

CENTER FOR DRUG EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Public Hearing – March 23, 2012

**Using Innovative Technologies and other Conditions of Safe Use to
Expand Which Drug Products Can Be Considered Nonprescription**

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Opening – Day 1 Summary/Logistics

Jane Axelrad:

Okay, let's begin. Good morning again. My name is Jane Axelrad. I'm the associate director for policy in the Center for Drug Evaluation and Research at FDA. I'd like to welcome some of you back who attended yesterday and to welcome people that were not able to attend yesterday to our Part 15 hearing on using innovative technologies and other conditions of safe use to expand which drug products can be considered nonprescription. I'm the presiding officer for today, and because there are people who will be either listening today or in the audience who were not here yesterday, I'm going to repeat some of what we did yesterday in terms of having the panelists introduce themselves and going over some of the logistics. So I'm going to start with the panel members and I'm also going to say there are going to be people, I think, coming and going from the panel as there were yesterday. Some people may be coming a little late. Dr. Kelman is not with us today and some members of the panel will be coming and going because they have other obligations throughout the day. But let me start with Dr. Woodcock.

Janet Woodcock:

I'm Janet Woodcock. I'm the director of the Center for Drug Evaluation and Research at FDA.

Peter Beckerman:

I'm Peter Beckerman, senior policy advisor in FDA's Office of Policy in the Commissioner's office.

Alberto Gutierrez:

I'm Alberto Gutierrez, director at the Office of In Vitro Diagnostics in the Center for Devices and Radiological Health.

Charles Ganley:

I'm Charlie Ganley. I'm the director of the Office of Drug Evaluation IV in the Office of New Drugs.

Marta Wosinska:

Marta Wosinska. I'm director for analysis staff in the Office of Planning and Analysis in CDER.

Andrea Leonard-Segal:

Andrea Leonard-Segal. I direct the Division of Nonprescription Clinical Evaluation in the Office of New Drugs.

Joseph Griffin:

Joe Griffin, associate director of policy development in the Office of Medical Policy in CDER.

Mary Kremzner:

Mary Kremzner, acting director of Division of Drug Information, Office of Communications in CDER.

Diane Maloney:

And Diane Maloney, associate director for policy, Center for Biologics Evaluation and Research.

Jane Axelrad:

Some of you who were here yesterday will notice that I moved my chair and that's because it was so hard to see all the way down to the end of the table to determine who wanted to ask a question. I thought it would be better. I would have a better view and make sure that I don't leave anybody out.

Agency staff won't be making any presentations, but we have left ample time for the panelists to ask the speakers questions so that we can develop a full record of the proceeding. Only panel members will be able to ask questions of the speakers. We have a lot of time at the end of the afternoon today as an open public session for any people who would like to speak and did not register in advance. If you want to speak at the open public session, please make sure you register. There is a sign-up sheet at the registration desk and we're going to try and accommodate anybody who wants to speak. The slides for all of the presentations will be posted to the docket after the meeting and the transcripts will be available in about 30 days. Details on how to access the transcripts are at the bottom of the agenda for the meeting and I'd also like to mention that we have -- some people have moved their presentations around a little bit.

There were a few people substitutions and in one case, people who were speaking on the same topic just wanted to reverse the order of their presentations. So there are new agendas out there. If you don't already have one there are new agendas out there on the registration table. So if I'm going along and you wonder what's happening, that's what's happening. The docket will remain open until May 7 and we welcome any written comments as well.

This meeting is being webcast live. It's not an interactive webcast and participants who are participating via webcast will be unable to speak. Our goal for today's meeting is to have a fair and open forum for individuals to present their views without interruption. To ensure this process is fair, each individual will have up to 15 minutes. I'll announce the speaker's name and ask the speaker to come to the podium and we're going to use a timer. The timer will be turned on when the speaker begins to speak. A yellow light will come on after 14 minutes and then you'll have one more minute to complete your presentation. If you go over your allotted time I'll remind you to finish up your comments. We did a really good job yesterday and I don't think I really had to do that. At the end of each speaker's presentation, the panel members will ask clarifying questions.

General housekeeping information. There is guest wi-fi in this room. The network is called FDA Guest and the password is guestaccess. I hope it's working better than it was

yesterday. Many of the agency computers were down yesterday and it was kind of good, because we didn't get a lot of emails while we were here.

[laughter]

But I don't even know if it was working in the room. I know there were issues with the webcast, too, and I was going to say something about it, but then it occurred to me saying something about a webcast so the people who couldn't hear it anyway wasn't going to do much.

[laughter]

Everybody -- we ask anybody who attends the meeting to sign in at the registration desk. Presenters, please sign in at the speaker registration desk so that we know that you're here. Lee Lemley is our logistics person and Rachel Bauchman. Lee's in the back of the room and Rachel is sitting here in case anybody has any questions or issues. Lunch will be available outside at the kiosk for a fee or you can go off campus.

[break]

Session 1

Jane Axelrad:

So with that I think we're ready to begin and I'm going to ask our first speaker, John Delfs, to come to the podium. Sorry.

John Delfs:

I was surprised.

[laughter]

But I thought hey, you know, you take what you get.

Jane Axelrad:

I'm sorry. I'm sorry.

John Delfs:

Thank you.

Jane Axelrad:

Sorry. [laughs] I'd better -- I'd better. Okay, I guess I need to get the right copy of the agenda. Actually, I think I just was looking at session two instead of session one. Okay, it's David Bradford. I'm sorry and I'm going to stick to it, because people have plans and everything.

David Bradford:

Sorry, John. I'm Dave Bradford, one of the principals of PEGUS Research and also an adjunct faculty at the University of Utah School of Medicine. I'd like to start off by adding my thanks to those of yesterday's participants for the opportunity to discuss creative approaches to OTC switches. We, too, are pleased with what appears to be an effort to find a more efficient path to safe and effective self-care for drugs that treat conditions not historically thought of as amenable to self-treatment. We agree with the motivating idea that increased safe access to efficacious drugs will reduce the amount of under-treatment in the general population and are anxious to participate in continuing discussions about novel ways to assist in making those switches more feasible, as well as more predictable.

Yesterday's discussion highlighted some of the challenges this proposed initiative faces in the areas of public health, public policy, drug regulation, and legal affairs, that need to be sorted out in order to find a path for moving forward on these difficult switches. My presentation will deal with yet another area that needs to be considered, the implications for research design of incorporating conditions of self -- of safe use. It's our observation that it's in this context, in the actual operationalization, that many of the battles of -- for an OTC switch are won or lost.

I'd like to preface my comments with a brief summary of the development of actual use trials as an important source of evidence in the switch process. Actual use trials are designed to evaluate whether consumers can themselves perform the functions that normally fall in the domain of the physician when the drug is available only by prescription. These functions include proper diagnosis of the condition, correct selection of the drug, and monitoring the use of the product making adjustments as needed. There are two big challenges in designing and conducting an actual use trial. The first is constructing a set of operations that create a credible simulation of the proposed OTC environment. And the second is observing subject behavior in ways that introduce as little reactivity as possible into the test, by which I mean assessing past behavior in a way that has minimal impact on future behavior.

We've been designing and conducting these trials for about 20 years. When we first began we often encountered a kind of dismissive attitude by those who were only familiar with experimental trials. We often heard the comment that these studies didn't really seem like science at all, because they have few of the characteristics of the research model that they had been trained in. Our rejoinder, then as now, is that far from being unscientific, actual use trials demand a high level of scientific thinking, planning, and execution. Key elements of subject behavior in an actual use trial cannot be controlled by protocol, so a complex assessment of subject's self-directed decisions and behaviors must be made. The task is made more difficult by the varying degree of subject understanding of both the task itself and the questions we ask about their choices. All this is done with a very heterogeneous sample of subjects whose cognitive ability, familiarity with the drug and the indication being treated, general cognitive and reading ability, and disposition toward self-treatment range across a wide spectrum. We'd argue that compared to that complexity, the interpretation of the results of an experimental trial is a walk in the park.

The point of this digression is to note that with the addition of special conditions of use, we are proposing to add yet another layer of complexity into an already complex test situation. The special conditions that are created to solve real or suspected problems with drug selection or use will be social inventions that will almost certainly have novel, unfamiliar elements. The risk to the sponsor is not just an increase in the number of studies that need to be done, or the cost of these studies, neither of which is a trivial consideration, but also in the increased uncertainty of outcome that adding this additional component will risk bringing into the evaluation. In our view it would be unfortunate indeed if the very vehicle that is intended to help bring more switches over the counter actually resulted in fewer switches because of the increase in these costs and uncertainties. Thus, we'd argue that one crucial question is, how can the switch process be structured so that these additional measures are incorporated without increasing the burden of research beyond what sponsors are willing to bear? We think the answer to this question lies at least in part in not requiring sponsors to demonstrate the incremental effectiveness of a special condition of use. On this point the federal register notice of this meeting is unclear or at least ambiguous, but we argue that ultimately the regulatory decision about approval of a drug for OTC sale hinges on whether subjects select and use the drug properly. As long as the AUT shows that to be the case, the relative importance

of the various components of the simulation, which may or may not include a special condition of use, is irrelevant.

Let me illustrate what I mean by considering in more depth the approach that Dave Schifkovitz touched on briefly in his presentation yesterday where he mentioned the idea of a randomized trial comparing subject behavior in two groups, one with and the other without a special condition. This may at first glance seem like familiar territory, very analogous to a regular experimental trial; however, the nature of actual use results in a different and more complex kind of comparison that might be the case for a regular efficacy trial. Under usual experimental conditions, the experimenter has control over the independent variable of manipulation by specifying in the protocol the behavior the subject is required to perform. However, in an actual use trial, the researcher doesn't control the behavior of the subjects if the character of an actual use trial is to be maintained. Subjects are free to act as they determine they should. So the comparisons between a group where the special condition of use is merely available and one where it is not, whether the subject in a special condition group chooses to take advantage of that mechanism or not is out of the control of the researcher. Moreover, subjects in the other group are free to invent their own special conditions if they feel they need them. In other words, when you randomized subjects to conditions in an actual use trial, you in reality end up with two parallel actual use trials. Thus, any difference between conditions depends both on the existence of the special condition and the extent to which subjects take advantage of it.

So let's say that a study like the one I just described is conducted and the results of the two side-by-side AUTs are compared. How much of a difference between the groups actually makes a difference? And what does that comparison add to the basic question of whether the drug with the special condition or conditions in place meets the criteria for an OTC switch?

The second question that we think is important to consider and which was a topic that the panel posed yesterday, is whether some sort of authorizing step should be put in place to ensure that the requirements of the special condition of use have been met. On the one hand lies the impulse to protect consumers from themselves by limiting the sale and use of these products to those who have met the condition for use. On the other side is the perhaps more libertarian view that the duty of the manufacturer is to simply make the special condition available to the consumer without imposing any authorizing step at all. It would then be up to consumers to make the decision to use it or not, just as they are free to use the drug facts label or not in the current OTC environment. If that model were adopted, there would be a useful argument to be made for the importance of making a separate demonstration that the special condition did in fact by itself have an effect on subject performance.

The final question we'd like to pose or at least discuss has to do with the timing of the development and testing of special conditions. We agree with Dr. Soller's comments about an increased role for post-market surveillance and incremental refinement of conditions for safe use. Naturally, if there are significant safety issues that cannot be

managed without including some additional diagnostic testing, selection support, or usage guidance, measures must be put in place before approval; however, if the issue is reduced efficacy, real or anticipated, is it possible to develop supplemental measures after the OTC approval when the opportunity exists for testing methods using real OTC drug users in normal use situations? Even here we should note that the challenge of designing and conducting post-market surveillance of OTC drugs is different in some important ways from post-market surveillance of Rx drugs. It's also an area of inquiry with little tradition to guide the research and therefore will require particularly creative approaches.

In summary then, we'd argue that every effort should be made to ensure that the process for an OTC switch is as predictable and manageable as possible and that the agency be flexible in considering creative approaches to the design and implementation of special conditions of use. We plan to provide a more detailed discussion of the logic of our position in our written submission. Thank you.

Jane Axelrad:

Thank you very much. Panelists?

Charles Ganley:

Yeah, just so I understand some of your comments. Are you suggesting that if there is going to be a nonprescription product under certain conditions of use there should not be comparison to the Rx, you know, distribution or use of the drug in determining whether this is an effective way to deliver or increase access to the drug?

David Bradford:

No, the comparison that I had in mind had -- did not have anything to do with comparing with current Rx conditions, but rather comparing the proposed OTC condition with a special condition of use with a circumstance where you're proposing a switch that does not include that special condition for use. And the point that I'd make is that going to the extra effort to evaluate the separate effect of the special condition of use is not necessary because ultimately the regulatory decision will hinge on whether -- with whatever condition or conditions are put in place, whether the criteria for satisfactory OTC use are met in the actual use trial.

Charles Ganley:

Let's just take the example of the statin that was discussed a little bit yesterday and using the drug facts, alone, they weren't able to establish that consumers could use the product or self-diagnose correctly. So, in that situation are you suggesting then that someone would have to fail first in that trial and then show that but under these conditions of use, not in a direct comparison, you know, in a parallel fashion, but show that using some type of, you know, kiosk with some buttons the consumer pushed to improve self-selection, and is that what you're talking about then?

David Bradford:

No. No. What I'm talking about is making a sort of straightforward comparison, a two-group comparison, where you randomly assign people to one of two conditions, either --

or one of two groups, either a group that contains or a group that does not contain the special condition or conditions of use.

Charles Ganley:
Okay.

David Bradford:

And comparing the results of the performance of subjects in those two groups. So what we'd argue is that the comparison, itself, really doesn't add anything useful to the regulatory decision that ultimately needs to be made. So, for example, if there's a 5 percent improvement, is that enough? Well, that's really an irrelevant question if the criteria for OTC approval have not been met in either of the conditions, or if it has been met. So, we simply argue that in constructing these kinds of environments, these kinds of simulated OTC use settings, that the best wisdom be used to determine what kinds of structures or tools or techniques need to be put in place, put those in place, but not impose on the sponsor the requirement to kind of sort out the separate effect of each of those conditions of use.

Charles Ganley:

And I guess just going back, you know, some of the issues that came up during the statin discussion was that it had to be compared -- or it had to be as good as what we -- system we have now, including compliance and things like that.

David Bradford:
[affirmative]

Charles Ganley:

But if you have a -- an OTC conditions of use people are able to self-select, people are able to use it, people can decide I don't want to use this anymore, should that even factor in how it compares to an Rx? Particularly if we are saying that a drug could possibly be marketed Rx and also under the, you know, conditions of use as a nonprescription.

David Bradford:

Well, I'm not sure I understand all the ramifications of your question, but we are very much proponents of the idea of doing actual Rx use alongside an actual OTC use, and using the results of those studies to help understand what the implications of removing the physician from the process are. So, we like that idea. The point that I'm trying to make is that there may be more than one special condition of use. You may have something that supports selection and something else that supports use and you have something else that supports deselection or modification of use, and if you impose on the sponsor the requirement to tease out the separate effects of each of those special conditions of use, you create an environment, a research environment that's much more complicated and much more involved and dramatically less predictable than if you simply require that they construct whatever they think is the most sensible environment and then test that.

Andrea Leonard-Segal:

David, I wanted to just see if I can -- if I've got my head around this. What you're saying, I think, is that you would be -- you would be proposing that we would use the target threshold for success the way we currently do now for self-selection study or for an actual use study or even for a label comp study in this realm, and no matter what the special conditions of use are, those conditions would be there. People would avail themselves or not if we didn't have the regulatory authority to require it, the same way we can't require that they read the drug facts label now and if people succeeded in the environment that you're speaking about and met that target threshold for success, this would be the process forward, whether it's a pharmacist involved or whether it's some kind of an algorithm and some kind of a technological apparatus, no matter what that would be, that would -- is that sort of where you're going with this? And looking at the prescription environment as sort of a benchmark as we try to do right now, you're basically saying extend -- use the same paradigm as now, but to weave in these other things in --

David Bradford:

So, Andrea, can I include your summary in my written comments?

Andrea Leonard-Segal:

[laughs] All right. That's what you're saying. I wanted to be sure that I understood you.

David Bradford:

That is precisely what we're talking about.

Andrea Leonard-Segal:

Okay, thank you.

Janet Woodcock:

I'm Janet Woodcock. Welcome. One of the criticisms that pertains to the current -- for prescription drugs is that the randomized controlled setting, in which they are -- should we say, their efficacy is evaluated and their safety is an artificial construct, and we are frequently told by many proponents that this does not mimic the real world experience in both prescribing and use of these drugs. And so we have little information often about things like adherence and appropriate selection of patients in the real world prescription setting. So I'm curious, to what extent do you think that pertains to the kind of studies that you do in the OTC? Do they have more relationship -- how much degree of artificiality do they represent? And then how do you compare those to the prescription -- the randomized controlled environment in which we have judged the outcomes of the same compound in the prescription setting?

David Bradford:

Yeah, that's a good point. There are two sources of artificiality that we're talking about that I think are -- need to be sort of identified separately. The artificiality that you describe that is the case for efficacy trials, the experimental trials of that sort, is artificial because it's crucial in the context of doing those studies to ensure that you can make an

unambiguous comparison between the condition that contains the active agent and the condition that doesn't. And we'd argue that the impulse that surfaces from time to time to do what I think is erroneously called an actual use efficacy trial, is completely misguided, that the tradition -- this artificial tradition of designing experimental trials in a way that maximize the power to detect a difference that exists is a tradition that needs to continue. Admittedly, it is artificial, but the solution is not to sort of open the flood gates to subject heterogeneity or modifications of conditions of use. All that does is just reduces the power of the experimental design.

In actual use trials, the source of the kind of non-natural part of the assessment comes from the fact that we have to take care of subjects. We have to adhere to ethical requirements. And it's the adherence to those ethical requirements along with the need to actually do science that creates an environment that is less than -- or is different from the naturalistic environment. When I go in to buy an OTC drug I don't usually have to sign a consent form to do it. So, that involves a whole different kind of artificiality and the challenge and the design of actual use trials is to ensure that at key points in the process that subjects are making decisions that are based as much on the circumstances that exist in a real OTC environment as possible. So, for example, selection decision is made before they have additional information. So, what we'd argue is that, in fact, these are two different models designed for two different settings and that they are complimentary in the sense that you need to have the demonstration of efficacy that goes along with this broader actual use assessment.

Jane Axelrad:

I'd like to ask just one last question, and that is, I understand how difficult it is to structure these kinds of studies, but if our obligation is to determine the conditions of safe use are necessary for the drug, it seems that we would need to compare the drug with conditions of safe use with the drug without them in order to determine whether they're really necessary or whether the drug could be fully nonprescription without any conditions. So, how would we take that into account?

David Bradford:

Yeah, that's a good -- that's a fair question. The -- I believe that the issue is that many sponsors would be very interested in knowing what the effect of these alternative special conditions of use may be. But in point of fact, if a sponsor comes to you with a proposed OTC environment that they plan to market their drug in, the responsibility of the agency is to evaluate whether, with all of those pieces in place, whether they have been successful at creating or facilitating proper subject behavior. And so, aside from the complicated legal questions that this may raise, the position that I would expect the agency to take is that we have approved this OTC switch based on the characteristics that are incorporated into the design of the study and that it's only under those circumstances that this could be argued to be an appropriate switch.

Jane Axelrad:

Okay, thank you.

David Bradford:
Thank you.

Jane Axelrad:
Okay, our next speaker is Julie Aker.

Julie Aker:

Good morning. My name is Julie Aker and I'm president and CEO at Concentrics Research. I'm here really to represent the point of view of those who research consumer behavior. We design and we conduct consumer behavior studies. And I also hope to represent the voice of the consumer a bit in my comments today. Concentrics Research is a niche CRO that conducts behavioral research in the Rx-to-OTC switch space. We also do other types of consumer research, but we certainly do quite a number of label comprehension studies, self-selection studies, self-diagnosis, and actual use studies. And our comments today are based on over 27 years of experience, over 800 consumer behavior research studies, and research with over one million consumers. So I'd like to just remark on six key points.

First of all, consumers do want more control over their health and we've heard this reflected in the comments in the past day in a number of different ways, but we do ask consumers questions about, you know, their current habits and practices. How do you currently navigate the health care space? What's important to you? So we ask these questions so that we can hear it from their point of view. And they define more control as more -- not just more information, but more relevant information. They're very keen to get information about their own personal health conditions and they're very tuned in to their own personal health conditions and they do desire more information. They seek it out. They want more choices and more options and they define that as more access and more of a range of services. They also want more convenience. I don't know that I speak to anybody that doesn't need more hours in the day and consumers, young, old, and of all walks of life, really just don't have enough hours in the day. So, convenience becomes very important. So quicker options, self-care options, walk-in clinics, or ambulatory settings if they do need to seek out health care assistance and if they need to see their doctor, shorter waiting times. Consumers have definitely proven that they can learn and adapt to new processes and tools. There are so many of them. We live in a technological environment right now and it's evolving whether we want it to or not. It's everywhere. So we have ATMs. We have self-scanning at the grocery store. If you get home from work today you will probably have some automated message that's scheduling you or reminding you of an appointment and this certainly happens with health care. Many consumers have cell phones and smart phones and they're really quite adept in using the apps on the smart phones. If you don't believe any of that, I would just ask you to think of the range of individuals that play video games and how these have become extremely sophisticated and complex. It's mind boggling when you see the types of video games that are out there and these are also played by young and old and individuals of all levels of education and so forth. Consumers are also ordering consumer goods online and this includes drug refills.

If we're considering this whole issue of whether consumers can make correct self-selection decisions, if they can make those correct decisions at the retail setting and then also monitor their health, consider that we have blood pressure cuffs that you can go to any retail outlet and purchase and monitor your blood pressure. We've got diabetics that are doing testing and deciding when to administer injections. We have those that are self-catheterizing and we are having those that decide when and how to give nebulizer treatments at home. And I will tell you that Concentrics has been involved in a number of different types of studies where we are testing innovative technologies and tools. So, we've already started to test some of these new innovative approaches that sponsors bring to us. And they -- they're quite varied, but I will tell you that when we do test these types of tools or technologies that the consumers do quite well. They're not intimidated by the tools. They're used to it. It's the environment that they're in. And not only do they do quite well, but we notice that they do receive benefit, meaning that the scores on the self-selection studies do go up.

As we consider the conditions for safe use in this hearing, flexibility is critical when considering the use of these tools. So, I think we've all heard these comments that not all drugs will need a novel process or a decision making tool or technology. This should be a case-by-case evaluation. But I'd like to offer that the case-by-case evaluation should really be based on the complexity of the decision making for the consumer. And that really is in two main areas. One, the sheer amount of information that they have to digest and that could be on a drug facts label, but could also be in a brochure or instructions for use. It could be in a variety of different areas. And then two, the number and the complexity of the variables that they have to hold in their head all at the same time to make a correct decision can also make things quite difficult. So this varies by drug and it varies by the relevant populations.

So how do we actually assess complexity? Well, I would offer that if we listen to consumers they will lead us down the right path. They know. And so if we're doing label comprehension work and we have this process that we're all very familiar with where we test, we adjust, we retest, and this iterative testing is part of the whole process in order to optimize that label. We do the same thing with self-selection. We test. We adjust. We retest and so forth, and optimize that label based on the feedback. So, if we had a series of iterations where we are just still having quite a bit of problem with a particular area and a lot of times this does fall in self-selection, these might be situations in which a tool or a technology could be quite helpful.

Tools can facilitate correct decision making. As I mentioned earlier, we've done studies with various types of tools. We've studied aids, such as checklists, surveys, frequently asked questions, tracking tools. We've also tested technology tools, such as kiosks and computer-driven questionnaires, very similar to what you saw yesterday. And I will tell you that we do a two-arm study, like we were discussing just now where we have one arm of the study that does not have the tool and the other arm that does, and we've noticed that in using these -- when we look at the technology and we look at the overall scores for self-selection, they generally improve 10 to 50 percent. So there's quite a jump that happens overall when you look at average scores when the tool is used. I would also

say that those of lower literacy can also use the tools. Sometimes that is a consideration and a worry that those of lower literacy may not be able to use tools or deal with these types of interactions, and really they do quite well. But one thing to keep in mind is that those of lower literacy do not navigate the world the same way that we do. It's not lesser, it's different. And it's something that really needs to be respected in that they really do quite a good job of navigating the world. When we ask them if they purchase OTC products, how they use them, how they make a decision about OTC products, what's the process by which they make those decisions, they will tell us that number one, they use family members. Secondly, they use friends, and then sometimes they use friendly resources in the retail outlet like the nice lady at the Wal-Mart.

Tools can facilitate correct decision making and emphasize key information. We've been talking a lot about self-selection and that's a decision that's made at the retail outlet at that point prior to use. And so what we're talking about here is can the consumer make the determination that the product is right for them or not right for them? So, on that drug facts label we have our indications, which is under the uses section. We have the contraindications under the do not use section, but we also have conditional warnings that are on the drug facts label that are important and it really does not -- those warnings don't preclude someone from using the product, it simply states that there is an action that needs to be taken. Ask a doctor or ask a pharmacist prior to use. These tools and the technologies that we're discussing are also an important opportunity for reminders, key reminders, or education. So, you heard Dave Schifkovitz bring up a good example yesterday where education was intertwined into the tool, which is a great opportunity. But this is also an opportunity to emphasize key warnings, like a stop use and ask a doctor warning. So, you might see something on the kiosk that would say, remember to see your doctor if any of the following things happen. Or remember, it's very important to check the following diagnostics on a regular basis.

The next point is that the labeling and the tools need to be tested to optimize comprehension and ease of use. We all know that the drug facts label is pivotal to these OTC products. We test these labels in label comprehension and self-selection studies and ultimately in actual use studies. So we know this process and there are guidances out for label comprehension and for self-selection. But we also need to test the tools to evaluate if consumers can use them appropriately and if they can ultimately benefit from the tool. There are other guidances that have been very helpful in this regard, this interface between the consumer and the tool. There is draft guidance out of CDRH for human factors testing for simulation testing. There are formative studies. There are human factors evaluations. And those can be very instructive in designing a good study in melding kind of the best of what we know from label comprehension and self-selection guidance with human factors really gives us some really good guidance in the regard. What we do is we do design a two-arm simulation study with and without the tools, just as we've described here, and then we evaluate whether consumers do a better job, get better scores with or without the tools. Obviously this is an iterative process. We always learn something that can be improved and adjusted before we go into large quantitative studies. We would also put on the table that we should consider allowing those of lower literacy to use their typical compensating mechanism if it is real life for them to use their

sister, to use their mother, to use a friend, or the nice lady at the Wal-Mart. Those types of things really should be permitted in the testing regimen, because that's exactly what happens in real life.

And finally, self-selection and self-diagnosis studies should be considered as essential clinical investigations. In self-selection we're, again, looking to see if consumers can make correct decisions about whether the drug is intended or not intended for them, very pivotal. The self-diagnosis is really a subset of self-selection and it's really the ability of the consumer to correctly identify the condition or the symptoms for which the product is intended. That -- those types of studies often require clinical aspects where we have a physician's assessment, laboratory testing, or diagnostics in some way, shape, or form, to assure that we have a physician diagnosis to compare to the consumer so that we can confirm that they, in fact, did self-diagnose correctly. So based on the growth of these studies, the complexity of these studies, and the clinical elements in the studies, we would submit that these are essential clinical investigations and should be considered for exclusivity purposes.

So in summary, consumers do want more control over their health care and they're telling us this. They have proven to us that they can learn and adapt to new processes and tools and that includes the research that we've already seen with innovative tools and technology that proves that they -- they're not intimidated by these things and they can use them quite well with benefit. The conditions of special use should be flexible and dependent on the complexity of the consumer's decision making. But the tools should and can facilitate correct decision making, that the tools should be tested, though, in advance to optimize not only the process that's used, but the interface between the consumer and the tool itself. And finally, that self-selection and self-diagnosis studies should be considered as essential clinical investigations. And this is very aligned with the future, because we see physician's offices that are created absent portals for their patients to make appointments and to ask questions or request a refill, even in some cases to view their laboratory results. So, the consideration of these six key points are very much aligned with health care trends going forward to provide more access to relevant health care information and drugs, to connect with health care providers for key questions and referrals when it's necessary, and to create more convenience for self-care in the OTC environment. Thank you.

Jane Axelrad:

Thank you very much. Panelists? Andrea.

Andrea Leonard-Segal:

Julie, hi. So you made me think of something that I've been wondering about when you talked about not enough time in the day. We're testing these tools in self-selection and maybe even the pharmacist part of this, and I'm not sure how that's going to go in a setting where people are available, and I wonder what happens if there's a line next to the tool. Because if there's one tool and a lot of products on the shelf or if people have to wait to ask the pharmacist a question or if that's part of the process, how do we weave

that in and understand its effect on self-selection and people's likelihood to use the tool and take advantage of what it can add?

Julie Aker:

[affirmative] That's a good question. You know, a couple of things come to mind. One, it's lucky that not everyone comes into the retail outlet at precisely the same time and so what our observation in this testing has been is that consumers come in. They look at the drug product and so they're going to examine it before they start to use the tool. That's generally the process that's used. And so people will be in different stages of reviewing or using the tool. The other thing is that, you know, there may be multiple tools that are available. So there may be more than one, for example, so that -- more than one kiosk, for example, so that the line doesn't back up. So there are a variety of different ways. In some cases they can interface or ask a question of a pharmacist and in some cases, and I think we've heard this, they may choose not to use the tool. They may choose to look at the label and make their decisions in that regard. So there are a variety of different ways here. We've actually seen methods in which there were banks of these things, not unlike what you see at an airport where you've got a bank of these things when you walk in that you can put a card in and really assess what drug you're talking about and then proceed in that way. So there are many access points.

Jane Axelrad:

Okay, thank you very much. Jimmy Mitchell?

Jimmy Mitchell:

First of all let me thank you for the opportunity to present on behalf of the Patient Safety Clinical Pharmacy Services Collaborative and several hundreds of organizations across the country that are participating in the collaborative. So, thank you for this opportunity. The administrator of this collaborative, Dr. Todd Sorensen from the University of Minnesota, would be here but he had other commitments and so as a board member I am presenting for the collaborative. And if we can get this to advance.

[laughter]

Oops. There we go. Okay, now that we still have a slide projector and a screen. What I'd like to do is to quickly explain to you what the Patient Safety Clinical Pharmacy Services Collaborative is, what the -- we call it the PSPC and now then what is the alliance, and how the alliance is achieving change, and how the alliance could support the FDA's new paradigm. Quickly, the collaborative is a national quality improvement collaborative aimed at improving health outcomes and patient safety for high-risk, and read this, high-risk chronic disease patients. It does this by having teams in the communities, this is community-based. They changed their delivery system to fill in the gaps by enhancing care coordination. It focused heavily on multidisciplinary teams, strengthening patient-centered medical home. Many of these teams have safety net organizations that are embedded in their core and integrating what we call clinical pharmacy services or medication management, enhanced medication management, and other services to minimize harm and to maximize optimal health outcomes.

The collaborative was started by the Health Resources Services Administration back in 2008. It was led by its Office of Pharmacy Affairs and at that time I happened to be the director of that office and have since retired. It's based on health care improvements, model of small rapid iterative change designed to spread to large populations and services, start small and spread what works. It's based on a change package that we developed from researching the literature and visiting some 35 "high performing organizations" nationwide and cataloguing what they did and how they did it and then put it into a synopsisized change package and invited organizations from across the country to come and work with us to implement the change package using IHI's model.

We are happy to say that CMS has joined the collaborative, and its quality improvement organization's latest statement of work includes a provision for those QIOs to work with the collaborative and to bring teams into the collaborative. Now we're not particularly -- I'm personally not particularly happy that HRSA, due to funding constraints, has indicated it will no longer lead the collaborative after the end of this year, but I am happy to say that the PSPC alliance, a nonprofit organization, has been incorporated and is ramping up to assume the leadership that is currently shouldered by HRSA. The alliance is a nonprofit, not-for-profit, organization. It is incorporated in the District of Columbia. It's working to expand, to extend, to accelerate, all those good words, this great work of the collaborative. We think it's ground-breaking. It's an effort to coordinate care by integrating clinical pharmacy services into the care and management of high-risk, high-cost patients suffering from multiple chronic diseases. Some of these teams do not have clinical pharmacists on their staff, but most of the teams are getting clinical pharmacists to help with the delivery of services. They're integrating these services into their primary care delivery system. Where they don't, the service is provided by nurse practitioners, medical assistants, and others, and let me state, too, that many of these teams also have contracts and have relationships with community pharmacies and pharmacists to provide these services in an integrated way.

The alliance was formed by a coalition of the American Pharmacists Association, the American Society of Health Systems Pharmacists, the American Association of Colleges of Pharmacy, the American Nurses Association, and Apexus. Apexus is a prime vendor for the 340B drug pricing programs that many of these safety net organizations depend on. It has a multidisciplinary board and it's in action as we speak. The value proposition that the collaborative brings is that every community in this country has high medication risk patients and they're in crisis. The patient population that we're talking about, the current delivery system is failing them. They're out of control and these are the patients that we're focusing on. Community partners offer these high-risk patients an innovative delivery system that fills in the gaps that helps -- tends to bring improved health status and safety under control. They offer a business case for innovation where health plans can manage the reduction in health care costs by shifting patients from high cost, uncoordinated care to low cost -- lower cost, coordinated care.

Here we see a map of the United States. Every state except two has a team in it as we speak. We're in the fourth year of this collaborative. There are almost 500 organizations

that currently participate. They have formed almost 200 teams. Participating organizations also include almost 60 health profession schools. A large number of these are pharmacy schools with medical schools, nursing schools that are involved and, interestingly, the schools are seeing these teams as practice sites for team-based education. There are over 40 QIOs that are actively involved with teams as we speak and let me also state that in partnership from the get-go, the FDA's Office of Women's Health has been a full partner and we have utilized their patient education material throughout the country with these patients.

These teams are improving medication outcomes. It's not business as usual. Care is personalized. It's patient-centered. Providers monitor the patient and adjust medication. It sounds as usual, but it's in a different setting and a different mindset. Patient care is coordinated. Therapy is coordinated. They are changing their practice to improve safety and it requires the integration, this interprofessionalism, and the inclusion of clinical pharmacists into every aspect of their care delivery; and this is primary care that we're talking about. Outcomes in a nutshell. At the end of three years, teams report, and they do report their data. They collect data and they report it. After six to 12 months, teams entering the collaborative implementing the change package, report a 30 to 50 percent change in the populations of focus of these chronic diseases from being out of clinical control to being in clinical control.

Here we see the primary chronic diseases that these teams focus on, and this is a slide from the latest reporting cycle where 50 teams tracking over 78 populations of focus of chronic disease patients that were out of control that are coming into control, and you can see the percent on the right side of improved clinical markers by these teams.

Expanding practice. These teams were expanding their practice. They start small and they're ramping up. They have garnered the full commitment of their executive and clinical leaders. They're gathering and tracking data. They're data driven. As I said, they're patient-centered and they're integrating clinical pharmacy services throughout these teams delivery system. Medication safety is systematic throughout these teams. It's integrated throughout their processes. It's not in a back room. It's not the responsibility of one individual. Here we see for safe use systems that these teams tend to focus on is two stages. One is to identify the potential adverse drug events that are occurring in their system. Most of them are unaware of the potential and actual adverse drug events that are occurring because of their systems until they start to look for it. We've developed the tools that enable them to do that, to spot PADEs, to correct them, to control them, and then to manage them and eliminate them. This has a direct impact on the actual adverse drug events of diagnosing, treating, and avoiding them.

Here we see two graphs of these teams, and you'll see that the left one is the identification, the control, and the management of the PADEs. This line tends to maintain itself with all of these teams. On the right side you see the same graph -- line graph of the PADEs overlaid with the actual adverse drug events that they have captured. When they start out they find a high number and as they manage the system for PADEs, the adverse drug events tend to drop near zero. Just a recent reporting, 41 teams had an

average of 1.5 PADEs per patient. When they start measuring after four more months, they have then dropped to about eight. The actual adverse drug events that are measured, 39 teams reported almost 7.7 ADEs. That should be ADE and not PADE on that slide. Now after four months they report that -- to have dropped to about 0.5.

The PSPC, and the FDA's effort with this new paradigm, we're excited about it. We think if FDA carries forward it would enhance our ability to provide these services to the patients. It would enhance these teams' ability to form and to work successfully within the collaborative. We think we have the infrastructure, if FDA would like to pursue this further, for post-marketing evaluation in these teams and, again, these are community-based teams that are composed of all providers that are working together for medication safety and improved outcomes. So we think the revised medication classification system would help us meet our goals and we think we could help the FDA in meeting its goals. Thank you.

Jane Axelrad:

Thank you very much.

Mary Kremzner:

Hi. Thank you for that presentation. So, you mentioned that you have some outcomes data. Will you be submitting some of that data to the docket?

Jimmy Mitchell:

We'd be glad to.

Mary Kremzner:

Okay, thank you. And also, you mentioned that HRSA is ending their funding this year, I think it was, and your leadership is moving in a direction to offset some of the loss of that funding. So this is all based on grants? Is that how you report?

Jimmy Mitchell:

No. This is an unusual federal program that was ramped up. These teams are not given any money, not federal money, to participate and we were just really interested when we developed this program and we put the change package out on our website and used other means to communicate to -- starting out with HRSA's safety net organizations and others that the Office of Pharmacy Affairs worked with. We invited them to form teams and come and work with us. We told them we had no money. There is no grant money. No contract money. It's purely voluntary and it continues to grow. Almost 500 organizations now voluntarily participate. And the reason for it, let me say, you know, these teams and these clinics and these hospitals really want to do what is right. There is so much money involved in health care. I mean, we all know that. And these organizations also struggle within their own budgets, but the money is there. It's a matter of changing what they're doing to make better use of the resources and improve the outcomes and the cost of these out of control chronic disease patients is astronomical. So, if you can reduce that cost there are savings that can be redirected back into the program.

Robert Temple:

The estimates of success come from mostly what? Cohort studies? Or taking a look at the community at time zero and then eight months later? Or how do you do it? Can you say a little bit about what --

Jimmy Mitchell:

How do we collect the data?

Robert Temple:

Well, what's the design. I mean, you showed, you know, figures on how much improvement there was on potential side effects and all those things. How is that measured? Is it a single bunch of people followed over time? Or a slice of the community at one time and then a slice of the community at another time? It doesn't sound like it's likely to be random.

Jimmy Mitchell:

It's not that precise. Let me say, these teams when they form, they're not tracking, for example, adverse drug events. As the matter of fact, most of them think they have zero adverse drug events, whereas in fact, when they get into the collaborative they start looking and they use the tools. They found out they've got an enormous amount of problems with adverse drug events. What we ask them to do, and we ask them when they first join, is to report data in a certain format. It's self-collected and it's self-reported, and that's where the data comes from. And the data over time then is shown in those graphs. But it's self-reported data, okay? It's not controlled for a particular population. It does not -- it's not that precise. This is health care in the trenches, really, where data is being collected.

Andrea Leonard-Segal:

So, thank you for your presentation. I'm trying to understand a little bit more about who comprises these teams, whether they're similar to the concept of medical home. I don't understand how those things are different. And, how you perceive this process that you have underway as interweaving with this new FDA paradigm that we're talking about here, either with OTC technologies to enhance self-diagnosis and self-care, or the process of involving pharmacists in self-diagnosis and administration of certain medications.

Jimmy Mitchell:

Let me see if I can grasp -- there were two or three questions there, but let's see if I can respond to them. The organizations that participate -- I can provide you a list of the organizations if you would like, but categorically, the community health centers compose a large number of these sites. Disproportionate share of hospitals, these are hospitals that serve a disproportionate share of the uninsured, underinsured. These are safety net organizations that the Office of Pharmacy Affairs, where my roots were, was, these organizations with which we work. However, now when we started the collaborative, other organizations wanted to join and for good reason. These chronic disease patients are the responsibilities of local communities, as well as the community health center, the

[unintelligible] hospital, state health departments, local health departments. So we have health departments involved. We have schools involved, academia involved, and we -- as of this moment we do not have private physician's offices involved. It's been focused on primarily the nonprofit sector. Now that -- there was another question about how this paradigm might help. Is that correct?

Andrea Leonard-Segal:

Well, I guess that I was trying to understand who in this care, so you have physicians that are involved. You've got nurses. You have --

Jimmy Mitchell:

We have a large number of physicians --

Andrea Leonard-Segal:

-- pharmacists. You've got --

Jimmy Mitchell:

-- nurse practitioners, medical assistants, social workers, and others involved in these care teams. That is correct.

Andrea Leonard-Segal:

They sort of embrace the same notion of this concept of medical home that is so prominent now, and so how does this interface with the -- with this new OTC paradigm? That's the next piece of the question I'm trying to understand.

Jimmy Mitchell:

Well, let me see if I can give an example. These teams from Holyoke, Massachusetts, to Sioux Falls, South Dakota, to Tucson, Arizona, to San Diego, there are teams, huge teams some of these, that are focused on these patients. These teams have delegated to their teams their provision of medical services, changing medical regimens, drug regimens based on the needs of the patient. Much of this is pharmacist-driven within these teams. Some of these states have authorities that permit the pharmacists to make more decisions than others. But moving some of these drugs perhaps from prescription to nonprescription would enhance the ability for the collaborative to continue, whether it's Lipitor or some of the other statins, okay? There's a good example. Since dyslipidemia is one of the chronic diseases that are being tracked all across the country, particularly for patients who are out of control when they enter the collaborative. Does this answer the question? Was there another one that I missed?

Peter Beckerman:

Just following up on Dr. Leonard-Segal's question, given that your organization focuses on high medication, high-risk, high-cost patients, is there any concern about the potential cost implications of shifting products from prescription to over-the-counter with conditions of safe use if that has implications for the out-of-cost -- out-of-pocket costs per patient?

Jimmy Mitchell:

It reduces the cost of the drug. Most of these organizations provide the drug to the patients whether patients can pay for it or not. If the cost of Lipitor OTC happens to drop, then conceivably it would have cost implications for the overall delivery system for these teams, because you're dropping the overall cost, yeah. Where the patient is paying for it, it would have direct implications because they would be paying a lower cost for the drug.

Peter Beckerman:

I guess my question is, you know, we've heard in relation to other drugs that have gone on to the OTC switch that sometimes the out-of-pocket cost actually increases for a patient, right? They are no longer covered by insurance, so is this any sort of a concern for --

Jimmy Mitchell:

We have a real concern if insurance discontinued payment, if Medicaid discontinued payment because it's not a prescription, if the 340B program, which is prescription-driven, if all of the sudden these safety net organizations could not purchase reasonably-priced drugs for their patients that cannot pay, yes that would be a real concern. And I would hope that if you go down this road that the insurance companies and somehow the authorities would require insurance to pay. Otherwise, it's going to be a failure unless you're rich.

Jane Axelrad:

Okay, thank you. Whitney Englander.

Jimmy Mitchell:

Thank you.

Whitney O'Neill Englander:

Hi, thank you so much for the opportunity to speak today. A little bit about who we are and why we're here. I'm Whitney Englander with the Harm Reduction Coalition. We're a national advocacy and capacity-building organization that works to improve the public health of communities that have been negatively impacted by drug use. And we're really here today to offer the community perspective and the voice of advocates on the ground that face significant challenges with the prescription medication and access to a medication in order to address a very important public health threat. Let's see if I go the right way. Great, no screen falling.

A little bit about one of our greatest concerns is opioid overdose. It's a very significant public health problem that has been growing rapidly. And the standard of care and medication that reverses opioid overdose is naloxone, which is a safe and effective prescription medication, and we'll talk a little bit more about this, but naloxone has significant issues in terms of access, cost, and it's a drug often in shortage. So removing barriers to access naloxone is -- has the potential to save thousands of lives a year.

So a little overview. Here's a quote by the Centers of Disease Control. "Drug overdose death rates in the United States have never been higher." I think we've all been hearing a lot about this. Here is a chart. It goes back to 2007. This is a CDC chart. We do know that it continues on up through 2010, and we can safely assume it's continuing up in 2012, that the rates of overdose are exploding.

Here's a picture of the substances that are currently contributing. There is a rise in cocaine. Heroin deaths are staying about steady, but prescription medications or opioid analgesics are absolutely exploding. So clearly opioid misuse is not decreasing. Admissions are up 345 percent and hospitalizations for our very young, the 18- to 24-year-old range are up 122 percent.

So a little bit about naloxone. As I said, it's the standard of care in addressing overdose. It has been used for over 40, about 45 years in emergency rooms, and by emergency personnel in ambulances. It's also used in the operating room on the crash cart for anesthesiologists or to pull people out of anesthesia. It is a prescription medication. It's very effective and it rapidly reverses the effects of an overdose. When somebody's experiencing an overdose their central nervous system is being overwhelmed and their breathing has stopped and slowed. Within a couple of minutes after administering naloxone, breathing is restored, the person or victim regains consciousness. It works by dislodging -- the naloxone dislodges opioids from the opioid receptors on the brain. It's important to note that there are -- there's no potential for abuse of naloxone. There's no unpleasant psycho-after effects, and it's absolutely benign in an individual that has no opioids in their system. So if you happen upon someone and you think they're experiencing an overdose and you administer naloxone, it won't affect them. No harm, no foul. And again, it's the standard of care.

So, the rationale for lay person-administered naloxone was there was advocates on the ground who were working to improve the health of active drug users. There was an infrastructure laid and a lot of syringe exchange programs. And they were working really hard to prevent HIV and hepatitis C and other infectious diseases, but what they heard in the feedback that they got back to them is that number one, the people they were caring for very much cared about their health and well-being. They did very well at, you know, maintaining treatment and wanted to protect not only their health, but the community's health as well. But the overwhelming concern was not necessarily infectious disease, but overdose. The staff in these programs, what they saw was -- where they saw the deaths happening were overdose and that's what people on the ground were seeing. So, there was a real innovative thought about 15 years ago. Since naloxone is the standard of care in emergency rooms, it's really safe, it's really effective. It's benign if somebody is not experiencing an overdose. How can we -- how can we use that in the community? Because we knew that people were dying because people weren't calling 911. They were scared to call 911. When they called 911 instead of the paramedics arriving, the police arrived. So the rationale, let's give it to people most likely to witness an overdose.

Overdoses, there's a window of time, about one to three hours. Usually there are bystanders and most important, it's -- the quicker you can administer naloxone the greater

you are doing to reduce risk to vital organs and the brain. So many overdose deaths are preventable with prompt recognition and treatment. Here's just a little slide of the importance of calling 911, rescue breathing, and naloxone.

So naloxone can be administered in two ways. One, by an injection in the muscle, also through the nasal with an adapter. The nasal has, you know, clear advantages. It's very user friendly. You don't have to deal with needles and it's just a squirt up each nostril. And it's been known to be just as effective. Here's the kit. Very easy to assemble and put together.

So legal issues around naloxone. All states allow for prescription of naloxone to people at risk of an overdose. Of course the person at risk for an overdose is not going to administer it on themselves, so many states have passed legislation to allow for prescribing to people most likely to witness the overdose. Some jurisdictions have initiated their own laws and programs and, of course, some agencies just do it. The current settings of naloxone training and distribution are syringe exchange programs, drug treatment programs -- and I would just go back quickly and say that the syringe exchange programs, most of the ones that are funded by the city and county health departments, are also incorporating naloxone distribution into their programs. Drug treatment, when people are leaving incarceration and physician's offices as well. There is a very innovative program in North Carolina called Project Lazarus, which has this small county in North Carolina had the third largest overdose rates in the nation, so they developed this program, really innovative, where they had a lot of medically fragile individuals with high -- legitimate pain patients with high levels of medication, and those patients are going home, and there was cooperation with CMS to organize this, and those patients are going home with a naloxone prescription. And I didn't share those slides, but you can see the rapidly declining overdose rates. They also have incorporated it in Fort Bragg and Fort Campbell to Military personnel who are vulnerable -- coming home with significant pain injuries and issues and are vulnerable to overdose.

So new and potential models. A little bit of the flavor of what I'm trying to show, too, is that there are significant barriers to naloxone being over-the-counter, I mean, excuse me, prescription, and making it over-the-counter would obviously make access to naloxone -- remove a lot of barriers. In Italy it is over-the-counter. In Massachusetts approved trainers are able to distribute under the auspices of a physician, and there's also many other possibilities. It could be pharmacist prescribed. It could be, you know, behind the counter and you just had to show proof of training. There's many options to make it more available.

Some program support. New York, New Mexico, Massachusetts, Baltimore. Those are -- there's a lot of funding from state and county health departments. So, we did -- a colleague of mine, Eliza Wheeler, recently published in the MMWR a great overview of naloxone distribution and it documented 188 programs across 16 states and they documented that 53,339 individuals had received kits and there were 10,194 overdose reversals. We have done, since then, some targeted data collection and we do believe that this is probably significantly underreported.

So is it effective? And I just want to say before I begin, I can't obviously show confirmation, I can just show a correlation -- but in many of the areas that were suffering the highest rates of overdose rates, Baltimore, Boston, Chicago, New York, and Pittsburgh, they needed a solution. They needed a solution fast. They, you know, introduced naloxone distribution programs and right now these are the areas in the nation that are bucking the national trends. New York City just released some information the other day that showed a 37-percent decrease in their overdose rates. So here's Allegheny County outside of Pittsburgh and you can see a -- the lines of heroin use and prescription opioids and two arrows of when naloxone programs were introduced. So as you can see, unfortunately the way the distribution programs are designed, they're really reaching the heroine users and not the prescription drug users and, unfortunately, prescription drug deaths are continuing to rise. But heroin use in the county is actually rising at the same astronomical levels.

So national developments. Operation Opioid Safety. The U.S. Army is incorporating naloxone distribution into their overdose prevention plans. SAMHSA is collaborating with other partners on creating an overdose prevention tool kit for outpatient drug treatment programs and PEPFAR funding can be used for prevention services. I also will say, too, on the international front there was a resolution recently passed. We just got back from Vienna, Austria, and with a lot of U.S. support, an overdose prevention resolution, which signified naloxone as the standard of care to prevent an opioid overdose, was passed. It also urges international -- urges countries to incorporate overdose prevention strategies, including naloxone, into their drug strategies.

So we're very excited about national developments here as well, which is the FDA is holding a scientific workshop to discuss making naloxone more available and that will be on April 12th. And I think if we have just a quick illustration here. Are you able to press play?

So in conclusion, again, I just wanted to present naloxone as a perfect case study for a medication that is currently facing many barriers the community is facing in being able to provide it and distribute it to the people who need it. It's successful. It's effective and it's safe. We know that naloxone lowers overdose rates and expanding the use of naloxone has the potential to save thousands of lives. So thank you.

Jane Axelrad:

Thank you very much. Andrea.

Andrea Leonard-Segal:

Thank you for your presentation. I wanted to clarify one or two things. Your cartoon shows nasal administration. Please correct me if I'm wrong, I don't think that we have an approved nasal formulation in this country. Is that correct?

Whitney O'Neill Englander:

We do not, so it's an off-label use and if I'm -- if someone were to get a prescription from their doctor to get naloxone right now for the nasal, they would literally have to get a prescription for the naloxone and for the nasal adapter and it would have to be bought separately and put together.

Andrea Leonard-Segal:

So, well it also appears that there'd have to be efficacy studies to show that the administration of the product works and is safe. Correct?

Whitney O'Neill Englander:

Absolutely.

Andrea Leonard-Segal:

And could you tell me a little more about Italy? It's over-the-counter. What does that mean? Is that behind the counter in Italy? Is it actually out there on the shelf that people can just pick it up?

Whitney O'Neill Englander:

Yeah, it is actually -- and I wish I could tell you more about it. Unfortunately, it seems the Italians don't even know very much about it and haven't collected any good data, but we are looking into it. I just found this out while I was in Vienna last week and I literally saw a picture of it. It's just available out on the shelves. And there's an insert inside of it that explains how to use it.

Andrea Leonard-Segal:

And is that a syringe or is that for nasal instillation?

Whitney O'Neill Englander:

It's actually for the syringe.

Andrea Leonard-Segal:

For the syringe.

Whitney O'Neill Englander:

[affirmative]

Andrea Leonard-Segal:

I see. Okay. And so when you think about these new paradigms do you have ideas about what would be the best way for naloxone to be available OTC? Would it be just OTC or would it be with conditions of safe use? Or would it be with a pharmacist? We don't have behind the counter in this country.

Whitney O'Neill Englander:

That's an excellent question, I mean, I think just making it over-the-counter would remove significant barriers, make an enormous difference. I think it does need some amount of insert to show how to use it and describe it. I am not sure -- I'm really

interested in the hearing on the 12th to talk about these issues, and I don't know if I can actually say what I, you know, confidently one way or the other. I think both are great options. I mean, it's also very important that people recognize they still need to call 911 and they still need to get medical care. We just know people often don't. Number one, and number two, those moments are critical when you're not getting oxygen to your brain. If you can have that on hand right there, still call 911, but administer the naloxone as soon as possible.

Andrea Leonard-Segal:

I guess one more question if I could, Jane. I guess if there would be people that might have concerns about a product administered with a needle being on the shelf, how do you feel about that in terms of safety of use and other kinds of issues?

Whitney O'Neill Englander:

Well, I think that what we're hearing from the folks at FDA here are that they're very interested in laying down the pathways for intranasal naloxone. I would agree with you that there's -- and also there's a NIDA grantee right now that's developing another device like an EpiPen to deliver it as well. So I would agree that the injection form would not be the best option for an over-the-counter.

Jane Axelrad:

Okay, thank you very much. All right. We're going to take a 15-minute break. We'll reconvene at 10 minutes to 11:00. Thank you.

[break]

Session 2

Jane Axelrad:

Okay, let's begin. Is John Delfs here? John? Sorry, I was afraid you might've gone away after I mixed up the agenda this morning.

John Delfs:

Okay, I may need coaching on how to move the slides. Oh, oh, it's here. Okay. Okay, got it. Thank you.

Dr. Axelrad, Dr. Woodcock, distinguished panelists, ladies, and gentlemen, thank you for the opportunity to speak to these issues. I'm Dr. John Delfs, board certified in internal medicine and neurology. I formerly taught on the faculty of Harvard Medical School and Harvard School of Public Health and also was chief of geriatric medicine at the Deaconess Hospital in Boston. I have experience in medical practice, both in academic practice and private practice, as well as in medical education, disease management, and managed care. Currently I serve as medical director in a not-for-profit Medicare Advantage plan in New York City. I also serve as a senior fellow at the Foundation for Health Smart Consumers, a 501(c)3 organization with a mission to promote the development of a society of health consumers who confidently and competently take accountability for maintaining and improving their health in active partnership with health care professionals, and today I'm speaking on behalf of the Foundation for Health Smart Consumers.

Today I will speak from a high level view, first of the promise of our knowledge and tools, then of the reality of health care delivery in our country and of the outcomes, and therefore, of the significant gap between the promise and the reality of our health outcomes. Next, I will briefly discuss the challenges of primary care access and in that context the opportunity inherent in a new paradigm for additional nonprescription medications.

My message at its most basic level is that taking advantage of this opportunity does not mean simply that appropriate drugs become available on a nonprescription basis. Doing it in a safe and effective fashion means creating that new paradigm in which consumers are educated and empowered, there is appropriate access to and partnership with health care providers, and technology is used effectively for data collection and integration, including tracking of both prescription and nonprescription agents, and able to support both appropriate self-care, as well as care coordination and partnership between the consumer and health care providers. We have a significant opportunity at this juncture in health care delivery in the United States.

At the Foundation for Health Smart Consumers, we believe that expansion of nonprescription drugs of appropriate categories in the treatment of certain chronic conditions can be of importance in expanding access to treatment for chronic conditions in empowering patient consumers to take appropriate responsibility for their own health and health care and in facilitating efficient and effective engagement with physicians and

other health care providers. We believe that appropriate expansion of nonprescription drugs could both drive improved health outcomes and help control cost. This moment holds great promise.

We now have pharmacological agents that more effectively than ever before manage hypertension, hyperlipidemia, and diabetes. Properly used, these agents can, for instance, significantly improve vascular endothelial function and slow or even reverse atherosclerosis. They can help us live not only longer but have more functional lives and higher quality lives. They can decrease suffering and lessen economic costs and much the same can be made about agents in a number of other disease categories. For instance, say migraine, asthma, et cetera. Ideally, each consumer would have excellent access to preventive care. Each consumer would be screened regularly for important risk factors and each consumer, in partnership with their health care providers, would become educated and would commit himself or herself to good health behaviors, including adhering to appropriate medication regimens prescribed by those provider partners. That's our promise. That's our ideal.

Now for a reality check. The reality at the present time falls far short of the promise. We have major challenges that stand in the way of optimal health outcomes, optimal quality of life, and control of costs. For instance, approximately 75 million people in the United States have hypertension. Now we have made significant progress over the last several decades. We now have 72 percent of persons with hypertension in the United States who are given prescriptions for antihypertensive medicines, and 48 percent of the persons with hypertension in the United States are now under control. And this is an enormous increase over the last several decades. However, this leaves less than 50 percent of the persons with hypertension in the United States still hypertensive not treated effectively. Why have we been so unsuccessful? Well, part of the problem is awareness and access. Another problem is coordination of care, but adherence is also a huge part of the problem. For instance, a recent study by Conna and Colleagues, which is available electronically and soon to be published in *Population Health Management*, describes the adherence to prescription therapies of nonelderly Medicaid recipients continuously enrolled in the Mississippi fee-for-service Medicaid program for a two-year period in 2006/2007. The data that they have made available on the web and which will soon be published in print show that for patients under treatment for hypertension in that population, only 42 percent were adhering to the treatments prescribed. For hypercholesterolemia, the adherence was 32 percent. For diabetes, the patient's adhering to their medications was 35 percent. So despite the fact that we have much of the necessary knowledge and many of the needy -- necessary tools, we are failing to use that knowledge and those tools to effectively meet the challenges of treating chronic conditions adequately and of optimizing individual and public health. There is a great gap between the promise and the reality.

Now shortly, the Patient Protection and Affordable Care Act will likely expand insurance coverage and access to primary care to large numbers of additional persons. However, as great as that is, primary care practices are already overwhelmed. Wait times to get appointments are typically long and once there, visits can be fleetingly short. Important

new models, such as the patient-centered medical home and new structural approaches to reimbursement and quality management and integration of care, such as accountable care organizations hold promise, but we are terribly short of primary care physicians. Our system is complex and confusing. Adherence to treatment is suboptimal and patient consumers are often disenfranchised and alienated. That's the reality. In this context, a new paradigm for nonprescription medicines offers us an opportunity to think in new and creative ways. But for such a paradigm to be safe and effective, it should do things like promote and expand screening for important health conditions, educate and empower consumers, improve access to initial treatment, and facilitate a consumer's effective engagement in partnership with doctors and other health care providers. If the new paradigm can move us in these directions then long-term health outcomes, both for individuals and populations, can be achieved and costs can be controlled. But how? We believe that how is through the use of the power of the patient consumer taking responsibility for his or her own long-term health in partnership with his or her physician or other health care provider.

I now want to highlight several key process issues that are important in this story if we are to move forward successfully. The first is partnership. The engagement of the provider community, including physicians, nurses, and nurse practitioners, physician assistants, pharmacists, and other providers, both through their national physician organizations and other professional organizations, in the planning phases, and during implementation, is and will be essential. The new paradigm must not only be innovative but it also must be supported by the provider community and it must be supportive of the patient/provider partnership.

The second process issue is digitization. We're fortunate to be at this amazing moment when the power of personal computing technology can be harnessed in service of screening and testing, education, and empowerment, ongoing self-management, and communication in coordination of chronic care with the consumer's physician, and coordination with other members of the provider team. We have the capability to collect testing results from multiple sources, merge them with the consumer's existing health information, run the data against the guidelines and best practices, and present data in user friendly formats. But we also must integrate prescription and nonprescription information so that consumers and their providers can prevent drug-drug interactions, contract compliance, and can make treatment choices based on all the data. But such a consumer-oriented system can support both the self-advocacy and appropriate self-care and coordination -- self-care by consumers and coordination within the patient-centered medical home while supporting continuous quality improvement that make the system better and better.

The third process issue is case by case. Each of these agents that will be under consideration are unique. We need to build from what we have learned about patient/consumer self-advocacy and self-management and what makes it work, over the past several decades to create a new culture of patient/consumer empowerment and engagement and personal health and health care. But whatever mechanisms are put in place should not simply add additional unnecessary barriers or hurdles. New processes

should avoid driving up utilization unnecessarily, whether that's into a doctor's office or to pharmacy counters. Instead, they should facilitate consumer engagement, education, treatment, and appropriate partnership and access to the consumer's health care providers.

To realize the individual and the public health benefits of competent and confident health care consumers, we must position self-advocacy and appropriate self-care as an important part of health care. New paradigms for nonprescription medications offer a potentially important path. As a physician, I can imagine several different broad scenarios. One of them is that the consumer sees his or her primary care physician or primary care medical home and from there the consumer is referred to an educational and self-care support system that comes as part of nonprescription medication that the physician is recommending. Another scenario might be that the empowered and educated consumer armed with the data from testing and merged with current guidelines initiates their own treatment, continuing to collect data on its effects on the target parameter, gets guidance about follow-up testing, and coordinates follow-up at appropriate intervals with various parts of their primary care provider team. To make this vision a reality, we need to think outside current mechanisms. Importantly, we must also remove magical thinking, that doing more of what we're doing at the current time will result in the new outcomes that we desire and need. So to do this we'll need that coalition of physicians and other health care providers, consumers, health plans, and payers, et cetera, in order to create effective change and achieve appropriate and safe use of selected additional nonprescription drugs.

The Foundation for Health Smart Consumers welcomes an opportunity to be an important part of this work to make self-advocacy an appropriate self-care part of achieving our goals. Now is the time. Let's use this opportunity to meet and surmount the challenges to create effective paradigms and to move forward toward the health care promise that is within our reach. Thank you.

Jane Axelrad:

Thank you very much. Panelists? Peter.

Peter Beckerman:

Dr. Delfs, you gave us some fairly compelling statistics on medication noncompliance for chronic diseases and conditions. I was wondering if you could address some reasons for medication noncompliance and, in particular, if you have suggestions about what the new paradigm might do to help address those underlying reasons, that would be extremely helpful.

John Delfs:

Sure. The studies, the many, many studies that have been done on noncompliance, my read on it is it comes down to several central factors, the most important of which, in an overview, is that the consumer patient does not understand or believe enough about their disease process or their condition and does not believe or trust that the medication is, in fact, going to be important and good for them. And without enough of an understanding, enough of a cognitive construct about what their condition is, in a way that is understandable in their cultural context, at their educational level, and their understanding

of the world, without understanding that for themselves, and without believing that the medication they're getting is important for them, then they are not necessarily even going to fill the prescription, much less take it. But if you can -- but if you can reach that person, have them understand the basics at their level and consonant with their cultural and world view, their disease process and their need, the good path if they take medications, the potential detriment to their health if they don't, and empower them. In other words, have them understand this is a great powerful thing they can do, have it be understandable to them, and have them trust that their provider is caring and concerned enough about them to give them the right thing, then compliance goes way up.

Mary Kremzner:

Thank you for your presentation. I was just looking, when you mentioned your three key aspects, under case-by-case you said the new process should avoid driving self-care consumers inappropriately into doctor's offices or pharmacy counters. Now I understand we're trying to develop these relationships between these providers, so I'm wondering if you have any thoughts or examples of what's inappropriate.

John Delfs:

Yeah, I do. I think it would be inappropriate -- well, first of all, it's a case-by-case basis. So, but it would be inappropriate if there's not a value of doing it or if the barrier it creates is greater. The cost -- the cost of noncompliance, the cost of not buying the medicine the next time, the cost of not taking it, because you can't get in to see your doctor or the pharmacist who is short with you and you didn't believe them and all these different things. So I think a knee jerk reaction of well, we're going to have to create one mechanism and everybody is going to have to go through this mechanism, everybody is going to have to talk to their doctor, or everybody's going to have to talk to the pharmacist, is not necessarily a good way to go.

What we do want to assure is that the patient has been appropriately and adequately diagnosed, that testing has been done. For instance, with hypertension that that rules out renal failure as a basis for the hypertension, that tests for the sorts of things that you would get screening if you went to your primary care provider, but not necessarily having to go to that provider just to get what is a routine battery of tests and the simultaneous prescription. Perhaps in best of instances with a great description, but in the worst of instances, with coming away -- well, didn't even listen to me and didn't understand my problems and I'm -- didn't really seem to care about me -- and so I think what we want to do is we want to think about those things that can optimize the safety. We want to think about those things that can lower the barriers to appropriate use and we want to think about those things that will access, will facilitate the appropriate engagement with the provider, but not in a kneejerk fashion that drives up utilization.

Andrea Leonard-Segal:

Thank you for your presentation. How do you perceive the notion that maybe there's multiple options so that there could be an over-the-counter option and a prescription option at the same time for dealing with some of these diseases so that people have choices and it's not one way or the other? Right now, everything is either OTC for a

given indication and a given medication, given dose, et cetera, or it's Rx. How -- what about a blurring of that concept? Do you think that would get you somewhere in the direction this you're looking?

John Delfs:

I think options are good. I think -- I think that -- we have had a series of discussions and debates about this at the foundation, and one of the -- one of the realities in a physician practice is that physicians -- one of the things we do for people that's concrete is we write out a prescription for them and hand it to them. That's an important paradigm.

The question is can we do that -- can we -- even creating a new mechanism, for instance, for nonprescription medications where the -- it's a type of a prescription, but the person could get it either filled or could get it over the counter, but something that doesn't create the kind of barrier.

As you know, there's this enormous drop-off after the first prescription. People don't necessarily take it all. They don't necessarily -- even if they get it, they don't necessarily start taking it. If they start taking it, they don't necessarily continue to take it after a month.

I think that President Clinton is the poster child of that. After finding he had severe coronary artery disease and an intervention, and was put on a statin and told by his physician that "Hey, this is great. Your cholesterol is now where it needs to be," he stopped taking -- right? -- stopped taking his statin.

So if we can -- whatever we do, I think we should think about -- and it's the reason for the partnership. We need to think about current behaviors of providers as well as consumers and how we can facilitate entry -- appropriate entry and appropriating engagement and appropriate access to medications.

We need to think about how in doing that, perhaps in new paradigms, we can prevent doing it, for instance, in a standard prescription way which then just creates a barrier that -- and that's part of magical thinking. It's not working that way. Not working well.

Mary Kremzner:

Just a follow-up question. So in thinking about the Medicaid patients in particular -- and these are vulnerable populations, typically low-literacy -- my concern is -- or I guess what I want to ask you is do you think, if we were to make these products over-the-counter -- what are your thoughts about adherence rates at that point when now perhaps if CMS doesn't cover these products and outpatients would have to pay themselves -- so do you see a system where we would have to work with CMS to make sure that this new paradigm, these products would still have to be covered by insurance or have providers continue to pay for them?

John Delfs:

I think that you're probably -- I'm guessing you're more versed in this than I am about, but

there's sufficient data in numerous studies that shows the dramatic impact toward raising co-pays in various populations of -- who are impoverished, who are on Medicaid, et cetera; and so whatever system we use, we have to make sure that whatever changes in the process occurred, don't create the financial barrier to adherence. I think that's very, very important.

Jane Axelrad:

Okay. Thank you very much.

John Delfs:

Thank you.

Jane Axelrad:

Bob Lake.

Bob Lake:

Good morning. My name is Bob Lake, L-A-K-E, without the R at the end. But let me hasten to say that I am a substitute for the person who was going to be here, and I have to thank the staff for their willingness to make a name change at the last minute.

The Food Allergy & Anaphylaxis Network, FAAN, and the Food Allergy Initiative, welcome the opportunity to submit the following in response to Public Hearing Docket Number FDA-2012-N-0171. I am presently serving as a member of the FAAN board of directors; and as I indicated, I'm here this morning because the CEO of FAAN was not able to be here.

The FAAN and FDA -- and FAI websites contain much information about FAAN and FAI and what they do. Included is the following information: Founded in 1991, FAAN is a 501(c)3 nonprofit organization and a highly trusted source of information, programs, resources, related to food allergy and anaphylaxis. Its membership now stands at close to 20,000 worldwide and includes families, dieticians, nurses, physicians, school staff, and representatives from government agencies and the food and pharmaceutical industries. FAAN serves as the communication link between the patient and others. Please visit www.foodallergy.org for more information about FAAN.

The Food Allergy Initiative is the world's largest source of private funding for allergy research. FAI's mission is to fund research that seeks a cure, to improve diagnosis and treatment, to increase federal funding of food allergy research, and to create safer environments through advocacy, and to raise awareness through education. Founded in 1998 by concerned patients and grandparents, FAI has committed more than \$75 million towards the fulfillment of its mission. FAI is headquartered in New York with an office in Chicago -- in the Chicago area, and an active volunteer committee in the northwest and enjoys strong relationships with the food allergy support groups and advocates nationwide. A national 501(c)3 nonprofit organization, FAI supports solely by donations from dedicated individuals, corporations, and foundations. For more information about FAI, please visit www.faiusa.org.

Both FAAN and FAI have medical advisory boards that include prominent physicians who treat people with allergies, especially children. The medical advisory boards have asked that the following statement be presented at this hearing.

The FAAN and FAI medical advisory boards do not support full OTC availability of epinephrine. Education by a medical professional on the proper use and indication for use of epinephrine is essential to optimize its utilization and avoid either over- or underuse. The unattended consequences of improper use of epinephrine may lead to its failure to provide lifesaving benefit. The hybrid OTC approach described by the FDA public hearing notice may offer some potential advantages to patients but also may be associated with improper use of epinephrine without professional education follow-up. The medical advisory boards require more time to consider all of the implications of the hybrid OTC approach, including how it may affect patient education, insurance coverage, and patient access.

Both FAAN and FAI believe this hearing is important, especially as it relates to epinephrine, and we appreciate your consideration of the issues. Thank you.

Female Speaker:

Thank you very much. Panel?

Marta Wosinska:

If I could clarify what you mean by a "hybrid approach." I mean, my understanding of the -- of your statement here is that you are concerned about the initial use of epinephrine that patients might not know how to use it. What about established patients, patients that already have this? Is that what you refer by a "hybrid approach" or "hybrid" in terms of both Rx and OTC being available?

Bob Lake:

Well, I wasn't present during the discussions, but I think the medical advisers, advising both FAAN and and FAI, are really unsure about exactly what this new FDA approach might turn out to be and have many questions including, you know, I think, very importantly questions about insurance coverage. So I think it's partly, if I'm understanding correctly, a -- simply a lack of clarity on the part of their understanding about what FDA is really up to here.

Jane Axelrad:

Okay. Thank you very much.

Bob Lake:

Thank you.

Jane Axelrad:

Elizabeth Dawes.

Elizabeth Dawes:

All right. Good morning everyone. Thank you for convening this meeting and for the opportunity to share comments today. My name is Elizabeth Dawes, and I'm a senior associate at Reproductive Health Technologies Project, a national nonprofit advocacy organization.

I am giving comments on behalf of our president and CEO, Kirsten Moore, who is on business travel. Our mission is to advance the ability of every woman to achieve full reproductive freedom with access to the safest, most effective, appropriate, and acceptable technologies for ensuring her health and controlling her fertility.

Our HTP does not receive any funding from pharmaceutical companies. As implementation of the Patient Protection and Affordable Care Act continues, we think it is critical to explore creative strategies that will expand access to proven safe and effective medications used to treat reproductive health conditions and prevent unintended pregnancy.

Approximately 32 million Americans will have health coverage as a result of health reform. This means there could potentially be 32 million new patients in an already stressed system.

Making certain medications available without a prescription, thus eliminating the need for a costly and time-consuming doctor's visit, may be one way to increase access to needed medication and improve health outcomes while allowing clinics to operate as efficiently as possible.

The average American woman spends five years pregnant or trying to become pregnant and 30 years trying not to be pregnant. As a result, millions of American women rely on hormonal contraceptives to prevent unwanted pregnancy over an extended period of time.

In addition, hormonal contraception is prescribed on a long-term basis to treat medical conditions such as endometriosis, premenstrual dysphoric disorder, iron-deficiency anemia, fibroid tumors, and ovarian cysts, just to name a few.

Because hormonal contraception helps women protect their health and achieve their fertility goals and improves child health outcomes, we support innovative strategies to reduce barriers to access.

Despite the fact that a variety of contraceptives are available by prescriptions, about half of pregnancies in the United States are unintended. While pregnancy itself is not a disease, unintended pregnancy is a biomarker for poor health outcomes for women and children. Cost, lack of awareness of different options, cultural norms, personal beliefs, and concern about side effects, may dissuade women from seeking contraceptives.

The current service-delivery model that requires a prescription and requires women to refill that prescription on a monthly or three-month basis also acts as a barrier to

contraceptive use and continuation. To most successfully treat some reproductive health conditions and prevent unintended pregnancy, women need uninterrupted access to hormonal contraceptives. Unfortunately, the way the Food and Drug Administration decided to treat Plan B One-Step and other Levonorgestrel-containing emergency contraceptive products is an example of how not to reduce barriers to access.

Even though FDA recently recommended over-the-counter availability, earlier actions have put the product in a de facto behind-the-counter category. Keeping Plan B One-Step behind the counter does not enhance individuals' ability to access Plan B One-Step and, in fact, may deter them. Additionally, evidence shows that some pharmacists or pharmacy staff may impose their own personal beliefs on consumers and refuse to sell them a product they could use to protect their health and prevent unwanted pregnancy.

We hope that the takeaway from this disappointing episode will be that, when a product has met the standard for safe and effective use as nonprescription product, it should be put on the shelf and not subjected to additional review or point-of-sale restrictions. Similar to Plan B One-Step, there is evidence that women can safely and effectively use daily hormonal contraceptive pills without the supervision of a so-called learned intermediary. Studies conducted in metropolitan areas across the United States show that clinician or pharmacist presence is not required for consumers to understand product necessity, appropriateness, contraindications, and product utilization. In fact, in the U.S., there is little scientific evidence that clinical counseling actually improves contraceptive use.

Our HTP, like other public health groups, is exploring the potential for bringing a daily Levonorgestrel hormonal contraceptive over the counter. For the millions of American women who need or choose to use hormonal birth control, a daily OTC Levonorgestrel pill would mean improved access, convenience, consistent use, and approved health outcomes. For other hormonal contraceptives which don't have sufficient data yet to support nonprescription status, we strongly advise FDA to consider alternative models for dispensing these products and promoting their safe use in order to ensure that all women who need them can access them.

Electronic kiosks, retail clinics, and self-dispensing machines are under development and in use across the United States and having shown to be acceptable and appropriate for clients willing to forego an in-person consultation with the clinical provider. For those wishing to consult with a health care professional, expanded use of telephone or provider-to-patient video interface have similarly met with patient satisfaction, demonstrated acceptable outcomes, and helped to lower health care costs. Using technology to enhance reproductive health service delivery aligns with recent United States government investments. Billions of dollars are provided for health information technology programs through the Affordable Care Act and the Health Information Technology for Economic and Clinical Health Act, often known as HITECH Act. Telemedicine and health information technology allow health service providers to be more efficient and reduce costs and meet the needs of their patients to improve health

outcomes. We urge you to consider all possible innovative tools and technology so that women who do not need a medical exam can access hormonal contraceptives and continue using them on the schedule necessary to prevent pregnancy and as prescribed for other treatment.

We hope that the FDA will make expanded access to safe and effective medical treatment a reality. Thank you.

Jane Axelrad:

Thank you very much. Panelists?

Andrea Leonard-Segal:

Thank you very much for your presentation. I have a question about the electronic kiosks and self-dispensing machines that are in use across the U.S. Can you tell me a little more about how those are being used and what they're being used for?

Elizabeth Dawes:

There's one example from a few years ago where an electronic kiosk was piloted. I'm not aware of current -- specifically current models of electronic kiosks; but the self-dispensing machine, there was recently in the news mention of a vending machine that dispenses Plan B in a clinic while on the campus of Shippensburg University.

So there are things that like that are in operation. We may not be aware of them. They may not be in the news, but they do exist and are in development.

Andrea Leonard-Segal:

Are you aware of them being used for other medications?

Elizabeth Dawes:

No, I cannot speak to that at this time.

Jane Axelrad:

Okay. Thank you very much.

Elizabeth Dawes:

Thank you.

Jane Axelrad:

Daniel Grossman.

Daniel Grossman:

Good morning. Thank you very much for the opportunity to speak today. I am an obstetrician-gynecologist and practice in San Francisco.

I'm a senior associate at Ibis Reproductive Health, a nonprofit research organization. I'm assistant clinical professor at University of California at San Francisco in the Department

of Obstetrics and Gynecology and Reproductive Sciences, and I'm also the coordinator of the Oral Contraceptives Over-the-Counter Working Group which is a coalition of researchers, clinicians, reproductive justice, women's health advocates that are exploring the feasibility of a possible OTC switch for oral contraceptives. The working group is funded entirely by private foundations, and we don't accept any funding from the pharmaceutical industry.

We've heard a lot --

Jane Axelrad:

Can you move your mic up a little? I'm having a little trouble hearing [inaudible] --

Daniel Grossman:

Is this better? Okay.

We've heard a lot over -- since yesterday about the different kinds of medications that might be considered as we think about this new paradigm, moving forward; and I wanted to talk about it -- one that hasn't really come up until Elizabeth mentioned it which is oral contraceptives. Oral contraceptives have been around for over 50 years now. They're one of the best studied and safest medications that are on the market today.

We know from the latest data from the National Survey of Family Growth that oral contraceptives are the most popular contraceptive method in the United States. They're used by about 17 percent of women of reproductive age in the United States. Close to 11 million women are using the pill. There are two formulation groups of oral contraceptives that we talk about -- the combined oral contraceptives, which contain both an estrogen and progestin component, and the progestin-only pills which do not contain estrogen.

So I mentioned that, you know, these are the most common contraceptive methods; but at the same time, I think it's also important to keep in mind, as Elizabeth mentioned, the high rates of unintended pregnancy. About 11 percent of women of reproductive age, the number about seven million women, are at risk of unintended pregnancy and are not currently using a contraceptive method. In addition, one study found that about a third of current contraceptive users experience a gap in contraceptive use over the prior year, a gap that put them at risk of an unintended pregnancy. And you can see here on the slide some of the factors that have been found in studies to be associated with nonuse discontinuation and gaps in use, and I wanted to focus a little bit today on the access issues, specifically the difficulty getting a prescription or difficulty getting a method; but it's also important to keep in mind that cost issues can also be an important barrier. And you know, all this, I think, contributes to the high rate of unintended pregnancies. Elizabeth mentioned half of pregnancies in the U.S. continue to be unintended, and that's really a rate that hasn't changed over the past few years. This is a very serious public health problem, and one way that it could be addressed would be to confront these access issues head-on.

There's a considerable amount of evidence suggesting that prescription requirement is an important obstacle to obtaining hormonal contraception. These data come from a national telephone survey that was performed in 2004. And as you can see here, among women who had used or who wanted to use a prescription contraceptive, about a quarter of women complained about the long wait to get an appointment to see a physician. Similar proportions said doctors' offices were not convenient. The visits cost too much; was difficult to get time off from work or school or it takes a long time -- a smaller number of women also said they didn't want to have a pelvic exam and saw that as a barrier to accessing hormonal contraception.

So all this brings us to the question of whether removing the prescription barrier to oral contraceptives could possibly improve access to contraception, increase contraceptive uptake, improve continuation, reduce an unintended pregnancy, and also importantly reduce disparities in contraceptive use and unintended pregnancy. These are all unanswered questions that we need more data on. In fact, in most of the world, oral contraceptives already are available without a prescription. Only the countries shown here in dark blue -- it might be hard to see these, the colors here -- but obviously, the U.S., Western Europe, Australia, Japan, these are places where a prescription is required. And in the other colored countries, either oral contraceptives are already formally approved for over-the-counter sale or sometimes they're informally available over the counter even though they're supposed to be actually available only by prescription. That's true in Latin America. And in a few places such as South Africa, the pill is available directly in a pharmacy without a prescription after a woman goes through screening with a pharmacist.

So back here in the U.S., there's also quite a bit of data suggesting that there is a significant demand for an over-the-counter pill. Data from that national telephone survey that I mentioned before from 2004, the Pharmacy Access Partnership, found that 41 percent of women who were not currently using a contraceptive method said that they would be more likely to start of pill, patch, or vaginal ring, if it were directly available in a pharmacy. And we recently completed a nationally representative survey which is not yet published, looking at women of reproductive age who were at risk of unintended pregnancy. And in our study, 37 percent of women said that they would be likely to use an over-the-counter pill if one were available, including 59 percent of current users and 30 percent of women who were not currently using a method or were using a less effective method. From our survey in regression analysis, younger women, uninsured women, and current oral contraceptive users were more likely to say that they were interested in an OTC pill; and interestingly, women on public insurance were significantly less likely to say they were interested in using an OTC pill.

Might be useful to review here again the criteria for prescription to OTC switch and see how the pill stacks up. Certainly, the pill has no significant toxicity in case of overdose. Oral contraceptives are not addictive, unfortunately. Users can certainly self-diagnose condition for appropriate use -- that's women who determine if they are at risk of unintended pregnancy. But it's really these last two criteria that are important, particularly important -- one, whether the user can safely take the medication without a

physician's screening -- and we'll talk more about that -- and then, finally, whether a user can take the medication as indicated without a doctor's explanation, and there's a growing body of evidence suggesting that continuation is similar or perhaps even higher among women obtaining the pill over the counter.

These are data that we published last year in Obstetrics and Gynecology from a study that we did in El Paso, Texas. It was an observational study where, in this context, on the U.S.-Mexico border, some women cross over to Mexico to obtain the pill over the counter in Mexican pharmacies. So we did a cohort study where we followed about 500 women who were living in El Paso and obtaining the pill over the counter in Mexican pharmacies and compared them to another group of 500 women who lived in El Paso but were getting pills in public clinics in El Paso. And then we followed them over nine months; and as you can see that over time, some women stopped using the pill, and this was not was they wanted to get pregnant. This was discontinuation for other reasons. And we found that discontinuation was significantly higher for women who obtained the pills in public clinics, compared to women who were getting the pill over the counter. You know, I think we really went into this study, hoping to find that OTC use was no worse than clinic use of the pill but, in fact, we found that it was better.

Let's get back to that issue about whether women can accurately self-select for whether the pill's appropriate for them. This is probably very difficult to read for you that -- further away from the screen, but this is the list of relative and absolute contraindications to oral contraceptives, according to the Centers for Disease Control Medical Eligibility for Contraceptive Use. As you can see -- and on the left, it's the contraindications for combined oral contraceptives, and on the right were the contraindications to the progestin-only oral contraceptives. As you can tell, it's a much shorter list for progestin-only pills, a much longer list for combined COCs; but in fact, all of these conditions are evaluated in a clinical setting simply by asking questions about a woman's medical history. There's only one contraindication, hypertension, that actually requires some sort of intervention or test. In our research in El Paso, we looked at the prevalence of these contraindications in a convenient sample of women of reproductive age, and we were actually surprised to find that the prevalence of contraindications to COCs, combined pills, was quite high. It was 39 percent in this population. The proportion of women who had a contraindication to a progestin-only pill was quite low, 1.6 percent.

We also looked at whether women could accurately self-screen for these contraindications or self-identify the contraindications, using a very simple paper and pencil checklist; and in fact, we found that women were fairly accurate, focusing on the COC contraindications, except for two. One was hypertension. About 6 percent of women had had unrecognized hypertension; so they thought they were appropriate to use the pill but then when, in fact, they were screened by a nurse practitioner, they were found to have hypertension.

And then also a similar proportion -- about six percent had said they had migraine headaches and, therefore, they said the pill was not appropriate for them; but in fact, when they went through an evaluation with the nurse practitioner, they were found not to

have migraine headaches with aura, which is the actual true contraindication. We'll talk more about this, but I think these are, in particular, two contraindications where the use of technology or a learned-intermediary is particularly important.

So as we think about the possibility of moving forward with an over-the-counter switch for oral contraceptives, I think it's really quite clear that the data strongly support safety of an OTC provision of progestin-only pills under the current paradigm for OTC switches; also the precedent of the progestin-only emergency contraceptive being approved for OTC sale, albeit with an age restriction, is not based on any evidence.

I think all this makes it likely that a progestin-only pill would be the first over-the-counter oral contraceptive in the U.S. You know, the contraindications to combined pills, especially hypertension and migraine with aura [spelled phonetically] may be more challenging for potential users to identify on their own, without these systems of a learned intermediary or technological systems. And I think this is where the paradigm, this new paradigm that the FDA is considering is particularly relevant, and I'd like to highlight a few possible conditions for safe use that might dramatically improve access to effective contraception.

The first is modeled pharmacy access to hormonal contraception, which we talked about quite a bit yesterday. We talked about it with other drugs, where a trained pharmacist provides counseling screening regarding hormonal contraception, and then provides the method without a prescription. This model providing hormonal contraception in this manner was evaluated in the direct access study, in 2003 to 2005, in Washington State, where community pharmacists provided these services as part of a collaborative drug therapy protocol, and there was an evaluation of this. It was published and it found that the model was safe, that the screening protocol worked well, although there was a learning curve initially. It appeared to be effective. Continuation appeared to be quite good. Again, this was an observational study without a comparison group and there was a fair amount of -- about 30 percent lost to follow up over the year-long period, but continuation was 70 percent at one year, and satisfaction was very high both among users, women who used the model and among pharmacists; but one thing that I think is very important to highlight is that they were unable to obtain insurance reimbursement for the pharmacist services, during the entire period of the study, and eventually, my understanding is that it actually, although these collaborative agreements are still in place, the model has not continued, and that was a real big stumbling block for the model.

Also, since yesterday, the panel asked if there was any evidence suggesting that pharmacists are interested in playing a larger role in their patients' medical management. I thought it might be interesting to share the results from this study that was published a few years ago. There was a national survey sent to a random sample of APhA pharmacists members; had a low response rate, but still I think the results are interesting, which found an 85 percent respondents, the pharmacists said they were interested in providing hormonal contraception directly to their clients. You can see here some of the reasons why they said they were interested. I guess they thought it was an important public health issue but also because it was an opportunity to increase business. It's also,

since this issue of training has come up a lot, the pharmacists said, the vast majority, close to 90 percent, said that they would need additional training on a variety of things, including to help the clients select the best contraceptive option, and you can also see here some of the barriers that they saw to possibly actually implementing this in their practice, including lack of reimbursement, liability issues, time constraints, but interesting, actually, the lack of private counseling area was only mentioned by fewer than half.

So, overall, I think that this pharmacy access model of providing world contraceptives or even other hormonal contraceptives is promising. I do have some concerns, specifically about the reimbursement issue, also the issue of ensuring adequate training is very important, and also, while I think it's rare, the issue of pharmacists refusal is also an important one that will have to be dealt with, if this were to move forward.

But some of the other conditions of safe use would likely rely much less on the pharmacist and I suspect they would also be very safe and effective, although they would need to be evaluated. The first is an idea where perhaps a user would initially start oral contraceptives by prescription, and then they would be able to get refills over the counter. This, you know, I think is very unlikely that a woman would develop a new contraindication over a relatively short period of time, of one to three years, or use one that she wouldn't recognize. This would also be more consistent with recent recommendations for preventive screening services, such as screening for cervical cancer, which is no longer recommended for annual screening. So, if an OC user doesn't have another reason to see her primary care doctor or gynecologist, she shouldn't be forced to have to come in for a clinic visit, just to get a refill for a prescription. I think this also kind of reflects the reality that it's mostly current users who are going to be most interested in an OTC pill. This is something that we certainly saw in our national survey, where current users had a -- or were threefold more likely to report being interested in OTC access.

Also, just to mention this model was recently, or something similar, was recently approved by the -- in Australia, the Australian Parliament passed a bill that will allow pharmacists to dispense a single month's supply of oral contraceptives, or a month of statins to current users who run out of their prescription. They're able to get those methods directly to pharmacy.

I just wanted to mention quickly, also the possibility of kiosks. The next speaker is going to be speaking more about this, but this would be another technology where women could, I mean, an example of a technology that -- where a woman could come in and use this kiosk, get screened for all the contraindications for combined oral contraceptives, including getting their blood pressure check, and if she were found to be an appropriate candidate, perhaps the kiosk would then print out a voucher, which she could take to the counter to get the product, or perhaps it would dispense it immediately, like a vending machine kind of option. Alternatively, perhaps a woman could walk through the screening at home, on her home computer, print out this voucher, and come into a pharmacy, or a grocery store even, and get her blood pressure measured there. In our

study in El Paso, we asked women if they would be interested in using a kiosk like this to get their blood pressure measured, and about three quarters said that they would.

I think these conditions of safe use are very exciting and could significantly improve access to contraception, but I do think it's really -- it's very important to think about these issues of cost and reimbursement now, as this paradigm is being considered. As several panel members said yesterday, if this ends up increasing out of pocket expenditures for users, access will not be improved. As we saw from the example in Washington State, you know, where reimbursement wasn't worked out, in fact the model was not sustainable.

We do have some evidence about what women's current out of pocket costs are for oral contraceptives in a paper that we published last year, and that could give some idea about what a reasonable retail price might be for an OTC oral contraceptive. I also just want --

Jane Axelrad:

I need you to -- if you could wrap up --

Daniel Grossman:

Yeah.

Jane Axelrad:

-- please.

Daniel Grossman:

To highlight, I think, although insurance doesn't usually cover over the counter medications, you know, the recent HHS guidelines for women's preventive health services will require new private insurance plans to cover all FDA-approved contraceptives without cost sharing, including OTC methods. So, I think it's critical that oral contraceptives be provided -- that are provided under these conditions of safe use, be, you know, covered by insurance or available at an accessible price. Thank you very much. This is my contact information, if anyone would like additional information, I'm happy to answer any questions.

Jane Axelrad:

Okay, thank you. Martha.

Marta Wosinska:

This is actually a request rather than a question. Could you provide, submit to the docket, information about the Washington State direct access setting, actually, all the other studies that you basically reference as for all the other studies that you have [inaudible] --

Jane Axelrad:

Okay, thank you very much. Eleanor Schwarz.

Eleanor Schwarz:

Good morning. I am Dr. Eleanor Bimla Schwarz. I'm an associate professor of medicine at the University of Pittsburgh, where I'm the director of women's health research for the Center for Research on Health Care. I'm sorry, these slides look like they have a life of their own. Does the person who knows how to set this up, can you make sure it's not automatically advancing? I have no conflict of interest to disclose and no affiliations with any pharmaceutical companies.

As we've heard a couple of times this morning, half of U.S. pregnancies are unintended and abortion remains one of the most common procedures performed in this country. Prescription contraceptives are significantly more effective than over-the-counter methods.

Jane Axelrad:

Can somebody help her with this?

Eleanor Schwarz:

I'm not hitting it, no. Here, if you go up to the slide setup, usually there is a used, rehearsed -- if you go to slideshow, and this used timings button must have gotten checked, and it needs to come unchecked. Yeah, perfect. All right. So, moving right along.

Main point here is that a lapse in prescription is one of the leading causes of unintended pregnancy in the United States at this point. I'm a practicing clinician and board certified in internal medicine, and I'm very familiar with how hard it is to fit everything that our patients might need to discuss into a 15 minute office visit, especially in the acute care settings where women who are otherwise generally healthy tend to seek care. In a study we conducted in 2005, we found that over a quarter of the women seeking acute care, who stated they didn't want to become pregnant in the next year, reported they had used no contraception the last time they had sex, and 11 percent of these women had an acute need for emergency contraception, because they had unprotected sex in the last five days.

So, this led us to try to design a computer program in the hopes that we might be able to help women learn about emergency contraception and increase their use of this medication, in these type of settings. This program is similar to the one you see on the screen here, where on the left side of the screen, the woman had the option of clicking on a number of questions, and that then plays a clip where a video doctor answers the questions that she would use that to ask.

To evaluate the effects of this technology, we conducted a randomized controlled trial, with 446 women who were waiting to see an urgent care clinician, and the women were randomized to either receive information from a video doctor about emergency contraception, or about the use of preconception vitamins. When we contacted women six months later, we found that those who had used the kiosk were more likely to have learned about emergency contraception in the last six months. For instance, those who use the emergency contraception kiosk were more likely to know that emergency

contraception is safe and it does not adversely affect a woman's future fertility, and that it will not cause birth defects.

While women who used this kiosk were no more likely than those in the control group to have unprotected sex, we found, as you can see on the right hand side here, that women who used this kiosk can receive computerized counseling were twice as likely to have used emergency contraception at follow up; even though at baseline, women in the intervention group, which is shown here in green, tended to have been less likely to have used emergency contraception prior to enrolling in this study.

This led us to embark on a larger project designed to try to provide women with information on the full range of reversible contraceptive options. We wanted a program that would provide women feedback on the effectiveness of the method they had been using and to facilitate access to a prescription for contraception, if one was desired. To do this, we programmed the computer to screen for all potential contraindications to the use of estrogen, that had been identified by the World Health Organization, and we used audio headphones to make this accessible to those with limited literacy, and we programmed both the text as well as the audio, such that it was available in English or Spanish. What women would see is a screen similar to this one, where they had the option of clicking which button they would like to learn more about. It's seven different contraceptive methods. For each method, the computer would provide an overview and then the option to learn more about how this contraceptive method works, the pros and cons of using this method, and the method's effectiveness and safety. At the bottom of each of these screens, you can see there was a button to click, to learn about another method or to get a prescription for this method, if that's what the woman desired.

This is a map of the branching logic that was used in creating this program. You can see women were first asked about what their pregnancy intentions were. Those who were trying to conceive or were currently pregnant received information about folic acid supplementation, while those who were trying to avoid pregnancy had the option of learning about a variety of contraceptives or requesting a prescription. If women requested a prescription, then they were screened for contraindications to use of that product, and if no contraindications were identified, a prescription was printed with a summary of the screening that had been done to date and provided to the clinician, who is then asked to check the woman's blood pressure and find the prescription if her blood pressure was normal.

Here you can see that the large majority of women found this contraceptive kiosk easy to use. Most trusted the information the kiosk provides, and most would recommend this module to a friend or a family member. In addition, the large majority indicated that they'd learned something new by using this computer program. So, this led us to conduct another randomized trial, where we enrolled 814 women from four different acute care settings, and women were randomized to either use this contraceptive kiosk or a program that provided information about screening for chlamydia. Overall, we found that 19 percent of women who used the contraceptive kiosk requested a contraceptive prescription when invited by the computer to do so. Importantly, non-white women and

less educated women were more likely to request a contraceptive prescription, likely reflecting the greater underlying difficulty these populations have accessing health care or contraceptive prescriptions in the current model of care.

Women who had used no method of contraception at last sex were particularly likely to request a prescription. Specifically, 48 percent of women who used no method, asked for a new contraceptive prescription, and 60 percent of women who tried to use withdrawal at last intercourse. This population was at very high risk of facing an unintended pregnancy in the near future, as 57 percent of women who requested contraceptive prescriptions reported they'd had one or more episode of unprotected sex in the last month.

This flowchart shows the number of women who requested a prescription, who were notified of potential contraindication to the use of estrogen. We programmed this computer to be as sensitive as possible. For instance, it asks about migraine headaches, but did not ask women to specify whether they had aura with their migraine, and so the computer likely told more women with migraines they had a potential contraindication to estrogen than truly have such a problem. As you can see here, 23, or approximately half of the 41 women, were notified of a potential contraindication, because there are very few contraindications to the use of progesterone only pills, and women who have contraindications to the use of estrogen face increased risk, should they become pregnant. The computer offered these women a prescription for a progesterone only pill, with the advice that they further discuss their contraceptive options with a clinician. Thus in the end, 59 percent of the women who requested a prescription ultimately received a prescription for hormonal contraception from the computer.

This table shows the contraindications which the computers screen for. Just to re-highlight again, we based this on an extensive amount of work that has already been done by the World Health Organization and the U.S. CDC, to establish appropriate conditions for use of contraception, and again, the high rates of potential contraindications with migraines that we identified likely are due to the fact that we didn't ask women to specify whether or not their migraines came with aura. Our study clinicians spent less than two minutes reviewing the blood pressure measurements recorded in each woman's medical record, and ordering the requested medications. However, this process did identify an additional two women as having hypertension, and thus these women received progesterone-only pill instead of the estrogen containing contraceptive they initially requested.

Of the prescriptions that were requested, approximately 20 percent were for refills, and initially, we had debated whether the women requesting refills, who had presumably been screened by their clinician, even needed to complete computerized screening. We decided that the most conservative approach would be to simply screen all women prior to providing prescriptions, and in doing so, we found what I think is probably the most important point to share with you today, which is that women who requested new prescriptions were not more likely, and if anything, were somewhat less likely than

women requesting refills, to have a potential contraindication to the use of estrogen identified by computerized screening.

This leads me to believe that this computer program identifies women who can safely use hormonal contraception, as well or better than most clinicians. I spent a lot of my time trying to educate my colleagues about how to provide contraception, but in a large amount of other work we've done, we know that most practicing clinicians have somewhat limited understanding of the available contraceptive options, and in fact, in one recent study we did of 172 primary care providers practicing in four locations across the country, 81 percent underestimated a woman's risk of pregnancy without use of any contraception and 85 percent underestimated the typical use failure rate of oral contraception.

The other important point to share with you today is that this kiosk worked. It increased the number of women at high risk of unintended pregnancy, who received a contraceptive prescription the day they visited the clinic. Even though the computer was designed to be overly cautious and told 40 percent of women who requested a prescription that they'd need to talk to a clinician and have a more detailed conversation, 16 percent of women left the clinic with a contraceptive prescription, after using this kiosk, compared to only one percent of women in the control group. When we contacted these study participants three months later, those who had used the contraceptive kiosk had more knowledge about available contraceptives. Specifically, they were more likely to know that IUDs and implants are as effective as tubal ligation. They were more likely to know that the ring and patch are as effective as pills, and to know that one of every seven women who tries to use a condom to protect her from pregnancy typically becomes pregnant within her first year of use.

Another important thing we've found in these series of studies is that the amount women learn from these kiosks does not seem to depend on their age, race, education, income, or any other socio-demographic predictors. When we followed up with these women three months after using the kiosk, perhaps most importantly, we saw that use of this kiosk did increase use of any contraception at last intercourse, as well as use of a prescription or a more effective contraceptive at last intercourse, and I think most excitingly, we saw a difference in unintended pregnancy at three month follow-ups. We would need a larger study to have power to show that this is a statistically significant difference, but you can see that a rate of unintended pregnancy of 0.9 percent in the intervention group compared to 3.8 percent among women in the control group, is something that in my mind, has great clinical relevance, and if statistically significant, would be a number needed to treat about 34. So, with that, I will say thank you, take any questions you may have.

Janet Axelrad:
Thank you very much.

Peter Beckerman:

I may have missed it, but do you know, or do you have available how long it would take to go through the algorithm in the kiosk, and how does that compare to intervention in person with a doctor?

Eleanor Schwarz:

So, the amount of time women spent with the computer varied, because women had the option of reading extensively about every single option, and they had the option to say, "Oh yeah, I want a prescription," click here, and then just go through the screening. I would say most people spent about five to 10 minutes with it. Probably nobody spent more than 15. In terms of the amount of time available in most of my colleagues' clinical settings, I would say I think a conversation that's more than about two minutes is unusual in the spectrum of a 15 minute primary care visit.

Robert Temple:

Some of what you said at the end, in the follow-up may answer this question, but we've recently seen people trying to do online studies, which they gave informed consent online. One of the features of that was to have some questions at the end, to see if you understood what was being told, and if you didn't, you had to go read it again. Is there any possible room for something like that in here or are there critical questions you want to be sure they understood, that could be incorporated into some critical questions at the end, or is that not really necessary?

Eleanor Schwarz:

So, I think it's definitely possible to put in, you know, a forced stop at any point in this algorithm. I guess the question is whether it would be necessary or indicated, and I would say I don't have any reason to think that it would be necessary to force women to read the educational information, if they've requested a screening. They didn't have the option of opting out of the screening questions. They did have to go through all of those, in order to be eligible for sort of an expedited prescription. They could stop at any time, but then they couldn't walk away with a prescription. I'm not sure if that gets out what you were asking about.

Robert Temple:

Well, you're finding that at the end, the people treated, as opposed to control group, sort of understood a lot more. Sort of suggested they were getting it, but if there were critical questions that you were very concerned about, that might be a way of being sure they got that particular point --

Eleanor Schwarz:

And you could absolutely, you know, you could make them answer the same question three times. We do that sort of with the iPLEDGE program of [unintelligible] over and over again, but I think, you know, in most of these issues we're looking at with contraception, I don't think we have any reason to think women are less likely to understand this than any of the other issues related to any of the other medications that are available.

Jane Axelrad:

In conducting these studies, where were they conducted and how did you recruit subjects to be in the study, and what kind of, you know, did they have consent, or how did you deal with that, and also what was the age range of women who participated in the studies?

Eleanor Schwarz:

So, the age range of women in these studies was 18 to 45. We don't really have reason to think that women under age 18 would have a harder time using this technology. We just decided not to fight the battle with our institutional review board. We recruited women for the first studies, when I was based in California, and the last more recent studies have been based in Allegheny County, in the Pittsburgh area of Pennsylvania. Women were recruited while waiting in the waiting rooms of either emergency departments or urgent care clinics. Again, this coming out of my own experience as a clinician, where the healthier a woman is, the less likely she is to come in for a routine primary care visit, just because she doesn't make time for it, but when she has a rash or when she has a urinary tract infection, she'll go for the urgent care visit, and if there was a way to provide the services she needed in an expedited fashion, seems that many would be interested.

Jane Axelrad:

Okay, thank you very much.

Eleanor Schwarz:

Just to be clear though, because you had asked how was consent obtained. Formal consent was obtained from every person who participated, either written or a click to consent mechanism.

Jane Axelrad:

I could see how that wouldn't be so difficult. I mean if you were doing them because they were already in a health care setting of some sort, yeah. Okay, thank you.

With that, we're going to break for lunch. We will resume at 1:30. If there is anybody who is interested in speaking at the open public session, please make sure to register during a lunch hour, because we're going to figure out the timing for the afternoon, based on how many people decide they're going want to speak. Thank you.

[break]

Session 3

Jane Axelrad:

Okay, let's begin. For the afternoon session, a few schedule changes. Stephen Kendig, who was the second speaker, is unable to make it this afternoon. So, we have four scheduled speakers and we have two people who have signed up to speak at the open public session. So, my plan is to go straight through, without a break. We'll just have the four scheduled speakers and then the two speakers at the open public session, and then I'll do some closing remarks. So, Steven Francesco.

Steven Francesco:

Good afternoon, and I want to thank the FDA for allowing me the time to talk about my point of view. The following is the agenda, and I will touch on all these points, but in the interest of time, I will not have slides for all of them. First of all, I think there is this -- we should be aware that there are changing dynamics, [unintelligible] switch, for the first time in a very long time. I find that to be very exciting and that is largely due to the rapid pace of technology, and health care integration going on. There are other changing dynamics and I'll touch upon those.

I have coined the phrase OTCE. OTCE are drugs that are OTC and enabled; so that's a class of drugs under the OTC heading, and I have some illustrations for you. And finally, I have some suggestions, which I'm calling switching on. I should point out, first of all, that I'm delighted to be here and I was thrilled to find out about this meeting, because in October, my company, Francesco International, published a 100 page report with the title that you see: "The Major Global Expansion of Rx to OTC, Switch by 2016. OTC Drugs Will Lead the Way: A Forecast and Guide."

My background, just to give you two minutes, is I've worked in Rx to OTC switch for 25 years, in marketing financial business development and other aspects. I've been with sharing plow, Sandoz, Sterling Drug. I've worked a lot on switch, and I would say around 2003 and 2004, in my consulting business, I left switch, because I needed to make some money. And I left switch until, I'm going to say February of last year, where with a team of people, we looked at switch again, but we looked at switch from the point of view of how technology could make a difference. So, how sweet it is when I find out that the FDA decided to take a look at technology with switch. So, that's a good part of why I'm here. I should mention that I've also testified twice in public before, in 2007, when there was a discussion of a third class of drugs, and also in 2000, I believe, on the switch of non-sedating antihistamines.

The reason I'm here is because I feel that our industry, the OTC industry, and the switch industry, if you want to call that as a subset, should be aware of what's going on outside; and I'm calling it tech pharma dreams in process. As we speak right now, there are ongoing efforts to integrate tech and health care, and again, in the interest of time, I couldn't possibly list everything going on, but we've all read about smartphones and there's been some discussion in the last two days about smartphones, but it goes well beyond that. There are conferences that take place in San Francisco, San Diego, called

mHealth, meaning Mobile Health, or eHealth, and they are working with the prescription industry to combine tech with the drug. So, what I'm saying to you is after having seen that go on, I felt that there was an opportunity for certain types of technology in certain maybe therapies, that could be affected by technology for switch. Some of you are aware clinical trials going on, particularly like Pfizer using smartphones. Pharma, itself, is already combining diabetes and glucose monitors, as one simple example. Another example is the VA. I think the VA started a program in about 2008, and ended in 2010, which combined -- again, this is on the prescription side -- which combined using data from tools to create wellness programs, and again, in the interest of time, I haven't put out all of the results, but it reduced costs and improved outcomes.

Finally, I think it was July, the FDA issued first ever guidelines on enabling tools, which in this case, was specific to mobile apps and a definition of what was appropriate, and what wasn't. Now, as in any emerging industry, there can be some excesses. There can be some fund and I wanted to have you see this. This is real life, and I'm calling it Star Trek Meets Health Care. There is a \$10 million prize offered to come up with a Tricorder X. It's a combination of a major technology company, Qualcomm, who has just recently spun off a division dedicated to technology and health, along with another organization called X Prize. And the text here, if you looked at the last bullet point, what they're saying -- I didn't write this -- they want to have a tool with the equivalent of a board of physicians in your pocket. Wireless sensors and imaging, where you will be able to assess health, and determine health needs with a device in the palm of your hand. And here's a laugh for everybody, okay? Now, this is a mobile phone, which is designed, at least, as a prototype, to have a number of features. Now, people are working on this and the incentive is \$10 million. I present this to you not as I think of a practical way to move ahead, but I think that what we're seeing in mHealth and in eHealth is a bubble, an enthusiasm, which has yet to hit OTC and yet to hit Rx to OTC switch. So, part of my purpose here to sort of be a cheerleader and fire up the troops, because I think we have a long way to go, but I think that this has been an excellent start.

Now, at the beginning of the session yesterday, it was mentioned that, by Dr. Janet Woodcock, that there is a need for flexibility in order to look at this, but there was a desire for a vision, some way to see the future; and so I can tell you that in our work, we see the health care future in a somewhat of a different construct than that's been discussed here in the last couple of days, which is to a larger step dependent on pharmacy, pharmacist intervention. It is my belief that in 2007, perhaps there should have been more pressure to get pharmacy pharmacists intervention. With the technology available today and in the future, I think that we may be blowing past the pharmacist as the main source to help us get switches, in terms of new energy and new support, in part because of technology. So, this picture you see right now shows on the bottom left various types of devices, apps, or whatever, and there are new ones coming up every day. In the middle -- and this is borrowed from the home health care industry -- in the middle, you have what I'm calling the consumer personal health system and that can be in the home. That can be in the car. That can be in the pharmacy. But this is a way to get information to turn into data, and what you see here is the Internet is an integral part of this, and on the right box, where I have facilitators, that is not the physician, obviously,

because we're talking a switch, but it is not -- the next chart, you'll see the pharmacist, I apologize, the pharmacist should be on this chart -- but there are other ways of getting that data, to turn into information, and I think we had some presentations this morning, particularly, I believe by Dr. Eleanor Schwarz, for an excellent example of trying to get information, data, turning it into information, and then being able to get some next steps out of it that are pretty compelling. So, I think that if you want a visual of a model, and I've listed here diabetes, COPD, mild asthma, hypertension, as examples, simply examples. I think you're going to see that over time, and my timeframe is not 2014. Remember, my report is 2016. We're at the very beginning of this, after switch, it takes four plus years to switch. So, as far as I'm concerned, the way to look forward is to look forward five years, and I think this visual could be a very interesting and useful way to look at what's out front of us.

Now, what we have right now, there are two classes of OTC in the U.S. We have a behind the counter. We have in front of the counter. I do not believe, and I know this was discussed, and I know this might be contentious, but just as in 2007, and now in 2012, I do not believe we will ever have a third class of drugs, at least in my lifetime. So, if you want to get the pharmacists involved, it's not through legislation of a third class of drugs. I do believe that voluntary VTC [spelled phonetically], as has been discussed, will grow. I can tell you from my business experience, there is business there. We know the P&L is an issue, but there's no question that if you have protection, and you may even have a monopoly if you combine your drug with technology. You can make money.

Finally, and this gets to my other point about the universe we live in, the pharma tech echo system, and I'm talking now about providers, I'm talking about payers, I'm talking about patients, I'm talking about consumers. They are all starting to talk to each other. They are all starting to get together with each other, part of it is the drive by consumer care. Part of it is the interest in reducing costs, but we have some drivers going on right now in this country, one of which is the PPACA, the mandated health insurance. Now, these drivers that are making progress here on switch are not dependent on mandated health insurance. If that gets blown out by the Supreme Court, if you still have other drivers pushing OTC. So, I see this as a great opportunity. I would like our industry to be more involved in the technology part.

If you identify -- this is part of my report -- if you identify in switches where we have had problems, if you see the bottom three boxes, one is harmonization and enhancing labeling; two, reducing cell selection concerns; three, addressing emergency signs and symptoms. These are three areas that are fairly specific, but they all are major areas for switch, and our work, we're calling this specialty technology Rx to OTC switch enablers, and there is an analogy to what's going on right now, here in the prescription side, and I refer specifically to the specialty pharma business. If you remember the origin of specialty pharma, if you go back 30 years, if you had technology come in to deal with that pharmaceutical molecule and turn things from three times a day to once a day, there is various other benefits which went across therapy areas. That became a huge industry. Now, we have a lot of stuff going on, on the prescription side, with technology. It's going to cascade into the OTC business and affect switch. I think we're at the very

beginning of that stage. So, as far as I'm concerned, it would be great if we could focus the technology folks on these three problems. Now, there may be more ways to express these problems. There may be more problems, but these are the three that we came up with as dominant.

Now, with the OTC drug, first they have a strong prescription heritage. Two, they have been reviewed by a country's medicines review agency. And I'm being very generic here; it's not the FDA per se, it's a medicines review agency. Three, they're likely to have issued nonprescription status with the help of technology as enabled improvement of their safety margin, and reduce the risk of self-treatment sufficiently, to allow purchase and use without a physician's involvement. Four, they are likely to be used to treat chronic or frequently recurring health care problems. Five, they are likely to be older products, some of which have already had their patents expire. Six, they're able to be sold either as voluntary, behind the counter only, or as a typical, totally available over the counter drug. Seven, they have attractive profit margins and probably various competition, which is important. And eight, they have purchase incentives from insurance companies in OTC companies.

Another two slides here with images for you. I think that if we want to idealize, and this is idealized, now, where we're going, or where we would like to go, I'm visualizing this is a closed loop. What happens is the various tools intersect with a digital local and they have facilitators, and here's where the pharmacy has a role, but not exclusively. Technology drug closed loop, you have your tools. You have your drug source. You have your facilitators, and here, what's going on, on the prescription side, I think should go on here, and it's happening, and thanks to the FDA meeting, it's starting to happen here. We need to collaborate, but I think within the industry, you're going to see consolidation. I hear music.

So, in summary, that's my vision. I wanted to share that with you. It is coincident with the announcement for the meeting here today. I would simply like to say two things. I think it's great that you've had this meeting the last couple of days. I think it's terrific. The timing is excellent. I think you should have another one, but I think the next one, maybe shift the balance a little bit. Instead of having 80 percent pharmacy and 20 percent technology, let's have 80 percent technology and 20 percent whatever, because to have confidence in looking at the technology, you have to see it, and there's a heck of a lot of stuff out there. So, that's my suggestion. Number one, have another meeting, and have it organized so that technology has a larger role, and you can fill this room with toys. Thank you.

Jane Axelrad:

Okay, thank you very much. We actually thought about inviting some of the people to do -- to display technology. We actually had an internal technology exhibit, just for internal to FDA, in December, but in terms of getting the meeting notice out and giving people adequate timing out of that, I know people set up these displays, it takes a long time in advance. So, it's something we actually are interested in doing, if we can figure out the logistics of it. Okay, so, panelists, questions?

Marta Wosinska:

I wanted to ask you about part five of your definition. Maybe it's linked to part seven of your definition for OTC e-products. I think it's one or two slides back. Specifically, you're saying, you know, likely to be older products, some of which will have already had their patents expire. I would say the most prominent switches to OTC are actually companies that are trying to do a brand extensions, and they will -- they're moving the patent, and this is an opportunity for them to kind of keep the brand, and they go over the counter if they can, but if you're suggesting that sort of the best candidates might be the older products, do you actually foresee many generic sponsors and [unintelligible] holders coming forward, and investing these technologies, and saying, you know, let's --

Steven Francesco:

Let me answer it this way. If I look at the generic that I think are capable of going over the counter, I think there are quite a few. If they're partnered with technology, you have intellectual property. Now, remember, one of the criteria here is there is intellectual property. They'll be barriers to entry. That makes that opportunity really quite significant. So, in fact, taking an older molecule, rebranding it, combining with the technology, and taking over the counter, having intellectual property, it may be a patent. It may be a time of exclusivity. That's very attractive. And the bigger companies in our industry, the OTC industry, tend to be the drivers. I see older products and smaller companies getting involved, and I don't see it as expensive as you might imagine. I think that if they have exclusivity -- in fact, on that point, if I can just make two suggestions, because this affects the business model. It's really difficult for anybody to say, "I'll take my exclusivity in my BTC life." I think it should be considered, given the cost, given the challenge, and given the improved health care outcome, to have that three year exclusivity renewed, if they succeed in going full OTC, and that full OTC is based on data, while it was PTC. Then, you've got a heck of a P&L, and it's very attractive. So, I do think that generics with technology are a new combination product in a way, and they have a new life.

Marta Wosinska:

If I may just follow up, I'm not sure if you were here yesterday, when we had this discussion, but one of the challenges were the proprietary nature of these technologies, is that, again, this is for example, kiosks. There's limited space on the pharmacy floor and how many, you know, so one proprietary technology might preclude the ability for stakeholders to adopt it for other products.

Steven Francesco:

I need to understand. The proprietary technology that I'm talking about is not necessarily a kiosk, and the kiosks that I've seen are much smaller and more elegant than anything that has been presented, I think, to the OTC industry. In some cases, they look like an iPad on a pole. It's that simple, and you can have multiple iPads on a pole. So, I was here yesterday. I don't necessarily buy into that vision.

Jane Axelrad:

Okay, thank you very much.

Steven Francesco:

Thank you.

Jane Axelrad:

Robert Burroughs.

Robert Burroughs:

Well, thank you. As a technologist, I applaud the idea of a technology 80 percent focus, and would welcome the opportunity to participate in that, in the future. But thank you for the time, to the distinguished members of the panel, and fellow industry participants. I am a technologist. I represent Learn Something, we're an e-learning company that's been in the business for almost 20 years, which for those of you who know the business, that's pretty much a dinosaur. Been around quite a long time, and we have a specialty focus in the pharmacy retail space, and so I really wanted to come today and talk about a solution that we've already been deployed on the part of manufacturers into the pharmacy space, really addressing some of the concerns that you outlined in the call for presentations, because we're already doing some of the kinds of things that you'll need to do to accelerate the number of switches taking place, which by the way, as a private citizen I applaud, and I appreciate your efforts to do that.

So, we have been working for many years. We have about 85 percent penetration into retail pharmacy. So, we can reach out very deeply into the pharmacy and pharmacy tech space, and provide training. We've been doing that around continuing professional education, fraud, waste, and abuse, and a number of categories for most of the major pharmacy chains and many independents in the country. And that sort of evolved for us into an opportunity that we presented to manufacturers, who had a real need to get information into the hands of pharmacists, in a timely fashion, in a way that was trackable and reportable, and you could create accountability around things exactly like switches. We've dealt with switches. There are a lot of new delivery mechanisms and devices in the marketplace now. We provide training around those. Where we have an indication change, we've been a big part of that, providing training to pharmacists. So, we really have filled the void that manufacturers had in being able to deliver that information in a timely fashion, to what we all know is a very busy pharmacist, with very limited amount of time on the floor, and we've been able to do that in a very cost-effective way.

So, what we do for manufacturers is develop mini courses, basically. These have to be very compact, very brief, usually eight to 10 minutes, and we direct those at the -- we produce those at the direction of manufacturer, to address all of the critical clinical information that that pharmacist needs to have available to them, and we deliver this electronically, using the retailer's existing learning management systems. So, that's key. I think one of the messages here is although there are many new tools to be built, there are already very good technology tools in place, which you can leverage right now and this is one of them. So, there's no new infrastructure to build. This already exists in the

existing portals, and we deliver those, and the key is that this is measurable information. So, the alternative, as many of you know, is to put the insert into the mail bag, right, and get that out to the pharmacist or the pharmacy tech that way. The key to what we're doing is everything that we do can be measured. We can go back to that manufacturer. We can go to the head of pharmacy at the chain, and give them, with complete accuracy, the number of pharmacists that had participated in that training experience. We can assess their knowledge of that product, or that particular piece of information, before they engage in a learning experience and after, so we can prove the impact of the educational experience. So, it really becomes a win/win for manufacturers and for the pharmacy chains who know that their pharmacists need this information, but want to get that done at a very timely fashion.

So, and these are some slides that I use with our manufacturer. So, you can see some of the things that we've already been talking to manufacturers about, some of the things that we've been doing, but obviously, this fits right in to this one lane of switches, and of moving these prescription drugs into an OTC environment, and we believe whether that's behind the counter or in front of the counter, that pharmacist is always the trusted advisor, and frequently will need this information. So, as I mentioned, this reaches about 85 percent of retail pharmacists. I spoke to the need for brevity. These are very short clinical programs. So, this is not sales material for the manufacturers to be deploying to the pharmacists. This is clinical information that they need to do their job, and advise their patients correctly. We use existing portals, as I mentioned, and the key to this is that our retail partners on the retail side have been, obviously, the key to this. They see the value, so they're very cooperative in adding these programs to their existing learning systems. So, this becomes required training, not training that's optional. So, the pharmacist sees the information that's beneficial to both them and the manufacturer, and we provide summary information, both to the manufacturer and to the retail chain, depending on the arrangement.

I spoke a little bit about the ability to test on the knowledge transfer. I think that's a critically important part of this, and why the technology is valuable above and beyond just a mail bag delivery, or other forms. We're able to collect meaningful data, both in the pre-education -- before the educational experience and after. So, I think that can serve two very important purposes, one, the general information collected before obviously can feed into future decisions making about what points are important in terms of educational products, and then the comparison, obviously, to the post-assessment, gives you something about efficacy of the training.

We do survey, and I'll show you in just a moment the results of those surveys what pharmacists think about this, because that's very important, even though much of this training is mandated, compliance is an important issue, and so I think the pharmacists have to feel that this is beneficial to them. This is just -- you can glance at this. I won't go through all of these details, but a general outline of how we get this information into nine or 10 minutes. This one's a little bit longer than some, but you can see the pattern of the learning that we present around a particular product, fairly standard. It will vary, obviously, depending on the product, and we've done this for, as I said, switches, new

delivery mechanisms. So we've got a lot of new inhalers out there and injectables and all kinds of things going on. So we do it both for devices and for just standard drug therapies.

This is an example, I'm sure many of you've seen this, many of you that are pharmacists have participated in these programs, but just examples of the learning portals that almost, well, I think every major pharmacy and most regional and smaller chains deploy in order to train their pharmacists and pharmacy techs. And not only do we have these corporate retail pharmacies that we run, we partner with folks like the American Pharmacists Association and support a great deal of the delivery of their training. So there's -- there are more avenues than just the retailers themselves. That's a very important and critical avenue but we think there're other industry partners that have a stake in this, you know, associations, et cetera, American Pharmacists being one of those.

So this is, you know, this is the summary of the value benefit, you know, the benefits the manufacturer fits right into what you've been talking about, many of the points that you raised in your call for presentations. But the bottom line is we're talking about safer product use and better patient outcomes. Now, I want to add to that, that we have also done direct consumer training using the same model. So just as you can deploy very quick brief targeted training to pharmacists, you can do the same thing for consumers, and now we have so many folks using iPads and other mobile devices. We can actually do that in-store and we have several trials going now with the delivery of that using the tags that you scan, the quick read tags. And it looks to be a very successful avenue for getting information directly into the hands of the patient. And to your point about the limited kiosk space, we really see leveraging the consumer's own device as being the key to that. Many of those folks already have an iPad or an iPhone, or something of that nature in their pockets. So if they can walk up to the counter and scan a code to get all the product training they need or the pharmacists or pharmacy tech can direct them to do that, then you're able to deliver them that training to save the pharmacists some time and then they may answer questions or whatever the case may be. And it doesn't take up a lot of floor space in the store.

This is the response from pharmacists and I think this is a critically important point. As I said before, we want adherence on the part of pharmacy and pharmacy techs and we want them to see the value. And as you can see in the programs that we've already run, we've got 94 percent of pharmacists saying that the information presented was beneficial to their pharmacy practice. So we think that's a good endorsement of this type of approach and this type of program. I spoke a bit to our penetration. These are some of the customers that we work with. So you see that we have broad industry representation across the retail side, and in addition to this, we reach a lot of independents and others through our own independent retail portal and through partners like American Pharmacists Association, American Society of Health System Pharmacists, and other partners that we work with.

And then these are some of the manufacturers that have taken advantage of the drug advisor program and have approached the drug advisor network. And as you can see

we've done this, not just in the prescription but also existing OTC, and RMS [spelled phonetically]. Of course they're a rapidly emerging area of focus for us and we've even had some beauty [spelled phonetically] advisor, that's a different panel but they're work that we do for the manufacturers in that area.

So my key takeaway in all this is I just wanted to come in just a few minutes to point out that there's existing infrastructure already in place that can be leveraged to provide that critical information to pharmacists and pharmacy techs to support these kinds of switches and to make them productive. So, and very poor VP of business development that I am, I didn't include my contact information, so I'll be glad to make that available to anyone and have further conversation about this. Any questions or...

Jane Axelrad:

Thank you very much.

Peter Beckerman:

I think we've heard a little discussion already this afternoon about the technology. You indicated you've done direct to consumer in addition to professional education. Do you have anything to -- that you can tell us about what sort of technology was used in your direct-to-consumer education use?

Robert Burroughs:

Sure, absolutely, well the nature of the technology is such that we leverage the same learning products in many cases. So you can take the same intellectual property, create maybe a five minute course for the consumer at the same time that you create the 10 minute course for the pharmacist. What we're seeing is, I think in terms of the big bang that we're going to have around mobile it's actually still fairly early. I mean the penetration's very good but I challenge each of to think back to the last time that you took your phone out and scanned a QR tag. You've probably seen them many times, but I think when we get to things like locationally [spelled phonetically] aware devices and you don't have to scan anymore. I know who you are because the big data when you walk in the store. I know where you're standing. I can present [inaudible].

I think we'll really see the explosion, but having said that, we are getting the earlier doctors. We are getting uptake and the delivery mechanism is, as with any mobile device, it's web-based e-learning, so regardless of the device you're on you can access and take it. The issue and the difference of it is, is it is more of a broadcast medium. We can provide feedback statistics or statistics and feedback on usage, uptake, assessments, if you want to do that. But the truth of the matter is, most consumers don't want to take a pre- and post-assessment when they're standing at the counter or doing whatever they're doing. So there's a little bit of a difference in what we can provide you in terms of data around pharmacists and pharmacy techs versus the consumer. That's probably the biggest difference. And so we can tell you, yes, it was consumed but for obvious reasons we're not always tracking who consumed it and we aren't necessarily collecting the kind of feedback that we collect from pharmacists. But it's successful, it's taking off, not just in this space obviously but across all retail. And I think some of the things that were

eluded in the presentation before mine around getting people to adopt the idea of using their devices to track important medical information, provide diagnostics, all those kinds of thing. While some of that may be four or five years out, I think the very early end of that is getting them to use their mobile devices for simple informational consumption, tracking, reporting. And you see that with some of the major consumer brands that are on the web now on the website. There's not that much difference between mobile and what's happening on the web so...

Jane Axelrad:

I wanted to ask, exactly, like what you mean by 85 percent penetration? I think you then said it was into retail chains. Does that mean that 85 percent of retail chains use one or more of your services? Or --

Robert Burroughs:

Correct. Correct, and that doesn't necessarily mean -- and that's a good question. It doesn't necessarily mean that they are all using our LMS. Some of them are using our LMS for delivery of their learning products. Some of them are just using our learning products or one of our partners' learning products. So, and that's an important distinction. You don't need to try and build or define a single system. Let the corporate entities determine which systems they'll use and as our experience has been, we'll put our product into your existing infrastructure. We don't need to standardize around a single infrastructure, so...

Jane Axelrad:

And then I was also going to ask, would it be possible for you to put a sample of one of these courses in the docket?

Robert Burroughs:

I'd be glad to. Yeah, I'd be glad to follow up --

Jane Axelrad:

If you were able to do that it would be useful to see particularly something with a pre-and post --

Robert Burroughs:

Okay.

Jane Axelrad:

-- test to see sort of what it looks like and what level it is and how it works.

Robert Burroughs:

Sure, be glad to do that. Thank you.

Andrea Leonard-Segal:

I'm not exactly sure how I want to frame this question --

Robert Burroughs:
Okay.

Andrea Leonard-Segal:

-- but as I'm sitting here listening to the technology discussion this afternoon, you know, earlier we had been thinking about these devices in the pharmacy, but one thing that I guess we haven't talked about is the fact that consumers don't generally purchase OTCs for one person necessarily.

Robert Burroughs:
[affirmative]

Andrea Leonard-Segal:

It's not like a prescription drug that's defined for one person. Often these medications are brought home and they're used by multiple people in a household. And so thinking about these health selection questions for some of these, you know, opportunities for safer use of OTCs, I guess that I'm going to ask you to wax eloquently --

Robert Burroughs:
Philosophical? [laughs].

Andrea Leonard-Segal:

-- and philosophically for a minute about the use of these technologies in the home for multiple users because at the point of purchase it may be one self-selector but there could others in the household.

Robert Burroughs:

Right, I think that comes back to the point I was making about, you know, we tend to view mobile as this other thing, but mobile's just an extension of the Internet experience that folks have. So the experience should continue in the home. So I think the idea, around the idea of multiple parties, that's one of the great things about the technology now, is that as opposed to an insert in a package which might have indications and warnings and all the things that you have relative for a large number of audience members. If I can get you into a web-based experience, I can ask you who you are or who you're concerned about. Is this for you or for your children? Is this for a person that's elderly? You know, what are the circumstances? Then I can present you with data that's specific to you while still meeting the requirements that I have legally and ethically and everything else to provide you all the information, if I can target that information to you. So I think the same type of experiences that we're driving in a mobile environment, you should be able to go home and sit down at your computer and access those. So one of the things we'll have to do to drive that is have manufacturers think about that in their packaging and inserts and in another ways. I can only direct folks to those resources.

And then I think, and this is waxing philosophical, but I think the other thing, we have to ask ourselves how much can we get out of the consumer at that point of purchase? And it may be as simple as getting an email. It may say, look here's a little bit of information

but if you have more questions give us your email address and we'll send you a link. And then when they go home it's -- because they may not want as I said want to fill out assessments and all those things standing at the counter. But give us your email address and we'll send you a link and when you get home we'll let you participate in this program and we'll be able to target that information for you in a way that no other medium can. Now pharmacists, the human can do that, but there's not another technology that can target it for, in this age with these issues, you know, with this concern. What do I need to know? You know, here it is. So I think that's something that we just need to get the whole value chain to think about, is how do we push that experience? And what can we get the consumer to buy into? And it may be as simple as an email address that we can follow up with them, so -- is that sort of answer, is that waxing philosophical?

Andrea Leonard-Segal:
Yes, it was.

Robert Burroughs:
[laughs]

Andrea Leonard-Segal:
Thank you very much.

Robert Burroughs:
Sure.

John Jenkins:
I was interested in you talking about consumers using their own device in the pharmacy. There's an article in the front page of The Washington Post today about the early users of the new iPad complaining that the high speed data downloads are putting them over their data limits very rapidly so --

Robert Burroughs:
Tell me about it. [laughs] I feel that pain.

John Jenkins:
-- how are you envisioning this would be handled in the store? Are you thinking in-store wi-fi that the consumers would connect to or mobile networks or?

Robert Burroughs:
Now I can wax really philosophical if you want me to. I have this idea that one day we'll have this smart store concept. And so with the merger of big data, which we already have, and I know there are concerns around privacy and all those things but I would -- I'll speak as a consumer. I would love to -- I don't feel this is an invasion. If I walk in a store and you know who I am, I'm okay with that. I'm already on 50 different cameras anyway coming in and going. So now because of my device you may have at least some general idea of who I am.

Now if I go to the counter and I make a purchase or I speak to a pharmacist or I do other things, that information becomes more and more specific based on the information that you gather from me while I'm in the store. And if I was operating in that store I'd want to have a smart store. I'd want to be presenting that person now, because I know who they are, with the specific information that they need. So I think in-store wi-fi has to be a consideration there. I think that locationally-aware device issues have to be considered. So we already know that's taking place in packaging, but what do the retail stores need to think about in terms of sensing data within their own store?

So I think this could become very, very sophisticated pretty quickly, and I alluded to the big bang. I think everyone thinks we've already gone through the revolution. I think we're just getting started. I think we're going to reach a tipping point that is going to be quite phenomenal. As you're walking past a display and it shows you one ad and it shows me a different one. That's the world we're going to depending on who's looking at it. So, but in the meantime, even short of wi-fi, we define our programs in a way that they're device aware so I know what kind of device you're on and they're bandwidth-aware. So although I can't necessarily help with the where you went over your bandwidth and I pay that bill every month, but what we can do is at least deliver content that's appropriate for your device at the bit rate that's appropriate for where you are. But I would love it if every, you know, retail organization in the country got on our idea of, we want to build a smart store and part of that's access and part of that's censor technology, you know, there's several pieces to that. But the key is once again what we can do in the future and what we can do right now. What we can do right now is an awful lot just based on what we have.

Jane Axelrad:

Okay, thank you very much.

Robert Burroughs:

Thank you. I appreciate the time.

Jane Axelrad:

Michael Tarino.

Michael Tarino:

Good afternoon. Thanks for this opportunity to share some ideas with you. My name's Mike Tarino. I'm a health services professional. My background is in health plans, population health management, and health and wellness. I spent the last 12 years of my career trying to advance the consumerism dynamic in the health system. A significant part of that of time was with a company called Definity Health, a unit of United Health Group, where I was CEO. Today I represent Smartcare, Incorporated. We're a company that helps people appropriately use over-the-counter medicines. We've pioneered programs that leverage retailers, employers, managed-care organizations, to help individuals relieve their symptoms, manage their triggers, and become more involved in their self-care. The big promise behind our work is that as each of us gets smarter,

creating healthcare for -- creating health for ourselves, we collectively get stronger and we'll see that strength in our health system, in our economic position, and in our social awareness.

I'm excited we have the opportunity to talk to you today about the new paradigm. What I'd like to do is introduce two themes or principles that I can think -- that I think can help guide this work. And then a very practical application of those themes that shows how the marketplace that we're conceiving today can be a reality based on the infrastructure we have in place today and based on the consumer behaviors that are common across the marketplace.

The themes I want to introduce are two. First, I think we will be well served to leverage the power of healthcare consumers. And second given the dynamics that we're facing I think this is a grand opportunity to apply the promise of information systems and the innovative delivery of data to help address some of the problems that we're discussing in this forum today. The retail banking industry offers a great example of how these themes have come to pass, to drive more value for all participants in the marketplace. There was a time when we had to plan our entire weeks around when we could get to the bank. Those days are gone and they're gone because of these dynamics that we're talking about. Consumers are getting involved in demanding more value from their service providers and information systems are allowing us to deliver that kind of new value. It's a new paradigm in retail financial services and we've got an opportunity to introduce a new paradigm in the way our health system works as well. We've seen variations of these statistics from a bunch of participants in the forum today and yesterday. The bottom line is that it's a big problem. And these statistics are especially relevant to the context of the conversation today. Twenty-five percent of the time people take medicines that their doctor directs, that poor level of compliance drives a tremendous cost to the health system and by some estimates over \$100 billion a year.

Now think about the self-care, the over-the-counter marketplace. By definition, the individuals acting in that marketplace are fully engaged in their treatment decisions and that engagement can drive remarkably different behaviors. I point this out because I think this is a dynamic that's very useful for us to try to harness as we think about a new paradigm for over-the-counter medicines. The Patient Protection and Accountable Care Act recognizes this consumer dynamic and their dimensions of the bill, everything from the Navigator Grant Program to the Shared Decision Making programs that are in PPACA that acknowledge this. Leading health services organizations recognize this dynamic, too. I've seen this firsthand. The company that I was responsible for inside United Health Group was acquired specifically because it advanced that company's consumerism capabilities. And I've decided to share a quote from David Cordani, the CEO at Cigna. You can see that on the screen. I could have picked quotes from any number of leaders that recognize the importance of engaging consumers in advancing the way the health system operates.

Now I'd like to turn to the second theme: Engaging consumers is essentially important. So is leveraging information delivery in innovative ways. I think there are two important

reasons this is relevant to the conversation today. The first is the range of scenarios that we're going to need to support in the new marketplace. And this graphic tries to depict the range of scenarios that we envision the new marketplace is going to need to support. On one hand there are situations where the label on a nonprescription medicine is going to be sufficient to ensure that people can select and appropriately use the drug. I mean that's the way the marketplace works today. In other cases we imagine additional support will be needed for that kind of productive marketplace. In some scenarios we imagine that selection support or usage support is going to be necessary to demonstrate that consumers can appropriately select and then use those drugs. In other cases we can envision scenarios where an authorization is required. So this is a broad range of scenarios to be supported in a single marketplace. Consumers are going to touch this marketplace in these different scenarios and this kind of complex problem with lots of permutations is a perfect place to apply the power of information delivery. So that's the first reason why I think this theme is so important.

The second reason why I think we can get great advantage by thinking creatively about information systems and how they're leveraged is the behavioral challenge evident in a new paradigm. Today's over-the-counter marketplace we think about in terms of its -- well we're dealing with drugs where you understand the symptoms and you have discreet decisions. The paradigm we're considering now considers conditions that are very different; chronic conditions like high blood pressure, high cholesterol, migraine headaches, asthma management. But think of the behavioral shift that we're talking about here. We're going from decisions that are driven by symptoms, stimulus that people can feel to these continuous decisions, they're not discrete and they're in absence many times of concrete stimulus. There are no symptoms. This dynamic is a perfect opportunity for us to apply information technology because the delivery of personal relevant information can then become the stimulus and help us manage the behavioral challenges that are present in the marketplace.

Those two dimensions are essentially important. Engaging consumers, leveraging technology, and I don't mean this in a theoretical way, we have the practical capabilities to deliver a marketplace that meets these promises, and I want to introduce you to our vision for how that can be delivered. So we envision a consumer driven marketplace supported by a platform that I'll call the Smartcare platform. It's a consumer-driven marketplace. Our consumer's Sally, the little orange lady. She's interacting with various participants in the healthcare system to advance her own personal health. And she gets value from this tool, from this platform by using a particular tool, a personal health profile that we call the Smartcare profile, and it helps her unlock the value that's in this marketplace. So you can think about the Smartcare profile as a mini health record. Electronic medical records, personal health records are fantastic tools. They hold tremendous promise. They're comprehensive pictures of an individual's health situation, but they're not designed to be tools that consumers can use, at least not easily. The Smartcare profile contains basic demographic information and key personal health information, the numbers of the Know Your Numbers Campaigns that we're all supposed to know, available to that consumer. The profile belongs to Sally. She manages it and

controls it. It is populated by data that she provides or that she instructs other participants in the healthcare system to provide.

Now I'd like to apply this in practical ways to the scenarios that I described before that make the new marketplace challenging. Let's suppose that Sally is considering a hypertension medicine. She sees an advertisement for a medicine on television, she calls the 800- number to learn a little bit more about that medicine. During that call she grants the over-the-counter medicine company access to her Smartcare profile, but only to the information in that profile that's relevant to this particular medicine. The medicine company then can initiate a query that checks Sally's profile against the drug facts label and can give her a confirmation that the drug is right for her. She can go to the store, make her purchase with confidence just as she does today. So an example of how this platform can provide selection support. After she gets home with her medicine the platform might reach out with an offer for reminders to help her take her medicine and monitor how that medicine is working for her as an example of how user support can be extended by the platform.

Now imagine a scenario where the drug that Sally's interested in requires an authorization. So let's say the blood pressure medicine that she's considering falls under this category. Sally can go to the store, she can pick this medicine up off the shelf, takes it to the clerk, the clerk scans it, the point-of-sale system recognizes the barcode, sends an encrypted message to this Smartcare platform which checks for an authorization based on the information in Sally's Smartcare profile. It sees that her profile matches the details on the drug facts label, it issues that authorization that's passed back to the retail location. Sally can make her purchase, swipe her card without any trouble, and head home with the medicine that she wanted.

And here's a third scenario. This is a scenario where an authorization is required plus it needs to be validated. And in this case let's say Sally talks to her doctor about migraine headaches. Her doctor suggests an over-the-counter medicine that's right for her and he sends an encrypted email to Sally's profile indicating his authorization for this purchase. Later on Sally can go to the retail location, she can pick this medicine up off the shelf, bring it to the clerk, the clerk scans that and, just as before, the barcode is recognized. A query is sent over the internet to the Smartcare platform which recognizes Sally's physician's authorization, approves the purchase, Sally swipes her credit card or pays for medicine as she wishes, and then she could take her migraine medicine home and she has it available for her the next time a migraine hits. She does not have to go to the doctor to get a prescription to get relief from that situation.

Now we've talked about this in the context of a new paradigm, and it is new for OTC, but the challenge we're thinking about that it's new, is it might make a stink, that it's hard to deliver and it's not. All of the technology capabilities that I've talked about exist today. The data exists today. Just needs to be repurposed to deliver this kind of value. The other part of the equation is, are consumers ready to behave this way? And I'd argue that they're -- that they are ready. There are three key behaviors that consumers need to be comfortable with, that the marketplace needs to be comfortable with to make this work.

The first is the use of individual profiles and these are commonplace today. One hundred fifty-six million Americans have profiles on Facebook, millions more have profiles on services like LinkedIn, or with airlines or travel companies that they use. Profiles are very common. Consumers also need to be comfortable with one-to-one relationships with service providers that they get value from. These are commonplace too. I mean think about the relationships you have with retailers that you like and trust, like Best Buy for instance. Or the kind of information you exchange with invitation services like Evite, or even how effective your dentist is at helping you keep on an oral self-care regiment with the reminders that they send. And the dental example is a good one because so often it's in an old fashion channel, not a digital one like some of the other examples that I gave with you, but you can see the image of the checkup time postcard that so many consumers recognize and react to, to stay on a healthcare regiment. So the second dimension of consumer behavior, those one-to-one relationships with service providers, well established, and people are comfortable with them in the marketplace.

The final dimension that makes this work is the ability for consumers and the retail community to be comfortable with point of sale authorizations, and these are commonplace in the industry too. I mean think about the SNAP Program which was, you know, an analog for the development of this conceptual model, or how quickly the retail community adapted to the new FSA rules, is another great example. My favorite example of this is the blue laws that are enforced in some states. A six pack of beer could sit on the shelf at the grocery store untouched on a Sunday and if an out-of-town visitor picks it up and takes it to the counter that purchase is gracefully declined. So we have those elements in place, have consumers comfortable with the kind behaviors they will need to exercise in a marketplace of this design. This kind of a new paradigm delivers all of the benefits that we've talked about today. It's an opportunity to get therapy to more people and advance public health goals. It's an opportunity to help people save money, both consumers and the payer community. It's a way to lower the impact on already overburdened primary care system, but I'd suggest there's another benefit in this picture as well.

This is a data driven marketplace and as we collect information about the marketplace we get unprecedented insight into how the over-the-counter marketplace functions. This gives us an opportunity to manage and monitor this marketplace and I think it's going to be the source of other public health innovations as well. We've got the building blocks to deliver on this paradigm today. The technology capabilities are in place, the consumer behaviors are -- have already been demonstrated. If we are careful to make sure that we leverage consumer interaction, make them parts of the solution rather than keeping them sort of disintermediated [spelled phonetically] from the system, and we apply existing technology capabilities in creative ways, we can deliver on the promise of a new paradigm in self-care. Thanks, and what questions can I answer for you?

Jane Axelrad:

Thank you very much. Panel members?

Charles Ganley:

Hi, this may be a very simplistic question. If someone didn't want to fill out a Smart profile I'm presuming your platform would allow to have something in the store where they could just fill out or answer some questions and it would allow them to purchase a product if there was a requirement for preauthorization?

Michael Tarino:
Sure.

Charles Ganley:
As if they had to fulfill certain, you know, an algorithm and they had to answer it correctly. You know, I don't know if you were here yesterday --

Michael Tarino:
[affirmative]

Charles Ganley:
-- or where they, you know, there was an algorithm and you get to the end and it says you can purchase this product. I'm presuming you could do something like that within a store itself.

Michael Tarino:
Yeah, I think that people can access this solution anywhere, anytime, and it can happen in a retail location, it can happen at home, it can happen through multiple devices --

Charles Ganley:
Right.

Michael Tarino:
-- and you can use the Smartphone tablets as we've discussed. You can access this platform with an old fashion landline telephone and interact with the system that way. So it has the opportunity to be universally available, which relieves some of the pressure on retail delivery alone of a solution like this. Does that address the question you were raising?

Charles Ganley:
Yeah, I think so and I guess the other thing is, if you had a product that required authorization it would be limited to certain retail outlets then that were willing to participate in this authorization program type thing.

Michael Tarino:
That's true.

Charles Ganley:
Okay.

Jane Axelrad:

Yeah, I was wondering, I mean we've heard, we're hearing a bunch of different technological solutions that are, you know, individual companies are developing. How do we -- and we're talking about a sort of something more generic look at a new paradigm where you might incorporate some of these things that could be fulfilled using any number of different models and there's probably, you know, dozens if not hundreds of companies out there that are sort of operating in this space. How do we figure out how to move the ball forward and what happens to each of these sort of individual solution-based systems since we're obviously, as a regulatory agency, not trying to say, oh, the sport profile owned by such and such a company or this learn smart system owned by another company is the one to use. How do we sort of deal with the middle ground between us sort of up here setting the generic framework and the specific companies coming up with solutions and how do you bring all the pieces of this together so that everybody's sort of moving forward in a direction that will work for the health care system?

Michael Tarino:

Yes, so I think the policy opportunities are to define a framework that's clear about the parameters for success and allow the marketplace to be innovative and meet those challenges. The vision I shared I imagine will be delivered by multiple parties. In fact, you know, the set of folks that shared ideas for how we can address the new paradigm offer solutions that I think can be complementary or integral parts of the vision that I am putting forth for consideration by this group. I especially want to show that I think it's very achievable given the existing set of capabilities that we've got and consumer readiness. And I think the great opportunity is to lay the groundwork for this innovation to happen and let us collectively find the best solutions that serve consumers, industry, and the public health interest.

Robert Temple:

So this is -- this follows up Jane's question. So would -- does it seem plausible that we could define the properties that one these systems would have to have, the achievements it would need to do, the information it would have to transmit and then leave it to people to design a system that they could show did that? Is that sort of what you mean?

Michael Tarino:

Well I think an even higher order, in the context of switch, I think you're going to have the opportunity to determine what the appropriate conditions are on a case-by-case basis for medicines that move from prescription to over-the-counter. What I'm suggesting is a platform like this. It's flexible enough to creatively meet the needs of a lot of different scenarios, a lot of different drugs with different demands.

Robert Temple:

Okay. So we'd define the scenario and then the idea is that one or another of these systems or maybe several could fulfill that.

Michael Tarino:

I think that's true. I think you can ask a sponsor to demonstrate --

Robert Temple:
Yeah.

Michael Tarino:
-- that consumers can effectively select, utilize a medicine, and solutions like this can help that occur. So I think that relieves you from the obligation to think about what are the requirements of a platform like this. And instead it's those conditions that ultimately the platform has to deliver on that you can regulate.

Jane Axelrad:
Okay, thank you very much.

Michael Tarino:
Thanks.

Jane Axelrad:
Donald Reitberg.

Donald Reitberg:
Good afternoon. My name is Don Reitberg and I have the pleasure today of presenting for Farmacia Electronica, Inc. Interestingly enough the focus of this discussion is exactly on Dr. Ganley's question just a few minutes ago, and that is I'd like to focus on algorithmic self-selection and treatment methodologies. We've been working on these for about two years and I appreciate the opportunity to discuss this with you today.

Farmacia Electronica was founded in 2009, specifically to create systems and methods for delivering individual consumer-specific information on how to mitigate risk and enhance effectiveness of medications. Now, the majority of the founders of this company happen to be from an ethnic minority. So it's not a coincidence that a major focus of this company is on technological solutions to assure adequate knowledge and product selection by patients and consumers regardless of their language, ethnicity, or level of education. The company developed a first rendition product and filed for patent protection for its methods in February of 2011, and our applications on underdevelopment include several areas. We have risk evaluation and mitigation strategy methods for prescription drugs, medication therapy management for use in pharmacies, and in addition Rx OTC switched products, which is the current topic, our topic for today.

It's become clear to us over the last two years of development of products that we need to minimize our deviations from clinical practices and current regulatory practices and policies in order to be successful as an organization and, as such, we made assumptions during the development regarding technology-based safe-use prescription to OTC switches. The most important of these is that the current OTC regulatory framework need not change significantly to do this and also no core policy changes are really necessary. For only a limited subset of potential Rx to OTC switches candidate -- nearly

all consumers may have to self-select properly to create a favorable benefit to risk relationship. And only for some drugs this may be based upon potentially undue risks incurred by inappropriate population exposure and this could result in otherwise avoidable adverse advance and outcomes. We're assuming that a technological solution must accurately communicate the drug facts label so that the consumer can self-select and continue or discontinue treatment appropriately without intervention by a healthcare professional. We also assume that this should not require significant policy changes in the drug facts label requirements such as, for example, not requiring availability of the drug facts label in multiple languages other than English. We also assume that innovative technologies that support consumer comprehension of the drug facts label should be designed to foster an equal opportunity for all consumers regardless of their language, ethnicity or literacy level, and that consumer-specific communication and screening technologies are needed to create a level playing field for all who are proper candidates based on the product drug facts label.

Supporting technologies are not for all switches. These technologies should only be required when, based on definitive label comprehension self-selection and/or naturalistic testing, it is evident that unusual measures are needed to assure safe use. We're mindful that there's a long history of safe and effective use of OTC drugs in the U.S., and we hope to build on this success and help create new opportunities on a case-by-case basis.

The company has a self-selection and screening products under development. Now there was some discussion earlier about the need for kiosks and the importance of that, but the technologies aren't currently available at the retail setting in the form of scanning technologies, the same technologies that are used for checking out a product and also couponing. So these technologies can be designed for all retail environments with an option for restricted purchase availability only to consumers who properly self-select based on their product label. The technologies we're working on assure comprehension of risk to benefit relationship, proper product selection and usage, and we use iterative and repetitive approach to education and questioning. We, first of all, question in the consumer's language and we also iterate to a certain literacy level in order to acquire responses. The technology uses multiple devices in a cloud computer platform. For example, the consumer can obtain a verified self-selection number or barcode, kind of like a coupon, which can be accepted or rejected, to present to the store clerk to allow purchase, or a smart vending machine with an educational touchscreen can assure proper self-selection. Multiple other possible verification processes and devices for consumer-label education and queries are all linked on a cloud computer platform so that you can conduct these tests and these educational approaches using smart vending machines, kiosks, desktop computers, portable computers, smartphones, et cetera. You can even use the telephone for this purpose to get a number.

We have other applications in development and this is where we are heading as an organization. We hope to acquire capability that for every refill we can monitor each consumer's persistently correct self-selection, their adequate comprehension of labeling, and their efficacy and safety experiences. The benefit of cloud computer technology is the ability to track each consumer regardless of the point of purchase. If they have

purchased a product at a drugstore, at a gas station, at a convenience store this can be followed -- their histories can be followed over time. The cloud technology can continuously compile and statistically assess population self-selection, label comprehension, product usage and efficacy, and safety data. The real opportunity here is continuous improvement of the educational content and the effectiveness of the queries based on the collected consumer data over time. The system approves -- improves upon itself continuously as more and more data is acquired.

So with that description, and I realize it may be somewhat complex to understand all of those moving parts at one time, but there are certain advantages that, to be considered here. First of all, no learned intermediary is needed, although such interaction can be optional and can be built into the system. In addition, no behind-the-counter distribution or policy change for the drug facts label would be required. There is no need, once again, for multiple languages in the drug facts label. And during the development process the technology can be used in label comprehension, self-selection, and actual use trials as a part of the basis of approval for a switch NDA. Once the product has a commercial application it can continuously collect data to monitor efficacy and safety and possibly provide justification to remove the technology support requirements and initiate a traditional OTC distribution approach. That is, it can have an accelerated and continuous surveillance application, and the technology need not outlive its usefulness. It can outdate itself and remove itself.

Other advantages to this approach. The medication can be dispensed and in some cases may only be dispensed if all queries have been completed satisfactory, in a satisfactory manner. So a gatekeeper function to prevent risk and harm can be built into the system. The system can reeducate for refills and collect outcome data. The system once again could be extended to multiple interfaces: kiosk, IVR, telephone, webpage, mobile, smart dispensing devices, et cetera. And once again, because of this, it can extend to all retail environments. But very importantly, its use of language and the capability of addressing the issue of literacy, the technology can be and perhaps should be designed to empower all consumers, regardless of their ethnicity and education, with the ability to provide feedback on their comprehension of drug risks, benefits, and proper usage, and to report the actual product usage and outcomes.

The previously silent populations that FDA are currently -- are trying to address and have difficulty acquiring information from, can have a voice under these circumstances. You need to speak their language and work at their literacy level. Also, based on the data received, the communication methods can be continuously improved to overcome the disadvantages of ethnicity, education, and compromise the literacy level. It's not a onetime deal to work in multiple languages and ethnicities. It will require a rollout over a long period of time to fully realize the benefits of this type of technology.

So let's look at it perhaps from a stakeholder perspective. You know, we're calling this approach now, and I'm sure we can change the name at some other point, but we're calling it Validated Comprehension Risk Mitigated Nonprescription Drug Distribution. And for what it's worth, we think that the benefits to key stakeholders are as follows.

Consumers, consumers can safely gain access to additional self-care products. I believe that there is consensus that there's a need for that in society. In addition, FDA can support documentable and continuously improving risk management of healthcare products with enhanced engagement of minority and educationally compromised populations. Manufacturers can gain new OTC drug approvals using documentable approaches. Because these approaches are documentable they have the potential to mitigate legal risks and may offer prolonged marketing exclusivity periods. I'll talk about that in a little while. It's been alluded to earlier in this discussion, this discussion period. Pharmacies can gain new products for sale but importantly without additional labor requirements. And private and government healthcare payers, they can experience reduced overall drug costs with decreased labor and administrative burdens on healthcare providers. There's also the potential for reduced iatrogenic disease burdens. And as a result of all this the healthcare system in general can experience cost reductions and more effective use of scarce resources.

Farmacia Electronica is currently evaluating an Rx to OTC switch candidate using the company's technology specifically for the purpose of addressing proper self-selection, and deployment is ongoing now. It's in collaboration with Pegus Research, an independent testing organization. The platform under evaluation is designed to assure and document achievement of essential consumer self-selection requirements for the OTC drug facts label. This is based on three critical criteria: self-reported responses to education in the consumer's language, iterative reeducation to adjust for literacy and educational level, and queries to screen for proper self-selection and safe use. The primary commercial application for what we're doing now would be a gatekeeper function to make sure that only proper self-selected individuals would obtain drugs.

Now, what are the barriers that we feel exist to implement such technologies? Well we believe that industry sponsors may be concerned about unconventional approach development risk. There's been some discussion earlier about the fact that actual use studies could be very, very difficult to implement, they may be large, they may have multiple legs, and as a result of that the development risks and the potential rewards may not have the same level of acceptability as a traditional switch. So with that said, there's also the possibility of reduced consumer eligibility for purchase because we will be selecting consumers out of the marketplace for their betterment, for their wellbeing, but clearly they will be selected out and this will represent a smaller marketplace. There may also be concern about a requirement that all future switches will need supporting safe use technologies. And if that were the case the cost of development and the risk profile for the entire portfolio of companies would go up.

So how can these barriers be overcome? Well some possible solutions to this, the discussed safe-use technologies that I've been addressing are patent pending. There was an earlier allusion to the possibility that patented technologies could provide exclusivity to companies. Well industry sponsors who may be concerned about unconventional approach development risk or about reduced consumer eligibility for purchase may be encouraged by an enhanced period of exclusivity possibly afforded by incorporation of the patented safe use technology in product labeling. Now this may compensate for

concerns about development of risks and the possibility of sales volume limitations. And I would add that --

Jane Axelrad:

If you could wrap, sorry --

Donald Reitberg:

Sure.

Jane Axelrad:

-- you're a little bit over.

Donald Reitberg:

Okay. I would add that FDA may consider providing additional guidance on safe-use technologies that encourages use only for Rx to OTC switch efforts with self-selection education issues, not for all drugs, based on label comprehension, self-selection, and naturalistic research. My take-home message is that safe use modern technologies are in development for switches if deemed necessary and appropriate, and I appreciate very much the opportunity to present to the Agency today.

Jane Axelrad:

Thank you very much.

Andrea Leonard-Segal:

Thank you for your interesting presentation. I'm sitting here mulling over this multiple language issue and how you envision -- or FDA's ability to review this if it were going to become part of the -- part of the requirement for, you know, with approval, that this self-selection tool was part of the product and had to be available in multiple languages even though drug facts would not be and, you know, that would be according to my best understanding of the current regulations, on how -- we would need to review and understand that the self-selection part of this in multiple languages was actually accurate in terms of conveying information about the drug properly. This is a very new issue and potentially one that would require an awful lot of thought, my guess is on the part of the Agency, and so I'm just wondering, you know, where that goes with that.

Donald Reitberg:

Well we've taken a very simplistic approach to this. Rather than using services that translate into various languages we've been using pharmacists who speak the language of the individual and routinely discuss with them the drug therapy and, therefore, extremely knowledgeable of how to do it. This is at the level now of early research and we recognize that, and we fully appreciate the fact that the Agency would need to be assured that the processes that we use are compatible with accurate representations to consumers going forward and we'd be pleased to work with the Agency to make that happen. We're not sure exactly how to do that now but we certainly do understand what you're saying and why.

Andrea Leonard-Segal:
Thank you.

Jane Axelrad:
Okay, thank you very much. That concludes our scheduled presentations for this hearing.

[break]

Open Public Session

We have three people who have registered to speak at the open public session. Dr. Layson-Wolf, are you here? Okay, yes? Also I'm going to say that we're going to keep people to the same timeframes that we had for the speakers who registered, you know, 15 minutes on the timer. Go ahead, come on up.

Cherokee Layson-Wolf:

Good afternoon, everybody. I want to thank the committee for giving me the opportunity to provide my comments at this hearing. My name is Cherokee Layson-Wolf, associate professor at the University of Maryland School of Pharmacy in Baltimore. My main area of training is a within community pharmacy and also ambulatory care. And I come in front of the committee today to testify regarding the roles the pharmacists can play in safe -- in the safe use of nonprescription medications. With the changes in community pharmacy practice pharmacists have had the opportunity to engage patients when deciding whether to self-treat or seek additional healthcare. In the recent years, much effort has been put into empowering patients, excuse me, to meet more of a role in their health such as the Script Your Future Campaign which emphasizes the importance of patients taking their medications as directed, and also the most recently Million Hearts Campaign where four of the six areas of emphasis involve medications and medication classes that have been discussed at today's hearing.

At the University of Maryland School of Pharmacy in 2006, we launched the P3 Program, pharmacists, patients, partnerships, where pharmacists serve as coaches to help in the self-management of diabetes. You may recall Tom Menighan yesterday, CEO of APhA, had mentioned the diabetes 10 cities challenge and we were actually one of the pilot sites for that program. In the P3 Program, during regular patients' visits, pharmacists used the concept of medication therapy management to engage patients, involve the patient in discussions about their medications and how it ultimately impacts their health. I am actually a P3 pharmacist myself, and I see employees at a company based in Hunt Valley, Maryland. Employees are also able to see the network pharmacists also in the community setting. So our network pharmacies -- pharmacists are all over the place and around the Baltimore area. Thus far the program has been able to demonstrate a decrease in A1C over one percent in 60 percent of the population and almost a 2 percent reduction in 32 percent of the managed patients. For LDL we reached demonstrated goal of less 100 at 85 percent of the patients' diabetes, and also we saw the reduction to the goal of less than 130 over 80 to 64 percent of the patients in the P3 Program.

This model really allows for the direct interaction between the pharmacists and the patients, and it also works towards changing the perception that patients might have about pharmacists. As you've probably heard, a lot of people have talked about the fact that pharmacists may be sometimes difficult to access, but through these programs like this, patients are more able to see exactly what a pharmacist can provide to them. P3 patients have also demonstrated or indicated a high level of satisfaction regarding their interactions with pharmacists in the program.

In the school training at University of Maryland we offer several resources that can help in the expiration of the role in patients -- in assisting patients with self-care. We actually train our students to engage patients through communication, education, and counseling. And in our self-care courses I teach the students that our interactions with the patients in the community setting do not consist of telling the patient, that item is now in the bottom shelf in aisle five, but it actually the discussion should begin with a series of questions to determine whether or not that patient can actually use that product or refer them to further health care. We also carry these skills on through their clinical training on their rotations.

So one of the major points that I want to bring to you is that consideration of a pilot program is important in these discussions that we've had today. First, we're in FDA's backyard at University of Maryland and we can work to create these models in the surrounding area. The University of Maryland in Baltimore is a research institution, can engage the formal evaluation of such pilot projects. The P3 program itself actually already has an existing network of pharmacists in Maryland and also Virginia. And in addition, you know, we also utilize a web-based program where we document these actual interventions that we make with patients and also can use that system to communicate directly with physicians.

One other note that I wanted to bring up is in relation to the University of Maryland, one of the other things that we do there is that we also have community residency training programs. And in these programs we actively train pharmacists to provide care in that setting. So they realize what kind of barriers they already have interacting with patients and our goal is to teach them how to overcome those particular barriers. And it's this type of training that will really push pharmacists in the right direction in terms of knowing how to engage patients and also provide them appropriate care.

In addition, with available diagnostic technologies that a lot of the speakers have spoken about over the last two days that will allow for point-of-care testing, pharmacists will also be able to support patients in identifying and making self-care decisions, identifying patients at high risk for conditions such as cardio-vascular disease and diabetes and also make referrals to health care providers when needed. Recent regulatory changes in Maryland have now allowed pharmacists to be able to provide point-of-care testing within that setting. And probably in the next few months we'll be actively able to do that. And regulations are in existence all across the country to allow pharmacists to do such testing. So that concludes my comments and I want to thank you for your time and opportunity to comment.

Jane Axelrad:

Thank you very much. Panelists? Questions?

Mary Kremzner:

Thank you for presenting. Are you going to provide some more information related to P3 to the docket? Will you be able to do that?

Cherokee Layson-Wolfe:

Yes. Certainly Mary. Thank you.

Jane Axelrad:

Okay. Thank you. Our next speaker is Edwin Hemwall.

Edwin Hemwall:

Good afternoon, and my name's Ed Hemwall. I'm from Merck Consumer Care. I first want to thank the committee and the organizers here. This goes back to some dialogues we've been having over several years but most recently about a year ago. I want to thank Lee for putting this together, the excellent set of presentations, the science fair we had in December, and Charlie and Janet for having kind of the overall interest in pushing this forward.

I struggled on whether or not I was going to try -- ask to speak at this conference today or at this public hearing. And I sat for the last two days kind of twitching in my seat on some of the remarks that were made and some of the really good suggestions and overall questions, not all of which were clearly answered. And maybe I can have some help in that. But I do want to add the perspective that I have. I promise to be brief. I will be punished by extra hours on I-95 trying to get back to my home in Pennsylvania if I'm not. But I do think I come from an important perspective. I've worked in switch for near 20 years and over 10 of those years were spent on working on the statin switch of Mevacor. And I have the scars to show for it. But maybe if there's such a thing as a switch purple heart, I might also have one of those. But we worked on this for a long time and we started in 2000. And the story on the statin -- it's just an example I'm going to give. I have more looking forward into the future than just talking about that. But the lessons learned. Our first advisory committee in 2000 -- Bob Temple, you were there -- we debated whether or not we could tie the dose of 10 mgs milligrams to the AFCAPS study. Ultimately, the FDA advised us to raise the dose to 20 milligrams. We ultimately, over several years of work, pretty much answered the questions endorsed by the advisory committee in 2005, of efficacy, safety, long-term use, the benefit that would be seen in terms of cardio-vascular outcomes and the actual use of consumers in a one-year trial.

But the one part of the code that we were unable to crack was getting people to properly self-select. And we worked with Charlie and Andrea and others in the OTC group at FDA to come up with novel ways to do the self-selection part of the equation to get us to a place where we could be confident that consumers would understand what it took to basically approximate for themselves the Framingham risk score for cardio-vascular risk. Andrea, you might remember the box with the wheels on it where we tried to get -- everybody had to line up their wheels to get all blue on the top and that would get them to the appropriate use of the product.

Problem that we ran into was the agency was unclear on how they could actually regulate those self-selection aids and what we're calling the safe-use elements that have been part of today's discussion. And so we were advised to go ahead and develop this using a standard drug facts approach, and you saw some of the elements that we used to get

creative with how drug facts were used in the presentation yesterday by Dave Schiffkovitz. But although he probably came close to getting kind of to the sweet spot of the right consumer using the product, we didn't get there, especially with the specifics of the label and the exact elements of age, lipid levels, and cardiovascular risk factors.

And so at the advisory committee in 2007, we committed totally voluntarily, to have these other special aids that would be available to consumers in the marketplace to drive better self-selection decisions. Again though, when the committee asked, "Can you, FDA, make the sponsor do these things? Can you enforce these in the marketplace while other statins that come along later have to do the same thing?" The answer was no. And the comfort level of the committee, and I think of the FDA in general, was that as long as we couldn't enforce these extra voluntary measures that the sponsor was willing to take on, there was no way that it could be approved just with the pure drug facts labeling alone. So, that's history. That's behind us now and we learned a lot.

But let's look forward for a minute. Our conditions of use that we're describing today, conditions of safe use, are technology-based. They do not require a pharmacist as the gatekeeper. Now, we love pharmacists. Consumers love pharmacists. Pharmacists play a tremendous role in the overall health care continuum and in the direct ability of consumers to have someone to go to for advice at the point of purchase. But they are not required for these systems to work. There are no new issues about liability, about cost, about training or about recordkeeping with regard to pharmacy practice. These conditions and systems can be enacted now on a case-by-case basis for products where this is appropriate. I would expect that by and large most switches can still be accomplished by the traditional open-shelf paradigm. But we're talking about some newer and more complicated switches with a possible greater effect on public health that may need these technological aids.

Now we in industry need two things: two things from the FDA before we can invest in these types of products and these programs that are important to bring these to the marketplace. Number one, we need a clear regulatory framework that the conditions of safe use can be approved and enforced as part of safe labeling and if we do not use these then the product is considered misbranded. Second, the studies that are required to validate these systems must be viewed as essential for exclusivity. Ideally, they should qualify for the three years of Hatch-Waxman. But maybe more. The time and energy and effort put into these sorts of programs and the investment may require additional exclusivity. We certainly would like at the bare minimum to have the three years of Hatch-Waxman. A self-selection study in and of itself does not qualify because -- unless the patients are dosed with medication. Otherwise, it becomes ineligible according to the current interpretation of Hatch-Waxman. So that's very important to us.

But let's not allow the perceived complexities that have been raised here and over the last few days to overshadow the basic simplicity of the conditions of safe-use paradigm. Consumers are ready and willing. The technology is here now. Give us in industry the pathway to bring innovation to the table. We have a chance to impact public health on multiple fronts. Great access is a given. But we have enormous education and self and

support opportunities that these programs can bring. We have the ability, as you heard, for Pharmacovigilance tracking in ways that were impossible before. We have better utilization of our precious health care resources and we have a healthier and more productive America over the long term. Sounds grandiose but I think we could get there if we start taking the first main steps that we need to allow industry to start working in this way. Now I've heard Dr. Woodcock say, "We need to seize the day." You've probably heard that, yourselves. I agree. The imperative is clear. Let's make this happen. Thank you.

Jane Axelrad:

Thank you very much. Okay, and our last -- thank you -- our last speaker is Paul Brown.

Paul Brown:

Good afternoon. Thank you for the opportunity to comment on behalf of the National Resource Center for women and families. Our center is dedicated to improving the health and safety of adults and children and we do that by scrutinizing medical and scientific research to determine what is known and not known about specific treatment and prevention strategies. We do not accept contributions from companies that make medical products.

Under the Federal Food Drug and Cosmetic Act, the FDA approves new drugs as either prescription or non-prescription. In order to increase the public's access to medications, the FDA is discussing a new paradigm that would allow certain drugs that would normally require a prescription to be available over-the-counter or behind the counter, with certain conditions of safe use or for drugs to be available simultaneously as prescription and over-the-counter. We commend the FDA for presenting this new paradigm which may increase consumer access to medicines. But we urge the FDA to move forward cautiously.

The major public health problem that the FDA is attempting to address is the undertreatment of common diseases or conditions, such as high cholesterol, high blood pressure, migraine headaches and asthma. It's been suggested that patients who don't have the time or the money to go back to a physician to get a prescription refilled would benefit from the convenience of getting those products directly from local pharmacies. There is an assumption that many patients stop taking their prescribed medications because it is inconvenient or expensive to go back to their doctors. But they would take those medicines if they were able to go back to their local grocery store or pharmacy without a prescription.

That is true in certain situations. But we don't really know how often that happens. Sometimes patients stop taking their medication because they feel better, not realizing that their health could deteriorate if they stop taking their medicines. That would not be solved by making the drugs more available without a prescription. Sometimes patients stop taking drugs because of side effects, real or perceived. That is a situation where you would want a doctor more involved rather than patient perhaps switching to another medication without a physician's involvement.

The FDA also hopes to make rescue medicines, such as inhalers for asthma or EpiPens for allergies, more accessible in emergencies. Sometimes patients run out of these products when they need them most, such as at night or on weekends. It would make sense if they could easily get an extra one or a replacement at their local pharmacy without an additional prescription, rather than going to the emergency room. The FDA suggests several possible conditions of safe use for allowing what are currently prescription drugs to be marketed without the prescription or without a repeat prescription. The FDA suggests self-screening by patients using technological aids. We are concerned about the accuracy of self-screen devices without any assistance from a pharmacist or other health professional. If the patient answers questions incorrectly or misreads the question or multiple choice answer, the results could be dangerous. The FDA suggests pharmacist intervention as a condition of safe use in some cases. This seems quite plausible. Pharmacists successfully and routinely administer flu shots, for example. However, there are many issues to resolve. Will the pharmacists have access to the patient's health care records to review for possible adverse reactions to certain medicines? Will the pharmacist be able to enter data into the patient's record? We also wonder whether all pharmacists will have the time or training to adequately assist patients in making decisions about the drugs that have serious side effects. Many patients are taking many different drugs at once and they may not accurately remember the names of all the medicines or be getting all those drugs at the same pharmacy. If pharmacists are expected to spend more time talking to patients to make sure that the medication in question is a good choice for that patient, how will the pharmacist's time be compensated?

In addition, there are liability issues. Where happens if someone has a severe adverse reaction and is permanently injured or dies? Could the pharmacist or the drug store he or she works for be sued? Could this new category of drugs greatly increase the cost of insurance for pharmacists or pharmacies and therefore increase the cost of drugs?

We commend the FDA for starting down this path but we'd like to see it done safely. We'd like you to try a pilot program to study process seem most likely to help and least likely to harm, such as EpiPens and asthma inhalers, while continuing to require an initial prescription. We'd like to see -- allow more refills that would usually be permitted without a new prescription at the doctor's office, then evaluate the impact of those changes. Before the FDA moves forward on allowing such widely used drugs as statins, blood pressure medicines to be more easily available, it should answer a couple of key questions. Do we have data from other countries that have gone down this path? What evidence is available about the risks or benefits of such a change? Again, we applaud the FDA for presenting this new paradigm, which we think will increase consumer access to medicine but we urge the FDA to move forward cautiously.

Thank you.

Jane Axelrad:

Thank you very much. Panelists?

Closing Remarks/Adjourn

Okay, as we hoped when we planned this meeting, we've heard a wide spectrum of views about this paradigm. And, in fact, the last three speakers really epitomize the spectrum of views, I think, that we've heard here over the last two days. But I'd like to summarize a little bit about what I took away from the meeting.

I think the pharmacy organizations are generally supportive of the concept of making more prescription drugs non-prescription with conditions of safe use that require pharmacist involvement. They feel that pharmacists are adequately trained to assist consumers in identifying whether they have particular conditions, selecting appropriate medications and monitoring their use over time. They've identified as advantages the ability to provide access to medical care to people who might not otherwise have access, and to provide access whenever it's needed and close to home. They believe that this will improve medication compliance and overall health care outcomes and they point to the fact that they are often the first line of contact with patients in need of health care and that they can refer patients to healthcare providers when they identify that they need additional care or the care of a physician. Pharmacists cited many specific experiences where pharmacists have taken on an expanded role in patient care, including collaborative practice agreements in several states and medication therapy management models where studies have shown improved health outcomes.

We've heard from educators about the training that pharmacists receive in pharmacy school and about continuing education requirements that could be used to provide adding additional training that pharmacists would need to receive if the new paradigm were adopted.

Pharmacy groups did discuss several issues that would need to be addressed, including pharmacy reimbursement for services and integration of the new paradigm into the workflow of the pharmacy.

We also heard support for making drugs non-prescription based on conditions of safe use that rely on new technologies instead of pharmacy intervention or perhaps in some cases in addition to it, to guide consumers in making the right medication choices. Algorithms and other tools could be made available through kiosks, smartphones or other technological advances that would simplify decision-making for products that require more sophisticated analysis and guidance for patients to be able to take them safely and effectively without a prescription.

Some have suggested that making available non-prescription drugs with conditions to assure safe use can actually facilitate the efficient and effective engagement with physicians and other members of the health care team. And over the last two days, numerous drugs and categories of drugs were cited as examples that might be considered for this new paradigm. These included medications such as epinephrine for allergic

reaction, Naloxone for drug overdose, contraceptives, smoking cessation products, anti-hypertensive and diabetic medications, just to name a few.

But others, including patient advocacy groups, voice strong views that some of these products are not suitable for non-prescription use, even with conditions of safe use. There were opposing and strong views expressed about whether drugs to treat various diseases, such as asthma, would fit the new paradigm because of the characteristics of the disease.

We also heard from Nancy Junfield [spelled phonetically] that this new paradigm is appropriate and that it could reduce the quality of patient care. Concerns were raised about the ability of pharmacists to evaluate patients and make difficult diagnostic decisions and medication choices for patients in the place of physicians. Concerns were raised about fragmenting patient care and missed opportunities to identify even more serious conditions because of lost opportunities for patient interaction.

Some groups argued that there was no evidence that the new paradigm would reduce costs or improve patient care or ask for evidence or some indication of world evidence there was that this would work. Some groups argued that the existing system of prescription and non-prescription drugs was adequate and shouldn't be changed. They noted that we've already approved non-prescription drugs with additional educational materials and aids for self-selection and that various ways of making drugs available could be employed without creating a new category of non-prescription drugs with conditions of safe use.

There were practical considerations raised, such as the need to consider the effects of conditions of safe use on the drug distribution system and the need to develop a business model for the various ideas that would lead to adoption by pharmacies and others in the health care system. And we heard from some people about the challenge of conducting studies that would be needed to show how non-prescription drugs with conditions for safe use could be safely and effectively used by the consumer.

So we have received a lot of input and we're going to be looking very closely at what we've heard and at the comments that we hope will be submitted to the docket. We asked for a number of places during the hearing for people to submit specific things that they had referred to or cited to the docket. And we look forward to seeing some of that more detailed information that we simply couldn't cover in a two-day hearing.

A number of people have said that they would provide those kinds of materials. The docket closes on May 7th. After the docket closes, we're going to review the information that we've received and decide whether -- and if so, how to go forward with this. As Dr. Woodcock indicated in her opening remarks, we will likely need to proceed through rule-making to develop a new framework for doing this. So there will be many opportunities for further public input if the initiative does go forward.

So I want to thank everybody for coming and participating. I want to thank Lee Lemley and Rachel Bauchman and other staff who provided support for the meeting. And I want to thank the panelists for their patience and thoughtful questions and participation.

So with that, the meeting's adjourned. Thank you.

[end of transcript]

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