied to the
4 effectiveness of the drug in a prevention
5 setting.

6 Third piece of evidence that is
7 interesting here is that the study findings
8 that we just talked about, both the
9 qualitative study and then the recently
10 published study, are consistent with theory
11 from adult learning principles. So there is a
12 whole body of discipline called adult learning
13 principles. Some of you are experts in this.

14 And so one set of criteria that defines
15 elements of adult learning principles include
16 these: there should be a clear curriculum of
17 the content that needs to be communicated.
18 But secondly it is important to have an
19 enabling tool that enables the learner to
20 apply what they learned. It is one thing to
21 cognitively hear and understand. It's another
22 thing to actually change behavior. And all of

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1 you are very familiar with that as it relates
2 to professional guidelines. There is a
3 proliferation of guidelines, and yet the
4 adherence to those guidelines is very
5 challenging, because knowing how to comply is
6 difficult.

7 Third is application, which is
8 somebody showing how to apply, using an
9 enabling tool

10 And finally interactivity to
11 address the various learning styles of various
12 individuals.

13 So all of that comes together in
14 one example, which again is a recently
15 published study that shows that an enabling
16 tool in this case it's a presurgical check
17 list for professionals - again this is a
18 professional setting, but it's based on adult
19 learning principles that cut across
20 professional or consumer level. And this
21 shows that an enabling tool can actually
22 improve outcomes -- in this case it was a

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1 reduction in events in certain surgical
2 populations -- by having a check list that
3 helped to put into play content that you would
4 otherwise expect the learner to understand.

5 So finally what's the summary of
6 insights for risk communications out of all of
7 this?

8 Well, first is, what do patients
9 prefer, and in a qualitative assessment what
10 they preferred is to pull all that information
11 to the front, and tell them in a concise way
12 what the benefits and risks are, and
13 importantly, tell me the benefits first so I
14 have that as a context to understand the
15 potential risks.

16 Secondly was that the drug fact
17 box, which itself is just a call out of sorts,
18 was an effective way to help patients improve
19 their knowledge and make choices.

20 And then thirdly enabling tools
21 such as a checklist helped to apply knowledge
22 to behavior change. And this is actually

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1 interesting, because one of the things that is
2 now going to come forth is that as the first
3 round of assessments of REMS at 18 months and
4 of those medication guides that are published,
5 it will be fascinating to see whether the
6 thresholds are achieved, and if they are not,
7 what are the options? Will a checklist that
8 is an enabling tool or other enabling tools
9 may extend and augment the medication guide to
10 help make sure that the knowledge is actually
11 applied to behaviors.

12 Thank you very much.

13 DR. FISCHHOFF: Thank you.

14 Our next speaker is Pam Bundy from
15 Eli Lilly. Welcome.

16 MR. BUDNY: Good afternoon. My
17 name is Pam Budny, and I'm manager of
18 regulatory affairs at Eli Lilly and Company.

19 Can't hear me? Better? Okay.

20 This might be better. As I said,
21 my name is Pam Budny. I'm the manager of
22 regulatory affairs at Eli Lilly and Company.

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1 And today I am speaking on behalf of Lilly.
2 And I thank you for the opportunity to speak
3 at this meeting.

4 We consider the written information
5 provided to patients about their prescription
6 drug products, or as I will refer to them,
7 medications, to be in need of immediate
8 improvement.

9 We believe that the objective of
10 patient labeling is to improve patient
11 outcomes by providing written information to
12 patients that both assists them in
13 understanding the benefits and risks of their
14 medications, and enables them to use their
15 medication safely and effectively.

16 Patients should be able to locate,
17 interpret, and act upon the information in
18 written patient labeling. It should reinforce
19 or enable the communication between the health
20 care prescriber or dispenser and the patient.

21 To meet the objectives of patient
22 labeling we offer this recommendation for a

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1 working solution: communication of written
2 information about medications to patients
3 should consist of a single document for each
4 medication.

5 The content and format requirements
6 should be specified in regulation.

7 It should be prepared by the
8 sponsor; tested with patients and/or
9 caregivers prior to submission to FDA; and all
10 patient labeling should be approved by FDA.

11 Available from an electronic
12 source, it should be routinely provided to
13 patients by dispensers. And patient labeling
14 should be required for all drug products that
15 are not administered by a health care
16 professional.

17 It should be delivered to patients
18 each time a prescription is filled.

19 Now time does not allow me to
20 elaborate on all of these recommendations, so
21 I'll do that in our written comments.
22 However, I did want to emphasize a few points.

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1 With the written single document
2 approach patients would receive one written
3 piece of information for each medication that
4 they receive. Since all medications have
5 benefits and risk information that should be
6 conveyed to patients, we are recommending that
7 patient labeling be required for all
8 medications.

9 This patient labeling would take
10 the form of a patient package insert, or in
11 limited circumstances, as described in
12 regulation, a medication guide.

13 And such patient labeling should be
14 dispensed in place of CMI.

15 Promulgation of new regulations or
16 regulatory guidance to describe a standardized
17 approach to formatting and contenting of all
18 patient labeling would certainly improve
19 consistency and usefulness.

20 Similar to the approach that was
21 used with OTC labeling and the physicians'
22 labeling rule, standardization should be

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1 evidence based to ensure that the goals for
2 improved effectiveness and readability are
3 achieved.

4 Patient labeling should be prepared
5 by the sponsor, just as is the case for
6 physician labeling. Physician labeling and
7 patient labeling are inextricably linked in
8 terms of the information they contain on risk
9 and benefits.

10 Sponsor prepared patient labeling
11 would ensure consistency of the information
12 provided to patients in multiple venues. For
13 an example, the patient labeling that is
14 received at the time of dispensing of the
15 medication would have the same content as the
16 full disclosure accompany promotional
17 materials for patients.

18 Testing of the patient labeling
19 with patients and/or caregivers prior to
20 submission is a critical way to determine the
21 usefulness of patient labeling prior to
22 patient use.

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1 Provision of the results of the
2 testing of proposed patient labeling as part
3 of the submission to FDA will enable a more
4 evidence-based approach to the decision making
5 process on the content and wording of patient
6 labeling.

7 This approach would certainly be
8 consistent with the consultation requirements
9 in the European Union for the preparation of
10 the patient information leaflet or the pill.

11 FDA approval of patient labeling
12 will ensure consistency with FDA-approved
13 patient labeling. And this is also consistent
14 with the EU practice of regulatory approval of
15 patient information leaflets.

16 In conclusion we support the
17 efforts to provide patients balanced and
18 useful information about the benefits and
19 risks of their medications. We believe that
20 patient input should drive the development of
21 regulations on the content and format of a
22 single patient labeling document for each

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1 medication.

2 Patient labeling should be
3 developed by sponsors, tested with patients,
4 approved by the FDA, and delivered in ways
5 that are compatible with pharmacy dispensing
6 workflows.

7 This information should be made
8 available to patients each time they receive
9 their medication.

10 Again, I thank you for the
11 opportunity to provide comments this
12 afternoon.

13 DR. FISCHHOFF: Thank you very
14 much.

15 Our next speaker is

16 MR. MEHTA: Mukesh Mehta from
17 Thomson Reuters.

18 Thank you. Welcome.

19 MR. MEHTA: Thank you very much.
20 My name is Mukesh Mehta. I'm vice president
21 of Thomson Reuters Health Care, commonly known
22 in the industry as the publishers of

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1 Physicians Desk Reference, PDR, and also
2 evidence based information through our
3 MicroMedex group.

4 We have a long and strong history
5 of providing this information -- it must be my
6 Blackberry -- a long history of providing this
7 information to professionals for about 60
8 years through the Physicians Desk Reference,
9 FDA approved prescribing information.

10 When I was a member of the steering
11 committee in the mid-`90s, the Keystone Group,
12 and today I am also a member of the advisory
13 group for the EMEA EudraPharm Initiative that
14 is going on in EU.

15 I have three specific comments. I
16 do not have prepared comments. Three specific
17 comments. One is today the pharmacy or the
18 dispensing professionals are required to
19 provide medication guide to the patient,
20 package insert, or CMI. One recommendation
21 that I would offer to this committee and the
22 FDA is to explore the possibility of providing

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1 having the physician provide the medication
2 guide information to the patient.

3 The physician is in a better
4 position to give this information when he or
5 she is prescribing the specific drug or
6 medication to the patient. He or she knows
7 your medical history, and he or she is in a
8 better position to explain the risks as well
9 as the benefits associated with this
10 medication.

11 The second is the awareness of
12 availability of the medication guide. My
13 personal experience is a lot of pharmacy
14 professionals are not aware of the medication
15 guide. Personally I have received
16 prescriptions for certain medication where the
17 medication guide is required, and asking the
18 pharmacist about the medication guide, I was
19 told, what are you talking about?

20 So there is a need to create
21 awareness in the pharmacy community that the
22 medication guide is required. It is required

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1 to be given to the patient.

2 The third specific comment is for
3 the patient. Patients are given all sorts of
4 information. We heard this morning and this
5 afternoon, the CMI, the PPI, the medication
6 guide. However one question we haven't asked
7 are the patient really taking this
8 information?

9 I have seen personally that the
10 patient, when they get their prescription,
11 they usually take the bottle out of the
12 prescription bag, put it in their purse or the
13 pocket, and throw away a bag which where the
14 medication guide, the CMI, is attached.

15 So the question is also, not only
16 are the patients getting it, but are they
17 really paying attention to the medication
18 information? And if they are, do they
19 understand that information?

20 Thank you very much.

21 DR. FISCHHOFF: Thank you as well.

22 Our final speaker is Mary Mease

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1 from - okay, you will tell us where you are
2 from, thank you.

3 MS. MEASE: Good afternoon. Hi,
4 my name is Mary Mease. I'm here speaking as a
5 public citizen or individual, but in the
6 interest of full disclosure I am currently
7 employed by Quintiles. I began with them last
8 November after working at FDA for 11 years.
9 So some of these thoughts are from my
10 experience with FDA, and now I can see some of
11 it from the other side.

12 And I go back to our discussion
13 early this morning with the opening remarks
14 and background information on why we are here
15 today. And we are here today because we are
16 basically faced with a messy situation, with
17 consumer information that has evolved over
18 time, kind of stacked one on top of another,
19 and now we have to figure out how to fix it.

20 And my question is, is it best to
21 try to fix it? Or should we basically close
22 our eyes and think of, what should it look

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1 like today, in 2009?

2 It should look quite different than
3 it did 40 years ago.

4 And I propose that there needs to
5 be more than one method or vehicle for
6 ensuring that patients receive the valuable
7 information they need to make informed
8 decisions.

9 And I'm not saying we should throw
10 the baby out with the bathwater. Let's keep
11 the baby. We need the written information.
12 But as comments that have preceded me, the
13 primary point at which this information should
14 be shared is at the prescribing point, between
15 the doctor and the patient.

16 Now that probably presents some
17 issues in and of itself, perhaps reform of the
18 health care system which I don't think we can
19 address today. We can try doing that
20 tomorrow. But that is the most optimal point.

21 That is the point where you are going to have
22 bidirectional communication, and there is all

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1 the information in front of the prescriber
2 that he or she needs to know to help the
3 patient make the best decision.

4 In addition you can have the
5 written information, think it needs to be
6 restructured. It needs to be restructured,
7 but certainly it could be a fall back for
8 patients.

9 Perhaps we should be thinking about
10 identifying for the public trusted websites.
11 There are many out there; not all have very
12 good information. But identify the trusted
13 websites for information resources, and then
14 perhaps provide an 800 number for a health
15 care professional to be on the other end to
16 answer questions that patients may have after
17 they pick up their prescription.

18 Then I will move on to how should
19 we identify the success of consumer
20 information? I've heard it described, perhaps
21 it's consumer comprehension. Perhaps it's
22 behavior change.

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1 But I think that there are many
2 factors including personal values that
3 influence patients' decisions. And two
4 examples that I am going to bring up, just to
5 provide some thought provoking opportunity are
6 child car seats and drunk driving.

7 There is definitely a binary
8 outcome. There is a right and there is a
9 wrong. But we often hear about patients or
10 people making the wrong decisions. And why do
11 they do that when there is clearly a right or
12 wrong decision?

13 So we take that to our consumer
14 information; what are we expecting to be the
15 outcome?

16 And then finally regarding
17 medication guide evaluations, remember the
18 slogan, where is the beef? Where is the
19 target? What is the target for evaluation?

20 In my experience, albeit only four
21 months in industry, industry really does want
22 to do the right thing. And what appears to be

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1 biased may actually not be biased. It may be
2 a different perspective.

3 And the example I'll use there is,
4 surveying drug naive patients. Clearly not
5 all patients are on a medication day one.
6 They have to be new to the medication at some
7 point in time. So when they see the
8 medication guide for the first time it seems
9 to be an opportunity to learn what does a drug
10 naive patient think. What do they need to
11 know that is different from what patients who
12 are experienced need to know?

13 And then regarding the medication
14 guide evaluations and identifying the target,
15 I think that there really needs to be open
16 discussions between the stakeholders and CEDR
17 and FDA.

18 Thank you.

19 DR. FISCHHOFF: Thank you as well.

20 That concludes the presentations
21 for our members of the public. If we would
22 like, if members of the committee would like,

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1 we have an opportunity to ask questions of any
2 members of the public who have spoken with us,
3 or I suppose anybody who has spoken with us
4 earlier today. And when we are concluded with
5 that we will go to our discussion of what it
6 all means.

7 Christine.

8 DR. BRUHN: Thank you, and I
9 appreciate the presentations. They were I
10 think each very thoughtful.

11 I noted a good deal of commonality
12 in some of the thinking and some of the
13 recommendations. I only heard one person
14 address whether a single sheet or drug
15 information should be voluntary or mandatory,
16 and that was Mr. Lee, and I think he stepped
17 away.

18 But I wonder, I would like to hear
19 the thinking from those who spoke or others
20 in the audience whether your recommendation or
21 your company's perspective or your
22 organization's perspective is that this

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1 information should be mandatory or voluntary,
2 and why do you believe it is as it is?

3 DR. FISCHHOFF: Mr. Lee, but he
4 has left us a note saying that Crystal Riley,
5 the director of professional affairs at his
6 NCPA is here to answer questions. So let me
7 ask her to -- yes, please.

8 MS. RILEY: Good afternoon. You
9 had a question about whether or not we
10 believed that information given to a patient
11 should be voluntary or mandatory.

12 I do believe that information
13 should be given to a patient. That is our
14 organization's standpoint. It is very
15 important to make sure that patients are
16 provided with essential information to their
17 health care process.

18 We don't believe that it should be
19 up to the pharmacist to decide whether or not
20 to give them information. But the content of
21 the information that is given to the patient
22 is very important. And there needs to be some

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1 sort of standardization regarding that.

2 Did that answer your question?

3 DR. BRUHN: Yes, I guess that's a
4 good answer. He specifically said he wanted
5 it voluntary, and it just seemed like he was
6 moving away from the central thesis here which
7 is that people should have information.

8 And you know I forgot our first
9 speaker's name, but did he just return, who
10 presented the citizens' petition? Is the
11 citizens' petition specifying mandatory or
12 voluntary? I guess we don't have anyone from
13 the citizens' petition here?

14 DR. HAUSER: I'm Ronna Hauser from
15 the National Association of Chain Drugstores.
16 Mr. Wiesner had to leave.

17 In the petition, we have signed on
18 to that citizens' petition, it is mentioned,
19 voluntary.

20 DR. BRUHN: Why? Is it because as
21 our previous response was they don't want to
22 identify the pharmacist as the one who

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1 delivers this? Or is there -

2 DR. HAUSER: It would be a
3 voluntary program as to who is participating
4 and it would be their choice to participate in
5 that program. And that is how we have stated
6 it at this time in the petition.

7 DR. BRUHN: Thank you.

8 DR. HAUSER: You are welcome.

9 DR. FISCHHOFF: Could I ask while
10 you are still there as a follow up, so the FDA
11 staff, because it is under deliberation at
12 FDA, FDA can't tell us about the petition.
13 But since you are a petitioner you could,
14 right? Okay.

15 In the -- so the participation
16 would be voluntary. What about -- there were
17 several of the speakers spoke about
18 standardization, and at least one or two said
19 that the standardization should come from the
20 FDA.

21 Is the physician on the -- is there
22 -- does the physician have a position on the

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