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Public Hearing – March 22, 2012

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

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ADJOURN

Welcome

Jane Axelrad:
Okay, good morning. My name is Jane Axelrad. I'm the associate director for policy in the Center for Drug Evaluation and Research here at FDA. I'd like to welcome you to this Part 15 hearing on Using Innovative Technology and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Non-Prescription. I'm going to be the presiding officer today and tomorrow, and we have a distinguished panel of experts from across the agency and from our sister agency, the Centers for Medicare and Medicaid Services, to listen to the presentations.

I'm going to first ask the panelists to introduce themselves. Then I'm going to go over some logistics, and then I'll turn it over to Dr. Woodcock for her opening remarks. So, Janet.

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

Robert Temple:
Bob Temple. I'm deputy director of the Center for Clinical Science.

Peter Beckerman:
Peter Beckerman from the Office of Policy in the FDA's Office of the Commissioner.

Jeffrey Kelman:
Jeff Kelman. I'm the chief medical officer, Center for Medicare at CMS.

John Jenkins:
John Jenkins, I'm the director of the Office of New Drugs in CDER at the FDA.

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

Andrea Leonard-Segal:
Andrea Leonard-Segal. I direct the Division of Non-Prescription Clinical Evaluation in OND.

Marta Wosinska:
Marta Wosinska. I'm director for Analysis Staff and Office of Planning and Analysis in CDER, FDA.

Joseph Griffin:
Joe Griffin from the Office of Medical Policy in CDER.

Mary Kremzner:
Mary Kremzner, acting director at Division of Drug Information for the Office of Communications in CDER.

Diane Maloney:
Diane Maloney, associate director for Policy in the Center for Biologics Evaluation and Research.

Alberto Gutierrez:
Alberto Gutierrez, director of the Office of in Vitro Diagnostics in the Center for Devices and Radiological Health.

Jane Axelrad:
Thank you, panelists. Just for panelist information, you don't have to hold the mic to talk, but you should turn it on and then turn it off because it interferes with subsequent people if your mic is still on. The red lights shows when it's on, but you don't have to hold it.

Anyway, 30 presenters have registered to speak during the seven sessions scheduled during this two day meeting. We have consumers, pharmacists, physicians, and other members of the medical community, regulated industry, and managed care organizations here today to present to us on the feasibility of this potential new paradigm. And we hope that they're going to address many of the issues raised in the notice of the meeting as well as any other issues that might be of concern.

Agency staff will not be making presentations, but we have left ample time for the panelists to ask the speakers questions so that we can develop a full record for the proceeding. Only panel members will be permitted to ask questions of the speakers. We have allotted of time at the end of afternoon tomorrow for an open public session, so anybody in the audience who has not registered to speak but would like the opportunity to make some remarks can register. Please make sure that you let us know if you're planning to do that. There is a sign-up sheet out at the registration desk, and we're going to try and accommodate anyone who wants to speak.

The slide 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 available at the bottom of the agenda for the meeting. We also will keep the docket open until May 7th, and we welcome any written comments as well.

The 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 that this process is fair, each individual speaker will be allotted 15 minutes. I'll be announcing the speaker's name and ask the speaker to come to the podium. Then, to facilitate a smooth process, we have a timer up here. A yellow light will come on after 14 minutes, notifying you that you only have one minute left to wrap up. And I'll remind you if you go over your time to try and keep us on schedule. At the end of each speaker's presentation, the panel members will be given time to ask the speaker questions.

Some other general housekeeping information, there is guest Wi-Fi in this room. The network is called FDA Guest, and the password is guestaccess. Everybody who attends should please sign in at the registration desk. We want to get a feel for who's in the audience, what organizations are represented. So, if you haven't already done so, please do that. And Lee Lemley, over here in the blue, has been managing the meeting and you can talk to her if you're going to need any revisions to your slide before your presentation. Restrooms are outside the main conference room. You turn down the hallway to your left. And lunch will be available at the kiosk for a fee, or you can go off-campus if you can find your way off campus and back on, but Lee and others are around, will help you if you get lost. Okay, so that covers all of our housekeeping chores.

And now, I'd like to turn it over to Dr. Janet Woodcock, director of the Center for Drug Evaluation and Research, to make some opening remarks.

Opening Presentation

Janet Woodcock:
Thanks, Jane. Good morning, everyone. Thank you for attending this meeting. We really look forward to your input. The question that we will be discussing over the next several days is the following: Should there be more flexibility in our concept of non-prescription drugs? OTC drugs have had great success in providing consumers with excellent self-care options and, at the same time, providing significant health care savings from averted prescriber and emergency department visits, but our concept of self care is really limited to conditions that can be self-diagnosed and self-treated based on the information on the very nicely standardized drug facts box that's on the non-prescription drug, combined with common knowledge and common sense. The question we are addressing today and tomorrow is: Can we broaden the assistance that a consumer gets, for example, by augmenting the fact box information with information technology approaches or by utilizing pharmacist assistance to help the consumer understand the condition or the treatment better and thus increase the types of medicines that could potentially be available non-prescription?

FDA is determined that such a change would require rulemaking, and we're holding this hearing to gather information from stakeholders about possible impacts of changing the OTC regulations and our introducing this additional paradigm.

Some have asked us in the process of as we've been exploring this whether certain changes could be accomplished voluntarily by sponsors of drugs. And while it is possible that a single manufacturer could establish an enhanced OTC program, competitors could not be required by FDA to do so. Therefore, FDA could not view such a program as being essential to the non-prescription status of the drug. It would simply be an enhancement. And therefore, we feel that we need to be able -- would need to be able to require such changes if they were actually needed to make the drug appropriately non-prescription.

What specific types of medication might be -- we'd be considering? In general, we're considering the ways in which the drug fact box information could be supplemented. First, the rules for non-prescription status were established a considerable time ago, as most of you know. And that was a time when widespread access, certainly my personal access and probably yours, to information technology did not exist in the IT world that we live in today. And we also have to consider the fact that this world is rapidly evolving and that consumers of tomorrow will have access to all sort of media and sources of information that simply weren't available 20, 30 years ago. And so, it is clear that there are now many interactive mechanisms that can step the consumer through the process of self-diagnosis and medication selection in a much more comprehensive manner than would happen by them reading the drug facts box.

So it's quite likely that these could be displayed in a manner that could extend the concept of self-diagnosis and self-selection of treatment to additional conditions or drugs. So, that's one of the things that we'd like to discuss, is could information technology be deployed in ways that could augment the consumers' ability to diagnose their condition, really understand their condition, understand a drug and whether it's right for them, and even assist them in understanding how to use the drug properly, for example, with diagrams, demonstration videos.

And once we would really get into this, there are multiple media mechanisms that could be employed.

Importantly, we're not considering the process for -- we're not considering altering the process of the OTC switch itself; in other words, the scientific process. Comprehension and use studies could still be indicated to inform the evaluation and proposed switch. And any decisions we would make could be data driven and based on the data for that individual product and whatever technology enhancements were going to be employed with it. So, this is more about how the information would be made available to the consumer, not what quantity of evidence would be used to decide that the product could be non-prescription, if you're following me.

Now, a second scenario for evaluating self-care could involve pharmacist involvement. Pharmacists could help the consumer verify the diagnosis, perhaps by going through an algorithm with them or, say, interpreting results of various tests for them, helping them interpret tests, or they could help in deciding whether the medication was right for the consumer, and they could reinforce the directions for appropriate use of the medication. So, having the pharmacist assist and the pharmacist involvement be another condition of safe use is another type of expansion of the non-prescription concept that we are exploring.

We are also interested on input on pharmacist interactions with patients who already have diagnosed disorders. Large numbers of Americans, who have chronic conditions, as we all know, are not adherent to their medications, resulting in a significant amount of preventable harm, for example, cardiovascular events and so forth. We are interested in ways that the pharmacy community, who are much more accessible to our population, could improve access to adherence to these types of medicines.

Now, this, of course, raises concerns, this particular aspect raises concerns about separating patients from appropriate medical care. And I would point out we're talking about the future here. We're not talking about the past state of medical care and how it has gone forth. As our electronic health records and other electronic tools, such as e-prescribing, move forward, and patient portals evolve, for example, where patients are able to link with their health care providers. And this has been put forth as proposed aspect of meaningful use of electronic technology and health care. Pharmacies, patients, and providers will be linked in new ways. Greater pharmacist involvement could provide an avenue to bring non-adherent individuals back to health care and get them involved back in their health care. And methods to inform and link providers back from the pharmacy could be developed. And I think we already recognize this is extremely important in managing continuity of care of patients, because right now, about 20 percent of patients who receive a prescription do not fill that prescription. And often, their providers go unaware that they, a patient did not even fill the medication that was intended. So, much stronger links are needed. And I would just like to say I strongly believe that medicine needs to take medical care to where the patients are. And this is one way that we will really improve both access and adherence, extremely important aspects of particularly chronic care of patients.

Now, an additional role of pharmacists, as we put in our notice that we're considering, would be dispense what I refer to as antidotes to individuals who had -- could self-identify as having

conditions where such an antidote might be needed and they had already had such antidote dispensed to them. An example include EpiPens, where they are used for anaphylaxis but we frequently see instances where people lose their EpiPens or the EpiPen gets broken or is malfunctional or whatever, and then they're at risk for a life-threatening event, and they don't have access to that product. And also glucagon injections for diabetics who are subject to hypoglycemia, this is another area where people can experience life-threatening events, and we think this should be considered.

Pharmacists' involvement in dispensing non-prescription drugs raises another unresolved issue; however, that some of these drugs would have conditions of prescription use at the same time they'd have conditions of non-prescription use. And currently, this scenario does prevail. As many of you know, we have different strengths and dosage forms and so forth, some of the same drugs, some of which are prescription and some of which are non-prescription. But we don't have the identical same drug usually in both status. And so, we would have to figure out how to deal with that because in these -- in some of the scenarios, we are proposing the difference would be the condition of access, not the actual physical state of the drug.

Now, another thing we want to discuss in the next two days is that all of these potential changes raise issues of reimbursement, cost, liability, and so forth. And we have asked a lot about this in our notice, because these are obviously very important both to consumers and to the provider community and the business community. And we look forward to hearing your comments on these issues. FDA is likely less knowledgeable on many of these and many of the people who are attending this meeting. So, we really are sincerely seeking input.

Now, finally, there may be additional scenarios for non-prescription use that we haven't entertained. We're really interested to hear your ideas. And in addition, I think we are interested in crafting something, as I said earlier, for the future, a future that is not going to look like the past of 20 years ago. We would like to have -- I would like for us to have additional flexibility for non-prescription use and the ability to, as new circumstances and technologies arise, to incorporate those into our regulatory practices in a fluid and forward-thinking way. So, we really look forward to the two days. We will have an open docket after the meeting so that those who are -- have new insights after hearing all this discussion can submit additional information. And we do have an open mind, and we want to look at all sides of this issue. So, thank you very much for your attendance and your contributions.

Jane Axelrad:
Thank you, Dr. Woodcock. We are really looking forward to hearing from everybody over the next two days. And with that, I'm going to ask our first speaker, Eric Juhl, the director of Public Policy for the National Association of Chain Drug Stores, to come to the podium.

Session 1

Eric Juhl:
Good morning and thank you for the opportunity to present to you today. I am Eric Juhl, director of Federal Public Policy with the National Association of Chain Drug Stores. We applaud the efforts of the Food and Drug Administration to explore the public health benefits of using innovative technologies and other conditions of safe use to expand access to some prescription drugs without a prescription. NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies, from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including some 130,000 pharmacists.

NACDS is cautiously optimistic regarding the creation of a new paradigm. Pharmacists have extensive knowledge, are trusted health care professionals, and are the most accessible health care providers due to the sheer number of community pharmacies and extended hours. Research has shown that approximately one-third to one-half of all patients in the U.S. do not take their medications as prescribed by their providers. Pharmacy services administered by pharmacists and chain pharmacies have been proven to improve patient health and prevent unnecessary hospitalization caused by non-adherence.

The Patient Protection and Affordable Care Act, enacted in 2010, is estimated to extend health insurance coverage to an additional 32 million Americans. All providers, including doctors, nurses, and pharmacists, will face increasing pressure to deliver high quality health care services to a greater number of patients. In the post-health care reform world, pharmacists are in a unique position to absorb some of the pressure from physicians and other health care providers. In addition to medication and services available by pharmacist, it could ease existing burdens and help drag down health care costs.

There are many patients with disease states and conditions that can be assisted by pharmacists. Arrangements already exist in 34 states that allow physicians and pharmacies to engage in collaborative practice agreements. Collaborative practice agreements are written agreements between pharmacists or pharmacy and a physician or a group of physicians wherein the pharmacists work in collaboration with physician to manage the patient's drug therapy. Under collaborative practice agreements, pharmacists are generally permitted to modify, continue, or discontinue drug therapy, conduct tests and screenings, order lab work in accordance with written guidelines or protocols agreed to by the physician in the collaborative practice agreement. Physicians have ultimate authority to further delineate the activities what pharmacists may or may not perform in accordance with the law in a collaborative practice agreement. Under this type of arrangement, pharmacists serve as physician extenders and help to monitor and carry out physicians' drug therapy plans for their patients.

Another example of pharmacists' capabilities in improving public health through increased access is the continually greater role that pharmacists are playing in providing immunizations. In recent years, pharmacists have been instrumental in increasing the vaccination rate in the United States. The expanding pharmacists' vaccination authority can also lead to decreased health care costs. As noted by the Department of Defense recently published a rule expanding the portfolio

of vaccines that TRICARE beneficiaries may obtain from community pharmacists. Significant savings were achieved under the TRICARE program when the program was first implemented to allow beneficiaries to obtain the flu and pneumococcal vaccines from retail pharmacies.

For the first six months, the beneficiaries could obtain their vaccinations from pharmacists. Over 18,000 vaccines for H1N1, flu, and pneumococcal were administered at a cost of nearly $300,000. Had those vaccines been administered under the medical benefit, the cost of TRICARE would have been $1.8 million. Clearly, this represents significant health care savings, which one would expect to be amplified and replicated if pharmacists were allowed a broader portfolio of vaccinations or immunizations to a broader patient population. This would be on top of the savings that would result from fewer hospitalizations and lost days at work. Indeed, this is why the Department of Defense opted to expand the types of vaccine the TRICARE beneficiaries may obtain from community pharmacies to include all CDC-recommended vaccines.

Pharmacists are already one of the most trusted and accessible health care providers and experts in appropriate use of medications, and are uniquely qualified to take on this new role. Notwithstanding our optimism about pharmacies' role under the FDA's new paradigm, we do have several concerns. Structured properly, this new paradigm has the potential to increase access, improve patient compliance, and reduce health care costs. However, a flawed structure could result in a group of drugs with limited access, reduced compliance, and lacking in a clear compensation policy for pharmacies, despite the additional clinical and administrative responsibilities that it would impose.

Our concerns for pharmacies are focused on work load and costs. The potential increased work load for pharmacists to perform the necessary counseling and administrative tasks that might be needed in this new paradigm would be disruptive to today's pharmacy work flow. The costs associated with additional equipment or training would have to be considered. We believe that some of the most important components of this new paradigm are that it be clinical and not enforcement-based, safe, consistent, and predictable, that it creates a fair payment and coverage, liability protection, and is monitored and regulated appropriately.

This new paradigm should not be used to enforce age or quality-based limits on certain medications or otherwise restrict access. For example, requirements that products containing pseudoephedrine be moved behind the counter is not a good example of effective use of this new paradigm. This move was based on reducing diversion. There is no clinical need that these products do not -- and these products do not require additional counseling or other forms of pharmacist intervention. The time of the pharmacist is limited as is the space behind the pharmacy counter.

NACDS believes that this category should not become a temporary stopping ground for every drug moving from legend to over-the-counter status. If a medication is determined to be appropriate for OTC use, it should be made available in this manner immediately. Furthermore, patients, pharmacists, payers, and others need clear guidelines on what types of drugs would qualify for this new status. Consistency and predictability are needed to train pharmacists and other pharmacy staff, determine formulary placement, the reimbursement policy, and ensure uninterrupted availability for patients. As a result, NACDS advocates that this new paradigm

should be a permanent class for drugs that require special counseling, monitoring, screening, lab testing, or other clinical intervention.

While the FDA's role may be limited in determining payment for coverage of medications, this is arguably one of the most important factors in the success of the new paradigm. Traditionally, prescription drugs have been covered by payers, while OTC medications have not. It is possible that moving medications from legend to this new status would result in both public and private payers ceasing to cover these medications, which would also deprive patients the benefit of services such as medication therapy management or counseling that may currently be covered by the payer.

Without question, this new class of drug would require additional roles and responsibilities for pharmacists. Pharmacy work flow and procedures would change, and additional counseling, monitoring, and patient interaction by pharmacists would be required. These additional clinical roles must be appropriately recognized and compensated. NACDS urges health insurers and others to cover these medications, include them on formularies, and establish mechanisms for added reimbursement for clinical services such as medication therapy management that will be associated with this new class.

From the consumers' perspective, costs for some of these medications that were previously covered by the third party might no longer be covered if dispensed under this new paradigm and would therefore be an out-of-pocket cost to them. This may be viewed as a positive for decreasing costs to the health care system, but if the patient no longer can afford the product and adherence decreases, the costs associated with poor outcomes and increased hospitalizations and emergency room visits would increase.

Liability protection for pharmacists and pharmacies is also an important component. We believe that it is critical that liability for the safety and effectiveness of drug products in this new class not be passed down from manufacturers to retail pharmacists and pharmacies. As with OTC medications, manufacturers should be required to supply labeling or packaging inserts with adequate directions for use and warnings. While NACDS recognizes that an expanded clinical role for pharmacists may result in additional liability, it must be managed sufficiently to ensure robust participation by pharmacies.

Finally, NACDS believes that the FDA has the scientific expertise to determine which drugs are appropriate for inclusion in this new class. We believe that the FDA should make these determinations and state boards of pharmacies should continue to regulate the practice of pharmacy. Currently, state boards already hold the pharmacists responsible for proper patient education and drug regimen review. This partnership between the FDA, state boards of pharmacy, and state-licensed pharmacists and pharmacies works well today in regulating other aspects of prescription drug use and pharmacy practice. We see no reason why medication in this new paradigm should not fall into this existing model.

Thank you again for the opportunity to present our views here today. We look forward to working with the FDA and other stakeholders to address these issues and other unanswered questions regarding FDA's new paradigm.

Jane Axelrad:
Thank you. I'll start and then I'll go on down the row. I was wondering if you could elaborate a little bit about how the collaborative practice agreements, which obviously raise some of the same issues in terms of reimbursement, liability, and things like that, are implemented in chain drug stores and any particular approaches that have been taken to helping to make those work in chain drug stores.

Eric Juhl:
Like I said in the statement, it is currently allowed in 34 states. And I know that is something that our pharmacies and pharmacists have had success working with physicians through these agreements. But we can -- I don't know if I have enough information for you right here right now, but we can include a further explanation and expansion on that in our written comments.

Jane Axelrad:
Thank you.

Jeffrey Kelman:
Mr. Juhl, I have one question. Do you see this interacting in general with the retail clinic movement in pharmacies?

Eric Juhl:
I'm sorry, with -- I couldn't understand that.

Jeffrey Kelman:
In other words, many pharmacies are having retail clinics, mini clinics, take-home clinics, walk-in clinics where drugs can be currently dispensed and written, that are currently legend. Is that movement going to -- [coughs] excuse me -- interact with this kind of activity that we're talking about today.

Eric Juhl:
I wouldn't want to speak out of turn, but I believe that, you know, if we have pharmacies that do currently operate those clinics, and I would see no reason why it wouldn't be able to fit into that program if it's structured correctly and is something that we could do. Again, I'll make sure and elaborate in our written comments on some [unintelligible].

Charles Ganley:
I just had a question on these collaborative practice agreements. Within a state, are all pharmacies eligible for that, or what's the mechanism that that works? Do they have to -- is there one physician assigned for the state or does each pharmacy group have to get their own agreeing physician?

Eric Juhl:
No, I believe the agreements are between particular pharmacists or pharmacies and particular physicians and physician groups. States have laws that they have passed that allow for such an agreement to take place, so there's not, you know, there's not one that you can only work with.

It's allowed within a state, and then the agreements are formed between individual pharmacies and physician groups.

Andrea Leonard-Segal:
I had a question. I think I heard you say that you thought that there were many diseases that could -- for which pharmacists could be helpful to serve as physician extenders. Could you state what you think a few of those might be?

Eric Juhl:
I don't know right now that I have the expertise to provide certain specific categories. I know that we've provided examples of when we've been able to do this in the past through those agreements and, for instance, our work in providing immunization. I think, you know, for example, it was mentioned in the opening statement, things like EpiPens and that sort. But we can definitely go back and talk with our members and if you would like, we can try to develop a list of recommendations, but we do look forward to working with the FDA on a case-by-case basis when those particular conditions or medications do arise, to work through that and make sure that we select the right ones.

Robert Temple:
Well, this may be another thing that you're not prepared to address, but some of these agreements, are they -- can you tell, are they focused on single drugs and things like that, or like whole programs? I mean, my particular obsession is getting hypertension treated better. Any of them actually do that and link up, you know, elaborate and a full scale of treatment with hypertension by combining pharmacists and doctors? Maybe you don't know that yet.

Eric Juhl:
With our collaborative practice agreements?

Robert Temple:
Pardon me?

Eric Juhl:
For the collaborative practice agreements?

Robert Temple:
Yeah.

Eric Juhl:
Yeah, I don't know if they focus on what you're focused on, but the agreement can be structured in such a way that you could conceivably limit it to a certain area or a certain drug, or you could have it a more wide open program.

Mary Kremzner:
Mr. Juhl, thank you. You mentioned increased workload and costs. We know that right now the work load for pharmacists in retail community settings is really high, so I would imagine this

would be even higher. So, with that in mind, what's going to incentivize pharmacists to participate in a new paradigm? Do you have any ideas?

Eric Juhl:
Well, I think the obvious reason -- incentive would be, of course, a structured payment system that encourages participation by pharmacies so that it is something that they are willing and able to do. I think that would be the obvious incentive, as well as just wanting to improve medication adherence and improve patient outcomes through that kind of a system.

Peter Beckerman:
You clearly have heard a lot of interest about collaborative practice agreements, which is something that I think we don't have a tremendous amount of in-house knowledge about. One of the things I was going to see if I could make a pitch for in your comments, if you also would give us your thoughts, if you're not prepared to do so now, on what the most practical means for practice algorithms would be. Dr. Woodcock talked about both computer algorithms and also having algorithms to assist pharmacists in their work, and knowing how that would be most palatable and least burdensome would be useful, just enlightening us on that aspect of the practice of the pharmacy would be helpful.

Eric Juhl:
No, and I think we definitely would agree with that, that anything that would be able to help the pharmacist in making those decision in a more timely manner and that would be definitely something that we'd want to look at. I know that it was mentioned in the statement, the release that there was a talk of a kiosk or things like that, so we are definitely willing and would like to look at those sort of ideas as this moves forward.

Jane Axelrad:
Okay, thank you very much.

Eric Juhl:
Thank you.

Jane Axelrad:
We'll turn to our next speaker. Tom Menighan.

Thomas Menighan:
Good morning. Thank you for the opportunity to present the views of the nation's pharmacists. I am Tom Menighan, a pharmacist and CEO of the American Pharmacist Association. APhA is the first and largest pharmacist organization representing over 62,000 members who provide care in all settings.

We support the proposed revisions to the drug -- we support the proposed revisions to the drug paradigm. We agree with continuing the two-class system of prescription and non-prescription products with the added flexibility of OTCs being dispensed with conditions for safe use. This is a significant opportunity for pharmacists to improve public health and increase access, much as we've done with immunizations. We applaud the FDA for stimulating discussion on this public

health initiative and for taking advantage of the roles that pharmacists can play in public health. We're comfortable with the initial ambiguity and will work with FDA and other stakeholders on revised regulations and marketplace solutions to achieve the stated public health goals.

Our comments are based upon the following: support for the concept of conditions for safe use for certain medications, the opportunity to expand patient access, improve public health and provide another avenue to bring people who may have poorly treated chronic conditions back into the health care system, the opportunity to further communicate and collaborate with physicians and other health care providers, the success of pharmacist-administered immunizations and other patient care programs on improving public health, and a recognition that there are several key focus areas to consider as the new paradigm evolves.

Pharmacists are the most successful health care provider to many patients. This is not a competitive statement, but rather an acknowledgement of the fact that there are over 60,000 pharmacies in the U.S. where consumers can walk in often during extended hours and have access to a pharmacist. We view the new drug paradigm being considered by FDA as an important opportunity to utilize this open access. We appreciate FDA's referencing pharmacist intervention as possible conditions of safe use in addition to the use of innovative technologies. We believe that more opportunities for pharmacist-patient intervention and communications will lead to improved medication use and improved health outcomes.

Importantly, we also see this as an opportunity to reconnect patients within the health care system. We see millions of patients who may have dropped out of therapy, may be non-compliant, or may be the walking well with an undertreated chronic condition. It's widely known in pharmacies but often not well documented that pharmacists every day refer patients to an appropriate provider and improve care coordination. This proposed new paradigm may also ensure that patients have another access point to lifesaving emergency drugs such as antidotes and rescue medicines. We will need appropriate algorithms, documentation, standards of care, and other appropriate requirements for conditions of safe use for specific products as pursued by the product sponsor. But these are achievable ends. Pharmacists are committed to a team-based approach to patient care. The new paradigm being considered should not segment or silo patient care activity in the pharmacy but rather provide for redirecting undertreated patients back into care to reduce morbidity and decrease costs.

While we do not know what the future holds in health care, innovations in technology will continue to challenge current delivery structures and processes. FDA needs the tools and flexibility to utilize and respond to innovative technologies, patient care strategies and needs, challenges, and other developments as they evolve.

APhA sees the new paradigm fitting into the overall drug safety continuum much like the risk evaluation mitigation strategies or REMS do by allowing access to certain prescription drugs that might not otherwise be available. In the displayed slide, risk increased from left to right on a continuum. Focusing on the less risk to your left and the OTC side of the drug continuum, we can visualize how the proposed paradigm would allow more flexible access to drugs that would remain prescription only, absent the conditions for safe use.

Over the last decade or so, states enacted laws and regulations to empower pharmacists to immunize. As experience increased and opportunities to improve public health presented themselves, pharmacists sought out the training, and the rest is history. Today, more than 175,000 pharmacists completed certificate training programs. And in the 2010/2011 influenza season, pharmacists administered approximately 20 million influenza vaccines, thus meeting a major public health need for improved immunization rates and access. We believe that the proposed paradigm can build on the successful immunization model. We would hope to implement new training processes, scaled up across pharmacy practice headings, and collaborate with the medical community to help fill the needs of our patients and improve public health.

As FDA considers this new paradigm, we suggest focus on the following eight key areas. Number one, evidence and clinical experience. As currently described, we appreciate and understand that approval of any product in the new paradigm would need to be based on science, evidence, and patient safety in actual use.

Number two, public input. There must be an opportunity for public input on any sponsor's proposal for a product moving through an application process with conditions of safe use.

Number three, consistent definitions and processes. The process for drug availability through conditions of safe use must be defined in a uniform and standardized process. Any new paradigm must ensure that the patient care and drug-dispensing processes are not disjointed, variable, or confusing across practice settings.

Number four, communication technology. Our patient care activities should be communicated through phone calls and faxes, but more efficiently through the expanding use of HIT infrastructure and electronic health records. Many pharmacy organizations through the pharmacy eHealth Information Technology Collaborative are working together on HIT and privacy issues to promote the delivery, communication, documentation of, and billing for pharmacist-provided services. Any technology used to qualify patients must interface easily with pharmacy management systems to ensure capture of appropriate information.

Use of practice algorithms, number five. A pharmacist-patient intervention, as part of the condition for safe use to determine appropriate dispensing should be built upon consensus-based best practice algorithms for pharmacists to implement and communicate with other providers. Such interventions could include screening assessment and consultation or referral of the individual to the physician or other appropriate health care providers.

Number six, ability to bill for services. We must be able to bill via standardized mechanism and be compensated for the clinical services required to dispense products with conditions of safe use. We appreciate that in a meeting notice, FDA recognizes the payment challenges for any new paradigm. We understand that such payment solutions for conditions of safe use may be market driven and not under the purview of FDA. However, without a viable business model, these services will not be sustained, and the benefits would not be realized. FDA's initiative should not preclude payment for pharmacists' services by the patient, third-party payers, state programs, Medicare, the sponsor, or others. In addition, consideration should be given to legislatively provide CMS with the option of creating a regulatory system where pharmacists

could be compensated for providing these services to Medicare patients so that a viable self-sustaining business model can be created within CMS where other payers see value or when other payers see value in such an option. We recognize that payers will need to determine payment policies for non-prescription medicines that may require conditions of safe use. Immunizations is a good example where the business model developed once the approvals were in place.

Number seven, provider education. Education about a new paradigm must focus on the availability of a product, the target patient population, processes and logistical requirements of the program, clinical nuances, and resource materials for the pharmacist. Pharmacists are well qualified to provide clinical interventions on the safe use of the product. We train for a minimum of six years in clinically-oriented programs that lead to a doctor or a pharmacy degree. Additional information about pharmacist education will be provided in testimony from the ACPE this afternoon. We can help distribute appropriate information to pharmacists about requirements to dispense drugs that are available upon conditions for safe use. We think pharmacists have shown that they're willing to learn these new techniques.

Number eight, use of PDUFA. APhA supports pursuing broad and general authority through the Prescription Drug User Fee Act currently working its way through Congress. We believe that general authority can be achieved through legislation that is prospectively looking at more flexible ways in which we may access and dispense drugs in the future.

Before I close, let me highlight a few examples of pharmacists' success in current scalable patient care activities that have improved patient health in collaboration with medicine. This is not new. Pharmacists have been working to improve public health and patient safety for a long time. As part of the U.S. public health system, pharmacists have 49 years of successful collaboration with medicine to improve patient care. In a recent report to the surgeon general, the Public Health Service Office of the Chief Pharmacist highlight improved patient safety, enhanced cost effectiveness, and care delivery through pharmacist-provided service. The report further provided 27 pages of studies that document the value of our services.

Additionally, community pharmacists are working with self-insured employers to improve patient outcomes as highlighted in the APhA Foundation's work with the City of Asheville, North Carolina, and through the Diabetes Ten City Challenge activities. Through these pharmacist-patient encounters, we've seen improved public health, positive clinical and economic outcomes, use of guidelines-based care, improved patient education, collaboration among health care providers, and use of patient self-management strategies. In such studies as the Asheville project have demonstrated that quality health care outcomes and the number of referrals to physicians increase as appropriate when pharmacists are actively engaged in clinical interventions with patients. These studies further document that pharmacists assist patients in managing their medications, increase patient compliance, improve patient safety, and improve overall outcomes. This is the type of information that further supports FDA's consideration.

In conclusion, FDA supports the overall concept of conditions for safe use. We recognize in a more flexible process for ensuring access to certain medications also requires appropriate communication and collaboration with the medical community. And we support legislation that

would provide FDA with general authority to utilize conditions of safe use, knowing that specifics related to logistics, payments, challenges, and other uncertainties can be addressed in the future. We offer our support and assistance to the agency in future discussions and meetings about this important public health initiative. We led the efforts to coordinate communication among pharmacy organizations in advance of this meeting, and we will continue to do so as we prepare complete written comments in the coming weeks. While many details remain to be worked out, none of them are significant enough to stop this important initiative from being inactive. American's pharmacists view this proposal as "yes, if," rather than "no, but," and look forward to working with FDA and other providers and stakeholders to answer the "if" questions and make this concept a reality.

Again, the pharmacy community is excited for our patients and for evolving opportunities to improve public health and reduced overall costs. Thank you.

Jane Axelrad:
Thank you very much. Jeff.

Jeffrey Kelman:
Tom, specifically, who do you see paying for these enhanced [unintelligible] of safe use intervention in the three groups we talk about, the cash customers, the governmental insurers, and the commercial insurers?

Tom Menighan:
Essentially the same people who pay for them now. I don't mean to be flip about it, but, you know, if there's value in consumers receiving a certain medication, I think the policymakers can figure out that, you know, either CMS should pay for it. If there's more value, for example, to CMS paying for a drug that may have used to have been a prescription drug and is now a non-prescription drug, then I think CMS could probably figure out how to pay for it.

Jeffrey Kelman:
You do us a lot of credit, but --

Tom Menighan:
Pardon me?

Jeffrey Kelman:
What about cash customers, for example?

Tom Menighan:
Well, I think, you know, today pharmacies are free to charge under certain conditions. They would still be free to do that. And competition prevails. That's the case with vaccines. You know pharmacies charge cash for -- you know, make charges for vaccine immunizations even though many people have insurance coverage for those vaccines, they choose because of the convenience factor to just pay for them. I mean, you can charge for anything. It's a free market.

Janet Woodcock:

I was interested in the electronic initiative that you're engaged in. Obviously, it's key for many reasons, not just this subject we're discussing but many subjects that pharmacies and the clinical prescribing community become better linked, so that that feedback link is established. Will you all be giving us further information, or can you elaborate now on how that's going?

Tom Menighan:
Well, we have -- the pharmacy community has developed a roadmap that we will provide to you that describes the integration of electronic health records that are developed in the HL7-based system with the more NCPDP-based systems that are typically resident in the pharmacy community. We're in a very highly evolving marketplace right now. Those technologies are evolving. We do see them coming together more readily in the future. We already receive prescription orders electronically, but we desperately need the ability to read -- we, the pharmacists -- to read the electronic health record as well as to write into it our own observations. We see things like the dispensing of new OTCs, for example, possible being entered into the electronic system that's built into pharmacy already. Perhaps through consumer-facing interfaces to those, we don't know. That's something to be developed. But you can imagine a number of ways to get information into those systems and then to share them.

Janet Woodcock:
Because clearly one of the concerns is that, especially for people with chronic conditions or perhaps other conditions, that the care might be further fragmented. And therefore, we need to make sure if we were moving forward that the connections were built. But, at the same time, the fact that we don't have those connections is a barrier to providing better access for consumers.

Tom Menighan:
Sure. Well, I think your -- what you're seeking is the authority to consider new options. And we're very much in favor of that without necessarily knowing what all those options are. You know, you could imagine, for example, that someone selecting an OTC, you know, that may have been previously been a prescription drug, would still have the same interactions that it had when it was a prescription drug, and so, we would want the ability to check those interactions before the patient received that product and to get the appropriate counseling associated with that. How a fee gets paid for that, you know, to get back to the question on payment, may be up to the sponsor to help us figure out, you know. It may not be only that pharmacies can charge for it. People may, you know, there may need to be other resources put into it. If a sponsor really wants their product sustained in a marketplace, they may have to find ways to pay for that.

Robert Temple:
Can you say anything more about the Asheville project, which sounds like a relatively ambitious drug -- doctor-pharmacist interaction? And if you can't say too much more now, you could send it --

Tom Menighan:
We can certainly provide you the complete details. And that project, which is several years old, sustains itself and has been replicated in other markets. But basically, it was a process where consumers were enrolled in a relationship between pharmacist and physician so that they agreed to meet certain requirements. They were seen by a pharmacist on a regular basis for chronic

disease, and they got certain incentives in their third-party plan. The city basically forgave their copayments, and that sort of thing. And, as a result, we've seen very outcomes associated with this. But it's a very good example of that relationship among physician, pharmacist, and patient.

Robert Temple:
And I presume that one of the preferences you made is that certain standard algorithms would be used for defining therapy. I assume this made use of those and that --

Tom Menighan:
They were, yes.

Robert Temple:
-- to us, too.

Jane Axelrad:
Dr. Ganley, did you --

Charles Ganley:
Yeah, I just wanted to get back to the issues you raised about a business model. And so, when you mentioned that the sponsor should determine whether it's cost effective, so in other words, FDA shouldn't really be worried what the business model is. We should just be worried whether the algorithm may work or, you know, that this going to be able to be delivered safe and effectively, just as we do now. We don't take cost into account when we're approving an OTC drug or non-prescription drug. And so, it sounds like you're endorsing that we don't really need to worry about the business model. That's up for the sponsor and the retailer to figure out.

Tom Menighan:
Well, I can't advise FDA on what you should worry about and what you shouldn't. I think there are other agencies at the table here who will certainly take an interest that, and I hope that our government can find ways to work together. At the end of the day, you know, I hope that we can develop viable ways that new products can find their way to market and that they can be paid for successfully in a free market. But, you know, just I think it's also shortsighted to imagine that, you know, something with a heavy cost burden of service associated with it will find its way to market without some payment mechanism for that.

Jane Axelrad:
Dr. Leonard.

Andrea Leonard-Segal:
Yeah, I wanted to dovetail onto Dr. Temple's question about the Asheville study. You were speaking about the outcomes, favorable outcomes. What kind of outcomes were being looked at in that study? What are the types of things the study sought to learn?

Tom Menighan:
Well, certainly absenteeism and presenteeism were measured as were overall costs. Costs were reduced fairly significantly, if I remember correctly, well over $1,000 per enrolled patient. And

absenteeism went down considerably among the chronic disease population who were enrolled. So, those were the kinds of outcomes that were measured.

Jane Axelrad:
Dr. Leonard-Segal, and then --

Andrea Leonard-Segal:
So, were there any clinical outcomes sought in that study?

Tom Menighan:
Oh, certainly. You know, A1C was dramatically reduced to goal. And other appropriate guidelines for goals were achieved. Yeah.

Jane Axelrad:
Dr. Wosinska.

Marta Wosinska:
So, clearly, going back to the business model issue, access requires that pharmacies participate in this program. And we have heard this morning about the work flow impact, about various challenges. One solution is clearly reimbursement. You also raised the issue of REMS, and we have heard similar concerns around REMS, not only around reimbursement but also around work flow. And there's been a lot of discussion about how to try to minimize that burden. Are there lessons that you can bring in to this context around, specifically around ways to minimize the burden and kind of improve the work flow that might be actually useful in this paradigm?

Tom Menighan:
We'll give that some additional thought in our written comments to you. Just I will say that employment of systems and standards will make a huge difference. Pharmacists are comfortable, you know, handling large volumes of transactions. We do so every day. We do it through the use of these systems. I will also say that we need sufficient demand to make changes worthwhile to make. So, something that's just an episodic, once every couple of days experience is not going to cause pharmacies to do much to change their work flow. So, we'll have -- we'll be forced to consider new opportunities in that context, you know. Is there sufficient reason for us to make a change? But with that said, primarily, it's standard systems, standard processes. To the degree that you could, for example, create a monitoring system for a new drug, let's say that you wanted to know all the patients who were taking a new OTC, that there's an easy way to get that into a pharmacy management system through their standard way of doing that, you know. The patient's already enrolled in that pharmacy in the system. They get enrolled the same way they always do, and life goes on and nobody has to change much for that to happen.

Marta Wosinska:
It would be very useful if you could elaborate on it.

Tom Menighan:
Okay.

Jane Axelrad:
Diane.

Diane Maloney:
So, thank you for your presentation. I had a question on the -- on the statements you made about immunizations. And so, vaccines, of course, are prescription products. And so, your experience would be in that realm, and I'm assuming, yeah, there's the reimbursement and all. I would be interested in knowing about the hurdles, though, that were faced by the pharmacies in adopting that, the lessons learned, and then how that's translatable to the situation where it would be a non-prescription product, either now or in submissions. And also, that would be my question probably to the other pharmacists as well.

Tom Menighan:
Thank you. It's interesting. I had a conversation the other day with someone who was looking sort of a snapshot at, wow, all of a sudden I can get an immunization at any pharmacy in America. That was a new realization to them, when, for us, it's been well over a 10-12 year grind to get it to this point. And many in this room bear the scars of that. You know, there was a lot of resistance early on to the notion that pharmacists might immunize. There weren't many states, if any, a decade ago, who allowed for that. And it was literally a one state at a time dialogue with lawmakers and with other health care professions to get to the point where it was an accepted practice in one and then multiple states and ultimately every state in the nation now. It wasn't an easy battle. And you know the goal was to keep the public health at the forefront, keep the patients' best interests in mind, and work toward that goal together. And really, that's the lesson here is what's best for the patient.

Mary Kremzner:
Have you conducted any surveys of your membership to inquire about whether they're comfortable, feel prepared to take on this role if it becomes available?

Tom Menighan:
Very unscientific at the moment, social media that we get, my blog, and other social media that use suggest that they are generally ready to take a fresh look at this. This is not really new. You know, we counsel patients every day on OTC medicines. We counsel them every day. This is not a change in our scope of practice. It's just some new activities, maybe some new record keeping types of things. To the degree we can make them systemized, we're at a good place.

Jane Axelrad:
I think we have time for one more question.

Robert Temple:
It sounds like the Asheville project, which you're going to tell us more about, didn't actually require any change in status of the medications. It didn't require that we make them behind the counter. It was just an agreement by people to use the standard therapy in a different way. One of my concerns has always been that if only some members of a class, like any hypertensives, change their status that would really alter how everybody treated. But the thing you're

describing overcomes that, from the sound of it. I just wondered if you had further thoughts on that.

Tom Menighan:
Can you restate that a different way? I'm not sure I quite get what the question is.

Robert Temple:
Yeah. Well, as Janet said, we're talking about the possibility that certain drugs would have a somewhat different status if the conditions of use were met. Well, you already sort of did that for -- in the Asheville project, from the sound of it, to allow pharmacists working with doctors and the appropriate algorithms to treat hypertension. Well, there are probably 50 drugs to treat hypertension. It would be a problem, I think, if only some of them sought and achieved behind-the-counter status, because then what would the pharmacist-physician do with the, you know, [unintelligible] cardiology algorithm. They couldn't implement it, because only certain drugs would be on it. And maybe that's overcomeable. I'm not saying that's an impediment. But it sounds like this approach that was used overcame that problem because all drugs were usable by the pharmacist in conjunction with the physician.

Tom Menighan:
Those drugs, however, still remained either OTC or prescription drugs, just as they would in any new paradigm.

Robert Temple:
Right, but you allowed the pharmacist to --

Tom Menighan:
The pharmacist didn't have full reign to make therapeutic decisions without, you know, appropriate protocols in place that said if this, then this, if this, then check with the doc about this. So, you know, all of those things were in place.

Robert Temple:
That's what I meant by an algorithm.

Tom Menighan:
Yeah, right.

Robert Temple:
Okay.

Tom Menighan:
We're -- I mean, the same choices would be in place with -- you just, if you add a new drug to the mix, it's either an OTC or it's a prescription drug. So, the circumstance wouldn't change.

Jane Axelrad:
I have to allow myself a question. I was going to stop after Dr. Temple. But just to elaborate on what he's saying, I think that what he was saying was that if a few drugs go through this

paradigm and show a few anti-hypertensive, for example, make it through the paradigm and become non-prescription with conditions of safe use, that that might sway the use of them so that they would be the preferred drugs over other treatments that remained prescription. And the question is whether that might raise some concerns and that people wouldn't have as full a choice, and they might not actually be getting the right drug to treat the condition.

Tom Menighan:
Okay. I think the treatment of disease is something that we have to work very carefully with our physician colleagues and nurse colleagues and PAs and others to assure that patients are getting the appropriate care. Pharmacists are not going to presume to be able to make all the necessary assessments. We may be able to take blood pressures and some other general assessments, but, you know, at some point in any hypertensive life, a protocol is going to say it's time to go back and see your primary care doc. And we're going to make sure that that happens. I think that's an important part of this whole process. We see this as driving people back into the health care system, not helping them skirt out of it.

Jane Axelrad:
Thank you very much. Okay, with that, we'll turn to our next speaker, Scott Melville.

Scott M. Melville:
Good morning. I'm Scott Melville, and I'm with the Consumer Health Care Products Association. Founded in 1881, CHPA represents companies that develop, manufacture, and market over-the-counter medicines and dietary supplements. Thus we have a deep interest and a long perspective on the issues to be discussed over these two days. We applaud the FDA for holding this public meeting and recognizing the value and the contribution that OTC medicines can and do make to our nation's health care system. Access to appropriate medicines without a prescription empowers consumers to take greater control over their health, and provides tremendous public health benefits. Fueled in part by innovations in prescription-to-OTC-switch, the U.S. market for OTC medications is strong, providing consumers with accessible, affordable, and trusted options available 24/7 in a wide range of retail outlets including pharmacies, convenience stores, grocery stores, and other access points.

We welcome the opportunity to discuss our industry's perspective on the use of innovative technologies and other conditions of safe use to expand which drug products can be considered non-prescription. This morning, I'll review some recent findings quantifying the value of OTC medicines to our health care system and provide examples how prescription-to-OTC-switch demonstrates the power of consumer access. In my remarks, I'll highlight examples of how the OTC industry has worked with the FDA to develop and utilize methods to assess consumer behavior prior to a prescription-to-OTC-switch and where FDA has approved OTC medicines with tools beyond the drug facts label to achieve proper patient selection and use.

Of particular importance to today's meeting, I'll discuss how consumers today are accessing information and utilizing tools and technology as never before, especially in the health care setting. These developments have significant implications for our industry and may assist in enhancing the safe use of OTC medicines, but we believe the concept of conditions of safe use can be applied without changing the clear, existing distinction between prescription and non-

prescription drugs, the Durham-Humphrey drug definition. Our two-class system, Rx and OTC, has served the nation well. If a medicine can be safely and effectively used as an OTC, then it should be sold as an OTC. Many of the questions in FDA's meeting notice speak to pharmacists' dispensing of prescription medicines, including refills. In our opinion, this speaks the practice of medicine and the practice of pharmacy and falls outside our expertise and our comments.

Finally, we envision a future where innovative switches are made possible by a regulatory framework that accommodates greater use of tools and technologies. Application of these technologies on a case-by-case basis can provide a means to achieve novel future switches, those exceptional cases where reliance on the drug facts label alone might be insufficient selection and use.

This past year, CHPA commissioned Booz and Company to estimate the value of OTC medicines to the U.S. health care system. The study determined value for seven of the largest OTC treatment categories based on the cost of alternatives, including non-treatment if OTC medicines were not available. It looked at behavior, both on actual experience with prescription to non-prescription switches, as well as a representative survey of 3,200 Americans. Among the studies key findings, OTC medicines saved the entire U.S. health care system -- that's employer-sponsored health plans, government programs, self-insured, and the uninsured -- $102 billion annually. For every dollar spent on an OTC medicine, the health care system save $6 to $7. The availability of OTC medicines provides relief for 240 million in the United States, importantly, 60 million of whom would otherwise not seek treatment if OTCs were not available.

And the study found that OTC medicines offer an additional $23 billion in potential productivity benefits by keeping the American workforce at work and not at home or in doctor's offices. And it's important to note that this study captures the systemic benefits in seven major OTC treatment categories today by using tools and technologies in addition to the OTC label to allow more innovative switches, the future holds even greater promise for positive public health benefits.

There is a nearly 40-year history of prescription to non-prescription switches, providing value to consumers directly and to the health care system. And there is a long history of switches breaking what were thought to be the standard paradigm for OTC medicines. Let's look at a few examples. The 1960s brought the OTC introduction of an ingredient for long-term use and for conditions that may not be immediately self-recognizable, and that, of course, is fluoride for cavity prevention. Another example from the 1990s involved vaginal anti-fungals. Here, Medical School Dean Martin Lipsky found a 15 percent decline in doctor visits for vaginal yeast infections in the first four years after the switch of prescription medicines for this condition. The switches of vaginal anti-fungals were also paradigm busters. The sponsors of these switches conducted studies, finding women were just as good as their doctors in recognizing the recurrence of vaginal yeast infections, recurrence being the OTC indication. So here's a clear example of a successful OTC switch that didn't follow the usual pattern of immediate self-diagnosis.

The late 1990s brought us nicotine replacement therapies. And one study there found a 150 to 200 percent increase in their use in the first year after switching to OTC status. That enhanced

access, by virtue of being an OTC product, resulted in tens of thousands of people quitting smoking every year. That's longer, healthier lives. And that's $2 billion in a societal benefit.

More recently, consumers have benefited from OTC access to frequent heartburn and allergy medicines; they're labeled for longer than the typical OTC use of 7 to 10 days. In the case of heartburn medicines, an analysis by Neilson [spelled phonetically] found an average saving to consumers in prescription and office visits of $174 per OTC user per year, and a $.75 billion saving to the health care system. So we know access provides tremendous power to consumers. And that's why our association continues to advocate for policies that facilitate the switch of appropriate medicines for direct consumer use. That's why we agree with the agency's comments in the notice for t his meeting pointing out the quote, "The requirement to obtain a prescription for appropriate medicine may contribute to under-treatment of certain common medical conditions," unquote.

In sum, there's a deep history of successful switches that don't meet the typical paradigm for OTC medicines: switches for use for longer periods of time, even chronic use, switches for use after an initial diagnosis, and OTC introductions for prevention. Many of these breakthroughs switches utilize new methods to access consumer behavior, including label comprehension studies, self selection studies, and actual use trials. And more recent switches, such as those for frequently recurring heartburn, are examples where specific key questions prior to the switch were answered through the sponsors' self-selection studies and actual use trials.

In the case of nicotine replacement therapy and orlistat for weight loss or control, the approval of these switches went well beyond the drug facts label to include a wealth of tools such as help lines or online personalized information to support optimal outcomes, including behavior modification. These changes were evolutions, achieved over decades, and they benefitted consumers and our health care system.

As we look to the future, we know that today's consumers know more, have access to greater information, and can do more than ever before, thanks in large part to the ubiquitous nature of technology. Our collective challenge is to acknowledge these developments and keep up with these consumer capabilities and demands. There are now more cell and mobile phones and tablets than there are people in the United States. The day is upon us when consumers can and do access a wealth of information at home or anywhere to increase their awareness about a disease or a condition, or to seek information and gain education about potential treatments. For instance, one of our manufacturer companies reports that two in five of the visits to their website for a particular OTC medicine are coming from mobile devices. That is double what it was just one year ago. We know consumers are accessing information in the store. We know that they can and access information after a purchase decisions, and they can use that information when they're using a product in the home.

Google estimates that the number of platforms or sources of consumers used to make product decisions doubled over the past year. And this information access explosion includes health care. It includes OTC medicines. For instance, Google estimates search queries for cold and flu medicines more than doubled from 2009 to 2012. Pain management queries increased 110 percent over the same time period.

And it's not simply about the Internet. There are many ways for consumers to obtain information. We heard about enhanced roles of the pharmacist and the pharmacy to provide service to consumers, and we see a stronger role in that area. We see diagnostic kits, smart cards, 2D bar codes, in-store touch screens, kiosks, tear sheets. These are all tools or technologies to help guide consumers to make that right self-selection determination. Video in print technology, in other words, sound and motion on a chip embedded in print, is being used in magazines and in soft drink promotions today. There is no reason not to think about applying these types of technologies, case-by-case, where supported by data in the prescription-to-OTC switches of tomorrow. The point, of course, is not that we're not looking at technology for technology's sake; the commonalities that industry has a wide and growing array of tools and technologies that can be included and tested in programs to support consumer access to more challenging prescription-to-OTC switches.

As we think about the promise of using more of these tools and technologies to support innovative switches, it may well be that the rules and regulations around switch approvals and their interpretation need to be updated. As the agency considers this, it's important to remember three core principles under existing law and under existing regulations that have served our health care system so well. First, self selection, the ability of a consumer to be able to pick up a product, to look at it, to read its label and understand its label is the cornerstone of OTC medicines. Even with the addition of tools beyond the package label, a consumer-centered approach remains of highest importance.

Second, tools or special conditions of use are means to address benefits and risks unique to each switch, and should be applied on a case by case basis. As history has shown, not all switch products would require special conditions of use and there will be switches that can continue to rely on the drug facts label. Further, the application of special conditions authority on a case by case basis will assure that the design and application of tools are data driven. A place of sale restrictions, such as behind the counter requirement in the absence of data designed to answer a key question for a particular switch does not meet that data driven test.

Third, the existing approach of a clear distinction between prescription and nonprescription drugs, the Durham-Humphrey distinction has and should continue to serve our country well. Consumers understand the difference between a prescription and an over-the-counter product. They've become familiar with it. If a medicine can be safely and effectively used as an OTC, then it should be sold as an OTC.

Finally, pharmacists dispensing of prescription medicines, including refills, as I said earlier, we think speaks to the practice of medicine and pharmacy, and falls outside of our expertise. We do view drugs under those scenarios as prescription drugs.

In sum, there's tremendous evidence demonstrating the power and access, and public health benefits of OTC medicines today. We know that there are undertreated conditions because of barriers to treatment. We know the consumers have a growing ability to access greater depth and breadth of information than ever before, and they are doing so through a widening array of means. Prescription to nonprescription switches have evolved over decades, as have the type of

evidence and studies to support them. Switches have moved beyond the common conception that OTC medicines are for self-diagnosed or limited duration use. If some future prescription to OTC switches require looking at the interpretation of existing policies on authority or enforceability, we support that effort and are committed to working with the agency, to identify an appropriate path. Ultimately, we envision a future where innovative switches are made possible by greater uses of tools and technologies. Application of these technologies, on a case basis, supported by data, can provide a means to achieve novel future switches in exceptional cases where reliance on the drug facts label alone might be insufficient to ensure proper patient selection and use. We thank the agency for calling this important meeting and look forward to continuing to identify ways to enhance the value that OTC medicines provide to American consumers and our health care systems. Thank you.

Jane Axelrad:
Thank you. Jeff?

Jeffrey Kelman:
Would you like to comment on liability implications, or potential liability implications, based on the application of these kinds of conditions and safeties?

Scott M. Melville:
As a manufacturer of a product, obviously there's a legal framework that [unintelligible] liability issues around that product and I don't know how these conditions would change at the end of the day, because whether it's an over-the-counter product or a prescription product, the intervention it is still a nonprescription product, at this point. Under the scenario we're talking about, it is an over-the-counter product, perhaps with some enhanced conditions. So, I don't think it would change the liability. It does not make it a prescription product. It does not require a learned intermediary, unless that might be one of those conditions that you added.

Jeffrey Kelman:
But to develop that, the absence of learned intermediary in this case, the physician, does that have a liability shift in your view?

Scott M. Melville:
OTC medicines have been serving consumers in our country for 150 years. There is a legal framework around those products that is well developed and I don't see that changing under this scenario.

Andrea Leonard-Segal:
Hi. I've got a question related to comment. It says, "Finally, pharmacists dispensing prescription medicines, including refills, speaks to the practice of medicine and pharmacy, and falls outside our expertise. We view drugs under such a scenario as prescription." Was there -- so, if a product were approved under conditions of safe use as an OTC product that meant that a pharmacist would be involved in the providing of that product, and maybe refilling those products for a particular consumer. How would you view that? What's CHPA's view of that?

Scott M. Melville:

We think it's important that there be a clear distinction between prescription products and OTC products. So, the concept of perhaps a simultaneous status, both prescription and OTC, we think would be confusing to consumers, and would not be helpful. So, what we would support would be if you maintain that status and you add conditions, you're adding conditions to an OTC product. So, conditions of use, as I mentioned in my discussion, could cover a wide range of interventions. It could be a technology intervention. It could be a pharmacy intervention. I think it's incumbent upon the sponsor of that switch to identify means to assure safeties of that product, test them, and then work with the agency to, if necessary, make that a part of their switch approval decision. That answer?

Peter Beckerman:
You talked about a number of ways that FDA might consider using technology or other means to assure our conditions of safe use. You talked, I think, about additional roles for pharmacists, diagnostic kids, marked cards, 2-D bar codes, touch screens, kiosks, expecting all of these things potentially having cost, and if -- my question is if there is a decision to make a nonprescription product available with conditions of safe use, limited to certain -- those that actually paid for these additional means to assure safe use, does this have the potential to create confusion among consumers, or given that there is a cost involved with presumably some of these means to assure safe use, is there any reason to think that adopting a paradigm like this actually would go to addressing any of the existing inequities in access? I mean I live in a neighborhood with many different pharmacies and, you know, just across Rock Creek Park, where I am, you have to drive to get one, and so my question is, is this going to be a meaningful thing to actually increase access, and how do we address the potential for confusion with -- on the part of consumers, and if you're limited to a particular outlet?

Scott M. Melville:
Sure, great question. You know, when I mentioned our support for the dual status system and how that has served the country well, while there are 50,000 pharmacies roughly in this country, there are 500 to 750,000 retail outlets that can sell OTC products. So, not every town has a pharmacy and so the availability of OTC products broadly has a huge societal benefit in a country as large and as diverse as ours. So, the fact that the products would be made OTC the societal benefit right there is access that you might not get otherwise because of the barriers to treatment that might be a doctor's visit, or a lack of insurance, or things of that sort we know impact the availability of medicine.

So, working within that framework, it really, again, it is incumbent upon the sponsor to work with the FDA to identify if those additional steps are necessary. We view this as really more the exception. We still think the standard switch to unfettered OTC status is the model that serves most products so well, serves our country so well, but we recognize there may be conditions in certain situations that perhaps might need additional safeguards of use, and so it is up to the sponsor working with the FDA, and then working with the retailers to make sure that it can be implemented. So, these are not a lot of -- there's not a lot of history here. There are some examples, but it's important that you be able to operationalize it as well. So, it's very important for the sponsor to work with their retail customers, to make sure that it can be implemented.

Charles Ganley:

Yeah, hi Scott. You had mentioned that there needs to be data collected. Are there any limitations on industry now to be able to conduct studies that would help support an application for use of these technologies?

Scott M. Melville:
Not that I'm aware of. We could ask some folks from our industry speaking later today, maybe a question to ask to them, but I'm not aware of anything. It's an incredibly creative group that is using technology and looking for novel ways to get information out there. So, I'm not aware of any barriers or restrictions to be able to do those kinds of studies.

Charles Ganley:
To the other question I had to do brings up the question of the business model and you really didn't touch much on that, and we certainly have an interest. Should we be concerned about what the business model is as we're looking at these things or is that something that industry and retailers, and insurers have to just figure out, and we just have to give you the ability to market the products such as we do now?

Scott M. Melville:
You know, I don't have the answers on how the business model would work in this situation. I do think it's something that would have to evolve, again, on a case by case basis. There's been a lot of consolidation in the retail marketplace and I think in launching new programs, you can really touch a lot of people, by working with some retailers and getting experience, and then extending into others as well. So, there are different models out there to launch these kinds of initiatives, and I think the industry will be very creative in coming up with them, because it's in their interest, obviously, to get the product as widely available, as appropriately available as it can.

Charles Ganley:
One last question and it touches a little bit on your answer just now, is that, you know, certainly, this can open a wide variety of concepts to increased access and availability, and there may be some concerns on our part that, you know, generally, when you approve something, it goes nationally. Is there thoughts of limiting the approval to certain areas of the country, so you could collect information to make sure we've got it right, and then based on that data, is to give a different approval?

Scott M. Melville:
Well, we haven't considered geographic limitations. I know that perhaps a condition could be where a product could be available, perhaps on a case by case basis. You might say that it only has to be available in a pharmacy, in certain situations, but again, that would be on a case by case basis, driven by data. If the data required that it be restricted in such a way, the goal should always be in our perspective to make it as broadly available as possible, because that's where the societal impact is the greatest.

Charles Ganley:
Now, I'm not questioning whether -- I mean I agree. It would be a broad -- eventually a broad access, but I think of the models that companies use now, where they will bring out a product in

a certain geographic area to collect data on whether consumers would be interested in that product. Our interest may be somewhat different in that we're trying to make sure that we got the algorithm right, and things like that, and have a mechanism in place to be able to collect data and determine the success of it, and if there are flaws, fix them before it goes nationally.

Scott M. Melville:
[affirmative] you know, I would think that the actual U studies that a sponsor would be conducting, could be regionalized and to get the answers to those prior to the approval, and I think a lot of these technologies could be used to enhance surveillance post approval as well. If you're looking at 2-D bar codes and things of that sort, it enhances the ability of the industry to be able to monitor post approval adverse events.

Jane Axelrad:
I have a question. With regard to the kiosks, do you see those being approved, you know, the use of the kiosk being approved in association with a switch of a particular drug or would it be the technology that could be used with various different kinds of drugs? Who do you see pursuing the approval of the use of that technology and what effects would that have on competition? Let's say a particular sponsor decided to switch a particular drug using a kiosk, or touch screen, or whatever, one of these new technologies which obviously they would patent and probably have some kind of exclusivity for, what would that do in terms of other companies or somebody else who might want to do something with a different kind of technology, or a different kind of kiosk?

Scott M. Melville:
You know, I think it would be a question for the sponsor, if they go down that road. They would -- if they are doing additional studies to support the switch approval, and there's a period of exclusivity for that switch, they will obviously have the market for that kiosk during that period, but when private label products come onboard, and we have a very healthy dynamic in our industry between branded products and private label, that issue would need to be addressed, and how would the private label products that are the same molecule come to market? Would they be required to have the same exact kiosk system or would they be required to also come up with assurances of safe use that perhaps may not be identical, but achieve the same objective at the end of the day? So, I don't think I have the answer to how that would be, but I do know we can't have a kiosk for every product in a retail pharmacy. That would not work.

Jane Axelrad:
Dr. Wosinska.

Marta Wosinska:
To follow up on this question, I think this is -- the concern is broader than just products for the same molecule for the same product, and private label coming on. There's limited space in a drugstore. You put in one kiosk, let's say for a particular condition, and every drug in that condition goes through it, there are many other conditions. So, then the question becomes do we only then have kiosks for the first two parties that kind of came onboard, and these two conditions, and then there's no space on the pharmacy floor for any other kiosks. So, how do we deal with this? Again, this is sponsor driven, so they will think about their own product and

providing diagnostic codes, the sort of diagnosis algorithms for that particular condition, but there are many other conditions.

Scott M. Melville:
It is sponsor driven, but, you know, we, as manufacturers, don't sell the product. So, our manufacturers have to come up with solutions that work for their retail customers. So, they would have to work out with systems that benefit the pharmacy, and that are operationalized in the pharmacy. You know if you go to a pharmacy today, more and more you're seeing products in front of the counter, health care areas, OTC, dietary supplements. It's a destination for health care and we think that's a positive development, and the sponsors would have to work with the retailers to operationalize these programs, so that they can work beyond just that one product.

Jane Axelrad:
Dr. Gutierrez?

Alberto Gutierrez:
Yeah, I have -- let me turn the question around a little bit. The life cycle for devices tends to be a lot quicker than for drugs, so if you base the switch on the technology and the technology is obsolete in a couple of years, how do you propose we deal with that? Would that be data driven every time any technology comes in, the manufacturer of the drug would have to come back and show that the switch is appropriate for the new technology?

Scott M. Melville:
You know, I think through actual use and as you get more familiar with the product, it may be that the additional steps aren't necessary down the road, too. So, the FDA could come back and petition the FDA to remove something that was a requirement of the approval in the first place. So, I think the sponsor is going to have to evolve and monitor actual use of the product, and then adjust accordingly. If the technology becomes obsolete and is not achieving the objective of the condition, then the sponsor is going to have to look at other ways to achieve that objective.

Jane Axelrad:
Okay, if there are no other panel questions, I think we'll break for 15 minutes. Thank you very much.

Scott M. Melville:
Thank you.

Jane Axelrad:
All right, we'll resume at 11:00.

[break]

Session 2

Jane Axelrad:
Okay, let's start again. David Schifkovitz.

David Schifkovitz:
Good morning. I'm David Schifkovitz. I'm the vice president of regulatory affairs for GlaxoSmithKline consumer health care. As I looked at the Federal Register notice for these two day meetings, there was reference within that about a computer kiosk and computer algorithm as an aid for helping consumers with self selection, and we thought it would be helpful to help to visualize what that looks like, to show a little bit of a prototype that GSK had developed in this idea of using those tools, that technology, to assist consumers with the appropriate self selection.

So, the problem or potential problem is we get into some of the complex Rx to OTC switches, there's a lot of information within the drug facts. There are multiple headings within the drug facts that have multiple elements of what is appropriate for self selection and/or proper use of the product, and it's that multiple location and the flow sometimes can be confusing for consumers, or at least a lot of information to digest for all the individuals who want to use the product. The potential benefit of some kind of interactive system, and in this case, a computer algorithm, is that you can present information in a more logical format for the question that you're trying to answer. It can be done in a step by step process and it can provide consumers with recommendations based on their responses to individual questions. It also provides the opportunity to kind of strip out elements of the label and just focus on those elements that are relative to, for instance, self selection.

So, what we did was we wanted to pick a drug that -- to use as a prototype for what we were trying to do here, and pick the OTC statin for cholesterol reduction, which was a potential candidate for Rx to OTC switch, and it was an ideal prototype because it had a lot of elements that make up the idea of appropriate self selection. That includes gender, age, family history, current health status, and certain risk factors. So, it was a great drug to look at, to build an algorithm to say can, you know, with that -- some of those complex issues associated with appropriate selection, does it make it easier to present the information and get a response back?

So, again, based on what was actually, you know, shown as the draft label for Mevacor, back in 2007. That was what we based this on, their drug fact information, and if you think about the drug fact alone, the carton on the shelf, you know, it is the consumer who has read and understand all the information, and they're going to process it, and then make a product selection on that basis, and this is the example of what was the drug fact label, and you can see the information starts to present right in the front of it, in terms of gender and age, in terms of a factor for self selection. There is also the criteria that was identified, again, to make an argument for public health benefit of the use of the, product, healthy diet and exercise. You know, prior history, and trying to resolve cholesterol with appropriate actions, you had to have the appropriate number to fit into the, you know, the algorithm, which was the maximum benefit of the use of the product, and then this was very cleverly put together in terms of a visual algorithm within the carton, that had this idea of age and cholesterol, and risk factors, and again, this kind

of concept of go and stop, but then it was also, you know, all that blended into the drug fact information, and again, a lot of data here, the way it's presented.

So, what we've done with this demonstration, this kiosk, is we broke it down into those nine steps, those nine elements that are the basis of self selection, gender, age, diet, drug interactions, and have run this through this kiosk. Now, what I'm going to struggle with from a technology standpoint is how to use or find a pointer here. Oh, there it is. Got it. All right. Here we are.

So, this is just step by step, going through the elements of the algorithm, and so what I'm going to do is I'll run through it quickly, twice. There was something else. Okay. All right. Go to mail. Pick mail, and again, I'm going to run through this, quick, just to show correct responses and incorrect responses, and how we kind of managed it. So, male, 45 and older, have I had a fast and cholesterol test in the past? Yes. So, that's a yes. Again, we're going for correct responses. I know my score, so we've border lined time between 130 and 170. Have you tried diet and exercise? And that was a criteria to say you really should do those things first to try, so that will be a yes. This is to look at the risk factors that are also part of the elements of, you know, is there a benefit to the use of the product. So, you can pick heart disease runs in my family. Now, separately, this was designed so that you can incorporate some educational elements. So, we're asking consumers a series of questions here. If you click on the box that says, "What is heart disease," there's the ability with this technology to incorporate educational messages within the algorithm itself, or the system. So, if there are definitions there that may not be clear, you can imbed definitions within the algorithm, so they can read these, and it clarifies how it would help them respond to the questions. Now, you can hit back, and next.

So, these were the other conditions that, again, may not make you appropriate for the product. So, we will say, "None of the above," for this one. These are drug interactions that would be a recommendation not to use the product based on these conditions. So again, I want a positive response. So, I'll say, "None of the above," here. So on that basis filling out the algorithm the way I did, it came back to a recommendation of the product is right. If you go up and redo it, just restart, [unintelligible] okay. Restart it and we'll go through it real quick and so a negative response, and how we handle that.

So, I'll say male again. I'll say 45 and older. I'll say no, as if an inappropriate response and then I don't know my score. No. Maybe one of these will -- do none of the above. Next. None of the above. That's fine, and next. Pick large quantities of grapefruit juice, and next. So, what comes here then is the recommendation based on the way that you interacted and filled out the information in responding to the questions. The way this was designed, we list all the criteria and it would show them, you know, that they -- reading through it, there was some element they didn't meet. It could have been designed so it -- the first time they hit a wrong response, there could be a detailed explanation as to why it was an inappropriate response.

So, again, it's very, very simple technology, just a very simple way to look at the information, to be able to remove elements to the drug facts information, put in something like that, which becomes a little bit more interactive with the consumer. They can respond and they can make it personalized for them, and get a recommendation coming out of this. We designed this on the basis of a kiosk, but I know, as Scott had mentioned previously, cell phones and smartphones,

there's no reason that an individual couldn't run this algorithm from a home computer or in the aisle, you know, off a smartphone. The QR codes, the little puzzle boxes, black and white, could very easily with a smartphone, in a retail setting, link to a website that can run the algorithm and do it on the fly.

If you think about -- this was self selection. There's no reason that you couldn't also imbed a similar thing with repurchase, and so if you want to get a -- ask questions of the consumer about the level of efficacy response they got from it, you could ask about the potential for an emerging drug interaction with the use of the product. So, you could have both an initial purchase algorithm. You could have a repurchase algorithm. So, there's a lot of flexibility in this very, very simple concept of using this.

There is also the idea of, as I said, you know, smartphones as a good way to be able to manage this on the go. So, again, simple things -- companies have, if you look on the back of every OTC product, there's a 1-800 number. If I'm operating this off a cell phone, even simple technology like a link off an app on a smartphone to a 1-800 number, if I have questions about a product and I want to talk to a, you know, to a person, a real person about specific questions. Simple systems that are in place within the major companies and again, a simple way to use that kind of technology can be very beneficial for consumers. Thank you.

Jane Axelrad:
Okay. That's it? Okay, I'll start. If we were to approve the drug and believe that this was necessary to approve an over-the-counter, that they had to be able to walk through this algorithm, how would you make sure that they actually did walk through the algorithm, if the product is sitting out there on the shelves in a retail store?

David Schifkovitz:
Right now, we do trials for Rx/OTC switch that involves OTC simulation studies, and so my assumption is that in order to demonstrate that this product, this algorithm, these systems, this technology, if required, would be to run a simulation trial, and it could be that you've run it with the label itself, and then you'd run it with the corporation of this kind of technology. It would be then up to the sponsor and the design of such a trial, to demonstrate that there was a benefit.

Now, any one of these, we cannot force a consumer to use it, but I know what was mentioned before, you know, heath increase on the Internet are the number one search topic. Consumers want information. Those that need the information will go look for it and the same concept applies here, that there are some individuals, consumers, who will do fine with the drug facts information, but there's some who may benefit from the use of this kind of technology.

Jane Axelrad:
Just to follow up, if we think the label is okay and the sponsor wants to offer this kind of interactive information to help them use the drug properly, that's one thing, but if we think that the drug facts label alone is not sufficient and that it needs to have conditions of safe use, and that they must go through this algorithm in order to safely self select, or decide that this drug is right for them, again, how would you make sure that they did that if it's sitting out on the

pharmacy shelf? I mean how would this fit into the paradigm and the way they were talking about, that there would just be two classes, prescription and nonprescription?

David Schifkovitz:
Well, again, in a normal OTC setting, consumers, those that -- I think it goes back to my response about the OTC simulation trials. It would be offered. Some will use. Some will not. Some will be successful with it. Some will not be. It's a matter of looking at that information and saying, "Is this enough? Does it drive comprehension and compliance adequately enough to, you know, convince the sponsor and convince FDA that, you know, the policy is appropriate for OTC.

Marta Wosinska:
So, taking this a little further, what -- so is the idea here that as long as a pharmacy has a kiosk like this and a patient can self diagnose, then the product could be dispensed in the pharmacy. What -- I mean the speaker from CHIPA mentioned that there are 50,000 pharmacies, but there's 500,000 other places where one can get over-the-counter products. Many of them are convent stores. Clearly, a kiosk is not a feasible sort of a -- feasible in every setting. So, would that be sort of a condition for the store to carry, is that the kiosk would be present?

David Schifkovitz:
You know, I mentioned before, this is in vision for the typical Rx to OTC switch available in all retail outlets. We talked about the idea of a kiosk. Maybe that's impractical, but access to a home computer to this system, access on a smartphone, you can do that anywhere. So, it may be just a matter of, you know, sorting out what is the best, most appropriate way to make this available for consumers, make it easy as possible for them to use, and therefore, you know, it should work in broadly any retail outlet.

Marta Wosinska:
Okay, because my follow up question would be what would be the backup sort of system in case, for example, a kiosk were to be down, but if you're suggesting, you know, if a patient could potentially print out their results, but then again, who would verify this? I mean I get --

David Schifkovitz:
Well, but I think what we're talking about here, again, is it's the -- there is this verification on the basis of consumers making their own choices in terms of self selection. This is, you know, augmenting the drug fact information in the normal OTC, you know, Rx to OTC setting that we have now. So, this is kind of the traditional what you see on the shelf now, but a way of for more complicated switches potentially, making these kind of systems available to assist the consumers with appropriate self selection and use.

Female Speaker:
Hi. Thank you for that presentation and that demonstration. So, I'm thinking about this in the context of increasing access to vulnerable populations, perhaps the elderly, perhaps the underserved. I'm wondering if you've considered elements along those lines for people who can't manage technology perhaps.

David Schifkovitz:
Again, I think that's something that would have to be assessed within a simulation trial or some kind of test on these kinds of systems. I'm always surprised with who uses technology and how sophisticated they are. There is the assumption there's some limitation, but simple things like this, and it would be up to the sponsor and the designers to make it as easy and simple to use as possible. I mean I think those are some of the challenges, the logistics of availability of these kinds of systems and how easy it is to operate.

When we look at this very quickly in kind of a qualitative assessment of consumers' acceptance and use, everybody liked it, or at least there was 100 percent responded positively, and they actually got through it very, very quickly. I think the average was about eight minutes to get through the whole algorithm. So, I think, again, it gets back to the sponsor being very clever in how they offer something like this, how they design it, and making sure that they understand how a potential consumer would utilize it.

Jeffrey Kelman:
Mr. Schifkovitz, one question. How would it impact lacks of support of this project if it involved changes in third party payment?

David Schifkovitz:
I'm sorry, could you repeat that?

Jeffrey Kelman:
If this effort of the OTC switch led to a reduction of third party payment for the drug, how would that impact your efforts in this sphere?

David Schifkovitz:
I mean, what -- what Glaxo Smithkline Consumer Healthcare and our former organization, we are all about making sure that, you know, we can do the best for the patients, and that's what this is about. It's trying to make sure that we can take advantage of the current OTC setting in the U.S., which it really is unique on a global basis. It provides the most easy access and availability on very broad basis for the maximum number of consumers to use the product appropriately. So, I mean that really is our intent here. I'll leave the financial implications for the other folks that kind of work on those details.

Andrea Leonard-Segal:
David, can you envision a new system maybe where this new technology would be somehow interwoven with options for verification that could be then tested in actual U studies, and would enable us to have confidence that people -- that these technologies, which would be approved as part of the product, would in fact be used and verified? Can you envision a newer system, not the one that we have now, which makes this pretty hard, but a newer system, maybe under a different interpretations of regulations, or different regulations that would move this process forward?

David Schifkovitz:

I think that's why the discussion over the next days is going to be so interesting. The idea of a consumer using something like this to get a script, a printout, some verification that they are appropriate for the product, it involves some aspect of restricted access to the product. Again, I think there are so many options available to us right now, in terms of what makes the most sense. Again, to do the best, to make the most product available to the right consumers, so, yeah, I agree. I think that's a possibility, something like that, if -- depending on the drug and the circumstance that some level of restricted access for a particular drug may be where, you know, it ends up that's the right way to do it.

Jane Axelrad:
One more question.

Marta Wosinska:
So, you mentioned that the way to -- that it will be key for sponsors to be creative and try to address the very specific needs of the particular condition. So, I would like to ask you a question that we asked the previous speaker, which is if this is sponsor driven, do we create sort of access problems for other sponsors later on to come in with their own technologies, because there is a kiosk already put in place for this particular very customized kiosk, set up for this particular condition?

David Schifkovitz:
The, you know, as I said, this was presented in a kiosk. A kiosk may not be the best way to go. I mean if you put a kiosk into every retail store, it is maintenance. You know that gets a bit complicated. However, the basic, simple elements of a computer algorithm, you know, being operated on a home computer or a smartphone, those kind of things I think that -- I'm sure there's a way that would be shared with other sponsors, you know, further down the road in terms of loss of exclusivity, and generic availability. You know, there's no reason that the same or a similar system would have to be part of an approval for those applications, but I agree that it makes no sense to have 25 kiosks sitting in the retail aisle. So, there has to be a way, if we use this kind of technology, to have some overlapping or common systems.

Jane Axelrad:
Okay, thank you. I think we'll turn to our next speaker, Anita Ducca.

Anita T. Ducca:
Good morning. I am Anita Ducca, vice president for regulatory affairs for the Healthcare Distribution Management Association or HDMA. HDMA represents primary full service health care distributors. Each business day, HDMA member companies thrive to ensure that nearly 9 million prescription medicines and health care products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, long term care facilities, clinics, and others nationwide. In addition to storing and delivering pharmaceutical products, wholesale distributers provide many other services invisible to the public, but critically important to assuring that pharmaceutical products flow smoothly from manufacturer to patient. All told, the efficiencies generated by wholesale distributers save the nation's health care system $42 billion each year. We greatly appreciate the opportunity to present to FDA on its new paradigm, to approve certain prescription drugs as over-the-counter products under the conditions of safe use, and the critical,

but often unseen role of the wholesale distributer. HDMA supports efforts to ensure safe patient access to needed medications. For the purpose of this hearing, since our members are not health care professionals, manufacturers, state regulators, or payers, we will not be commenting on the broader aspects of this proposal, and instead, focus only on areas that might affect the drug distribution system.

I'll discuss briefly the implications of question B8 that FDA posed in the Federal Register notice. Specifically, FDA queries whether confusion might arise if availability of a nonprescription product with conditions of safe use were limited to certain outlets, such as a pharmacy that offers a particular technology or service.

To put our response to this question in context, let me describe further how wholesale distributers provide substantial services, value, and efficiencies to the drug distribution system. For example, each of the 1,100 plus manufacturers distributors work with do not have to establish individual contracts with the nearly 200,000 dispensing sites that may wish to purchase their products. Wholesale distributers streamline this process and handle these multiple business arrangements. Likewise, pharmacies and others who furnish drugs to patients do not have to maintain large expensive inventories of drugs. We do that for them. By the late afternoon each day, these providers can place their orders for all the drugs they need with their wholesale distributor, and be assured that their drugs will arrive first thing the next morning.

As FDA explores the possibility of making nonprescription drugs available to patients only at certain outlets, HDMA asks that the agency consider the practical aspects, administrative burdens, and potential costs. This approach begs the question will FDA expect manufacturers and wholesale distributors, as part of the conditions of safe use, to assure that drugs only reach the eligible outlets and not be available at non-eligible outlets. We ask this question because this may result in a restricted distribution requirement such as seen in certain risk evaluations and mitigation strategies, or REMS programs like I pledge, where wholesale distributors are responsible for verifying the status of eligible pharmacies and manufacturers must maintain registries of qualified dispensing sites.

If FDA contemplates limited which outlets can carry these nonprescription drugs, this is a substantial change over current distribution and business practices, and we are concerned that manufacturer and wholesale distributers may be expected to implement gate keeping restrictions. In whatever system that is developed, HDMA asks that FDA remember that any regulatory changes could have a broader impact on these settings and on the efficient flow of drugs to all outlets. Instead, HDMA suggests that such restrictions on wholesale distributor shipments would not be necessary, as they are currently only required typically under a REMS when a substantial concern about patients' safety leads the agency to conclude that a patient taking the drug should have extra care, monitoring, testing, or other measures as a condition of the drug's approval, and I note the difference between approval and safe use; therefore, if a drug is placed in a class where it is considered safe enough to be dispensed without a prescription at all, even though there must be pharmacists counseling or other interventions, we suggest that a REMS like control is not warranted for drugs to be even lesser risk, the non-REMS prescription drugs.

Should FDA proceed with developing such a restricted distribution approach, it will be imperative to standardize the processes, format, and content of electronic communications and data interchanges between manufacturers, wholesale distributors, and dispensing sites. Standardization will be particularly important for providing the wholesale distributers with information that they may be expected to use, to determine which pharmacies and customers may receive the drug.

We have found some experience with REMS programs that variations in the elements of data to be communicated among these organizations increases the complexity of data sharing. This complexity would only be magnified if, as with the REMS, drugs in this class experience varying restricted distribution data requirements and components. Additionally, if FDA considers its options in developing this new system, also consider that nonprescription drugs are delivered to many sites such as gas stations, hardware stores, non-pharmacy grocery and convenience stores, and other retail operations.

Last, as you proceed, we ask that you continue to coordinate with stakeholders to help the process of building, transitioning to, and implementing this new system. We find that meetings such as this are very helpful in understanding how such programs will be implemented.

In closing, wholesale distributers bring considerable value and efficiencies to the nation's health care system. All members of the supply chain will benefit from the swift, reliable, economic distribution of millions of drugs. We stand by ready to continue to provide these and other vitally important services. We want to work with the agencies, supply chain partners, and other stakeholders, to help ensure the safe and appropriate use of medications and increased access for patients, and again, we appreciate FDA's efforts to seek input. Thank you for the opportunity to speak today and I'll be happy to answer questions

Jane Axelrad:
Thank you.

Charles Ganley:
Yeah, hi. I have several questions. First of all, there are house brands for certain retail chains and so there's already some mechanism in place to limit distribution to those chains. So, why wouldn't this something that we're envisioning here apply no different than what's going on now? You know, if you go into a supermarket here, they have their own house brand, and you don't see that house brand outside of that chain, and so if, you know, the conditions of sale were based on limiting it to a certain chain or a certain store that has a pharmacy, why is that different what's already going on now?

Anita T. Ducca:
Let me try to clarify what I'm referring to, and I'll do it by using the iPLEDGE REMS program as an example. Only certain pharmacies that agree to iPLEDGE conditions may dispense the isotretinoin products. So, what happens is each day, the wholesale distributer receives from the manufacturer's agent a listing of the latest numbers I'm aware of are about 44, 45,000 pharmacies that have agreed to participate and agreed to the conditions of participation. The wholesale distributor, in order to distribute isotretinoin products must on a daily basis match

their customer list against this list that the manufacturer's agent provides. That list changes daily, as pharmacies enter into the program or exit the program, or allow registration to expire.

So, on a daily basis, they receive and must match up against these pharmacies. If that type of approach were to be used in a condition of safe use type program, and if it were to vary from product, to product, to product, and the pharmacies or whatever entities were participating were to vary as frequently, that would become a very large scale IT challenge for the wholesale distributors to have to do that with that much variation and that much variability. So, that's the kind of thing that I was referring to.

Charles Ganley:
Right. So, the -- just in hypothetical, if we had a company coming in with an application, the burden should really be on them to help figure out -- and they be responsible for making sure that if they wanted to limit the distribution to just, say, pharmacies, the burden really falls on them to make sure that occurs, because, you know, we have situations now where companies are asked by retailers to create a certain product that still has the same brand name that could be bought anywhere in the United States, but that specific product is only sold in that chain, okay, and so I'm trying to understand why that type of distribution can occur, that was generated by the company in an agreement with the retailer, and how this would be so different from that. The burden is still on the company there, I think, and --

Anita T. Ducca:
I'm assuming you mean for example, a chain pharmacy might want to have their own brand made, then they --

Charles Ganley:
No, no, no, no, no, but this is if you have a -- I don't want to name any brand name, but you can take a pain reliever and they want a certain configuration where they say you get 20 percent extra or 20 tablets extra, and it's only sold in that chain. You can take any of the big box store chains or pharmacy chains. They do that now and that product, they make agreements with companies that only limit that specific SKU or shelf keeping unit to that chain, and so it's already done and I'm trying to understand why is what we're talking about different if they just come up and say, "We're limiting it to these five chains,"?

Anita T. Ducca:
It depends on how the conditions of safe use program is set up.

Charles Ganley:
Right.

Anita T. Ducca:
If it is set up only for a few limited drugs, probably not a problem, but if you're going to drugs that have much more broader appeal and much wider distribution, and a larger potential patient population, then you would be running into the problem that I'm describing.

Charles Ganley:

All right. So, for the agencies' prospective, then the burden should be on the company that submitted the application, and not necessarily on the distributor.

Anita T. Ducca:
You mean the sponsor?

Charles Ganley:
Yes. Yeah, the company that submits the applications to the agency that wants to find certain conditions of use. The burden is you're asking us to put the burden on them, to assure the program is successful, and not on the distributor, the wholesale distributor.

Anita T. Ducca:
In our most recent survey of our membership, we estimated that approximately 87 percent of the drugs, that are distributed and dispensed in this country, are first purchased by the wholesale distributor. It's only a relatively minor amount of drugs that are not handled through a wholesale distributor. So, we think it's pretty safe to say that a lot of these drugs will be wholesale distributed, rather than by that individual, single chain or company.

Charles Ganley:
All right, and to implement certain programs like the iPLEDGE program, the wholesaler, do they charge the company or sponsor extra to maintain that program?

Anita T. Ducca:
Each of our members does it differently and frankly, because of our antitrust policy, we don't discuss with our membership exactly how that all works out. So, unfortunately I'm not able to answer that question.

Charles Ganley:
Thanks.

Jane Axelrad:
Any other questions? Okay, thank you very much.

Anita T. Ducca:
Okay, thank you.

Jane Axelrad:
Dr. Fryhofer.

Sandra Adamson Fryhofer:
Well, good morning. I'm Dr. Sandra Fryhofer and thank you so much for the opportunity to speak to you at this public hearing. I'm a practicing general internist in Atlanta. I'm chair elect at the AMA Council on Science and Public Health, and I'm speaking on behalf of the AMA, the American Medical Association.

The AMA continues to strongly support having two classes of drug products, prescription and over-the-counter. Currently, over-the-counter products can be used to treat conditions or diseases that can be self diagnosed without interaction with a physician or other health care provider, and that don't require a practitioner's input for use. However, when a drug product is not safe for use by consumers without supervision, this could be due to concerns about toxicity, method abuse, or other measures necessary for safe use, a practitioner must be involved, and that's someone who is adequately trained to evaluate, diagnose, and treat a medical condition licensed to prescribe a drug, and also responsible for supervising the use of that drug. And the background materials provided by the FDA for this public hearing, the agency asks whether an expansion of the types of drug products available over-the-counter is needed in order to improve patient access, and medication adherence for chronic disease management. Key barriers cited by the FDA include the ongoing need for physician office visits to get prescriptions, and to get refills, and also to receive diagnostic or monitoring measures, like labs and physical exams, measures that physicians feel are necessary to ensure safe use; and let me tell you, a lot happens during those routine office visits, and none of its actually routine.

The FDA also suggests that the increased availability of certain over-the-counter products will significantly increase the time physicians could otherwise spend with their patients on more critical issues, and reduce health care costs. We're not so sure. We agree that medication non-adherence is a very important and expensive issue. In the outpatient arena, many factors influence the degree to which patients adhere to their prescribed medication regiment. There are patient factors, practitioner factors, as well as drug and health system characteristics; all of these influence adherence.

There are also many patient reported reasons for non-adherence: poor drug efficacy, difficult with administration, out of pocket costs. Some patients worry about the possibility of an adverse drug reaction, especially those that might have had an adverse drug reaction in the past, and also some patients might not be convinced that treatment is actually needed, another reason that doctor visit is so important.

The AMA is concerned about medication adherence. Effective interventions combine education with motivation and support. Reminders and rewards can also help. The AMA is a formal partner with the National Consumer League Medication Adherence Campaign, and they say that one of the most motivating factors influencing and promoting medication adherence is the patients' confidence and their physician, and the prescribers' emphasis about the need to take medication as prescribed. Therefore, in the expansion of the portfolio for over-the-counter products based on use of new technologies, or by engaging pharmacists in fundamentally new ways, needs to preserve, not undermine, the relationship that a patient has with his or her physician.

FDA has not offered any evidence establishing that it's safe or that patient outcomes are improved when patients with medical conditions like hypertensions, hyperlipidemia, asthma, or migraine headaches, self diagnose, and manage these conditions on their own. In fact, the balance of medical evidence strongly suggests otherwise. Now, we're not talking about yeast infections here. We're talking about managing chronic medical diseases, chronic conditions, hypertension, hyperlipidemia. These are risk factors for the number one killer of patients in this

country, which is heart disease, and there are aspects that have been presented about this new paradigm that sort of undermine the national quality strategy. We now have this Million Hearts Campaign and it's antithetical to making all those pieces connect, and making that happen. This is why the AMA believes that the range of chronic medical conditions or diseases currently managed by prescription drug products that might improve patient outcomes that diagnose and treated under a new OTC paradigm is probably very limited. On the other hand, increased OTC availability of certain prescription anecdotes, such as an EpiPen, does have many benefits with few, if any, safety concerns.

Now, the immunization model has been referred to today by several of the speakers. It does not apply to chronic medical diseases. Everybody, every year, needs a flu shot and as a primary care physician, I appreciate pharmacists helping us get our patients vaccinated, but immunizations have a very limited and specific protocol. Treating chronic diseases is very different.

Another important factor, consumer education and awareness, and how this affects consumer behaviors. Programs that are successful at promoting adherence must be delivered by a trusted source. They must be personalized to the patient's situation. Patients want to know how does this affect me. They should reinforce medical need and expected outcomes, and target at risk populations. They should also reinforce and reward initiation and maintenance of treatment. If the intent of the new OTC paradigm is to promote adherence, then these attributes should be incorporated.

Lack of oversight from a practitioner is a serious concern. This is especially true for patients with chronic diseases. Diseases and how they affect patients' change over time, the disease itself can progress and get worse. A different or more intensive therapy might be required. Sometimes patients develop new diseases, new co-morbidity. This may call for a change in treatment plan. Not having a physician involved can delay that change in treatment and could harm the patient. This is especially concerning for older patients who might be seeing multiple doctors and taking multiple medications, patients with multiple co-morbidity. There are also situations in which OTC availability could mask misuse of a product. For example, increased reliance on a rescue medication for asthma control, when what the patient really needs is a steroid inhaler to reduce inflammation. What about situations in which the symptoms may be caused by different underlying illnesses that require different treatments, and what about patients who might be getting their medications from several different sources? How do all these fit into this new paradigm?

Major health care stakeholders, including the administration, are investing considerable time and resources into developing accountable care organizations, called ATOs. This proposed OTC option could undermine ATO team efforts and could create new challenges if patient OTC drug utilization is not captured, shared, monitored, or modified as needed by the ATO team.

Unfortunately, expanding the number and type of nonprescription drug under this new paradigm is not likely to reduce the burden on our emergency rooms. Establishing conditions for safe use for OTC products should not involve emergency room metrics nor should an OTC product be viewed as a substitute for an emergency room visit or care. Overuse or misuse of certain over-

the-counter products might even create the unintended consequence of requiring an emergency room visit.

How does this new proposed OTC paradigm fit in with the collaborative practice agreements? Collaborative drug therapy management is now a long standing and accepted practice for the clinical management of prescription drugs. It involves the collaborative practice management agreement between one or more physicians and pharmacists. Qualified pharmacists working within the context of a defined protocol are permitted to assume professional responsibility and authority for various clinical duties. These duties include patient assessments, counseling and educating patients, ordering and performing laboratory and related tests, also selecting, initiating, monitoring, continuing, and adjusting drug regimens. It is not readily apparent how these experiences which involve the clinical management of prescription drugs are relevant to the proposed expanded OTC paradigm.

Accordingly, we urge the FDA to ensure that any new OTC paradigm using new technologies and other conditions of safe use, be implemented in such a way to facilitate communication with the patients' physician, promote collaboration, and enhance existing relationships among patients, physicians, and pharmacists.

Let's talk about costs. It's very likely that out of pocket costs for insured individuals, including those covered by Medicare, would actually be increased as drugs are switched from prescription to over-the-counter status. This could actually create a new barrier to adherence. What about liability issues? Now granted, I can't speak directly for pharmacists, but I can tell you that even physicians who faithfully initiate an appropriately monitored drug therapy according to labeled instructions, and who also adhere to treatment guidelines or protocols, are not protected from liability concerns. Health care professionals who undertake independent decision making and offer clinical advice have increased liability exposure.

Finally, as the FDA contemplates allowing the use of innovative technologies and other conditions of safe use to expand which drug products can be considered nonprescription, the agency should also have in place a transparent process for obtaining the input of various stakeholders, including physicians, during the decision making process. I thank you for your time.

Jane Axelrad:
Thank you. Yes, Marta.

Marta Wosinska:
So, you mentioned how important it is for patients with chronic diseases to be -- for their care to be overseen by a physician, however there is a shortage of primary care physicians and the problem is only going to probably get worse. So, if AMA is opposed to this idea of extending this to chronic conditions, what about those patients?

Sandra Adamson Fryhofer:
Well, I think all patients need to have a primary care physician, as a primary condition -- care physician myself, I feel that that's an important piece of this puzzle. For example, when a

patient comes in to have their blood pressure checked, you know, they might say they have a new grandchild, and I have an opportunity to say, "Okay, have you had you Tdap? Have you had your flu shot?" and give some increased education. I might find out that they're complaining of increased urination. In fact, they might have a risk factor. They might need to be screened for diabetes. When I come in for a blood pressure check, I listen to their heart. I found atrial fibrillation in patients, the condition that if it's not caught can cause a stroke. Patients come in, their blood pressure's a little high, we check their weight and ask about reasons for that weight, and since I know these patients, I know a little bit about their social history.

I guess you can think of me as a human kiosk and this is my computer, but we have to remember that when we deal with patients, there has to be that human factor. We do need more primary care physicians and but I think that the type of paradigm you're talking about, it's not going to save money. It's going to cost shift and it undermines primary care, and actually it undermines the concept of a medical home, which his really one of the foundations of a cost efficient health care system. Yes.

Andrea Leonard-Segal:
So, I have a couple of questions about that. Can you conceive of a way that members of the pharmacy community could become part of the medical home concept? That would be one question, and it sort of dovetails onto my question that -- I mean I totally agree with you as a physician. I totally agree that anything that we would do in this mechanism to try to enable better access to necessary medications for everyone, for OTC consumers and for the entire community of people that need good medical care. I agree that facilitating communication is critical and so I'm wondering if along the circumstances, medical homes, which are intended to facilitate communication among all kinds of people, not just physicians, but social workers and nurses, and all the people that interface with patients, if you can make some suggestions to us as to how this communication could be facilitated, if these new processes did develop.

Sandra Adamson Fryhofer:
Well, one of the things that we're very concerned about is this problem with medication adherence and I certainly, I think David's kiosk, you know for some patients, might be very helpful in pressing the importance of taking medication and why it's important to take medications. Pharmacists, nurses, nurse practitioners, there's so many different pieces of this health care puzzle, and we do all need to work together to take the best care of patients.

I think that pharmacists giving immunizations is a great addition. It's very important for everyone in this country who's ever six months old, to get a flu shot every year, and I think that pharmacies have really helped enable us to make that happen, but bypassing a primary care physician, bypassing interaction with a physician for treating chronic diseases is a mistake. One piece that hasn't been brought up today, okay, we sell this kiosk that took hyperlipidemia, but let's think two or three steps down the road. Patients that have an elevated cholesterol, that have a family history of heart disease, we're trying to prevent a heart attack. If you don't have a physician, where's your connection to the health care system when you have an emergency? The patient's sort of left out in the cold and as we know, when patients have a heart attack, if you don't get to it fast, you know, that could mean the difference between saving a life and losing one.

Robert Temple:
All the concerns you raise certainly seem reasonable, but there are lots of data showing that people with chronic diseases, hyperlipidemia and blood pressure tend to leave therapy in alarmingly high rates. I would call that the most important adverse drug reaction there is, costing, I'm sure hundreds of thousands of lives a year. One of the things that seems promising is some combination of appropriate diagnosis and physician input that's relevant, and systems that are in place, walk-in clinics, whatever it is, that are better at following people, more aggressive at doing at, that have the time to do it, and stuff like that. Some of those have been talked about to that. I wonder how you feel about those, even if the initial diagnosis needs appropriate input, figuring out which drugs to lower the blood pressure with is not so hard. There are algorithms for it, at least for the first three classes of drugs, it's not that hard, and it's pretty standardized. Isn't there -- don't you think there might be room for systems that incorporate both elements?

Sandra Adamson Fryhofer:
Well, one of the concerns I have, and you mentioned doses of medications, as an internist, I take care of adults of all ages, adolescents. My oldest patient is 94 and I hope she lives to be 104, and if I have anything to do with, she will -- and I hear a clap in the audience here. So, I'm very concerned about doses of medication and that's a big source of confusion, especially for my elderly patients. The country, we're all in this bandwagon of electronic health information and one of these days, it's going to be a beautiful process when you input something and immediately it reaches the entire country, but right now, we've got a gazillion different EMRs. None of them talk to one another.

So, getting this change in that dose, although it might -- it sort of sounds minor, the difference between some of my patients taking 10 milligrams of a blood pressure medicine and five milligrams of a blood pressure medicine can be the difference between them being able to walk to the restroom or falling right out of bed and having a hip fracture. So, particularly in the elderly patients, reinforcing that dose is so important, and if I don't know the dose that the patient's on, and if there's any lag in when I get that information, that's problematic for me.

Robert Temple:
Can you imagine systems that would pose those questions, be able to deal with responses, either/or by the pharmacist, if this was well described, or I reference to the relevant clinician that's associated with the walk-in clinic, or whatever it is?

Sandra Adamson Fryhofer:
Well, I love my pharmacist. Every time I get a call from a pharmacist, I say, "Thank you very much," and it warms my heart that there are other people out there also trying to look after my patient, but as far as the management of chronic diseases, I don't think that helps me. I think that hurts patients and could threaten their lives.

Jane Axelrad:
We have time for one more.

Mary Kremzner:
Thank you. So, I understand that 80 percent of all treatments involve medication. Sort of thinking along the lines of the questions that have been asked before me, do you think pharmacists have the skills in training required to interpret blood tests, diagnostic tests, monitor chronic diseases, and if not, you know, and manage these chronic diseases, if not, what then would -- what are your thoughts about what would help them get to that place, since your concern is about managing medications?

Sandra Adamson Fryhofer:
I think they should go to medical school. I appreciate the knowledge base of pharmacists and I appreciate their help with interacting with patients, and helping with drug interactions. I think pharmacists have a major role in education. I will tell you something that I have personally observed, going to pick up prescriptions from the drug store. There is an education component when you're supposed to pick up your medicines, and I know it's there. I'm a physician. So, I should know the answers, but all we do is -- there's just a place to sign and it's almost like we're signing to pick up the medicine, and the pharmacists, you know, we're talking about there's being a shortage of primary care physicians. The pharmacists are some of the most wonderful, hard working people I know, and the pharmacists are very busy, and I would be concerned that they would have time to provide additional education, but I love David's kiosk. Maybe having some kiosks like that to provide additional education when patients are waiting for their prescriptions to be filled, would be very helpful, and I think particularly in some of the younger patients that are very IT savvy, and have the little, the cell phones, and that would work, but I can't see sending my little, old ladies who can't even do email, or who might be able to do email, being able to go through some of these algorithms online as you demonstrated.

Jane Axelrad:
Thank you Dr. Fryhofer. Okay, we have one more speaker before lunch, Beverly Schaefer.

Beverly Schaefer:
We'll pretend it's still morning. Good morning. I am Beverly Schaefer. I am a pharmacist and I am an owner of a pharmacy, Katterman's Sand Point Pharmacy, Seattle, Washington, and I'm a member of the National Community Pharmacists Association, NCPA. NCPA appreciates the opportunity to address the -- to present the community pharmacists' perspective related to the proposed nonprescription class of drugs with conditions for safe use. NCPA represents America's community pharmacist, including the owners of more than 23,000 community pharmacists, pharmacy franchises, and chains. Together, we employ over 300,000 individuals, including 62,400 pharmacists, and dispense nearly half of the nation's retail prescription medications.

Pharmacists are the most accessible health care provider. We have earned a high degree of public trust. Community pharmacies can be found across the country, including traditionally underserved and rural areas. Over 90 percent of the population of this country lives within five miles of a pharmacy. Pharmacies are also open when patients need the help that they are seeking evenings and weekends. As such, should FDA's proposed nonprescription drug class with conditions of safe use go into effect, pharmacists are in the optimal position to provide interventions for safe and effective drug use. The FDA has recognized certain conditions and

certain medications which consumers may benefit from, and may be appropriately used as nonprescription products with conditions of safe use. Consumers who may benefit most from this class are those seeking symptomatic relief for acute conditions. For example, antivirals for shingles or cold sore outbreaks, when this happens on Friday, what's going to happen if you have to wait until Monday? Trouble.

Rescue inhalers for asthma attacks, until recently there were rescue inhalers available that are no longer available. People that are having an asthma attack could benefit from this: burn ointment for minor burns, steroid nasal sprays to reduce sinus inflammation, antihistamine eye drops for allergy relief, EpiPens for allergic reactions.

Pharmacists have demonstrated over the years, their ability to provide increased access to health care with implementing mass vaccination campaigns throughout the nation. During the 2009/2010 H1N1 influenza season, nearly one third of all immunizations were administered in a pharmacy. People know where to access health care. Patients could also access successful medication, therapy, and disease state management programs in pharmacies. Community pharmacists can similarly play an integral role in increasing access to necessary medical care for those with acute and chronic conditions are those who need preventive care. Unfortunately, consumers are currently limited to emergency rooms or waiting days for a physician's appointment before receiving treatment in some cases. Availability of new nonprescription drug costs will reduce the burden on emergency rooms and other health care providers, and increase patient access to vital health care services at times convenience to patients, especially evenings and weekends.

Pharmacists are well trained. Medication experts and consistently one of the most trusted professions. Pharmacists undergo a minimum of six intensive years of undergraduate and professional education, and are able to identify when it is appropriate for patients to self treat, and when referral to a physician is necessary. They are also qualified to counsel patients on the appropriate use of the drug and follow up with patients, to ensure medication adherence, especially in the management of chronic diseases. Numerous studies demonstrate that incorporating pharmacist intervention for drug related decisions can bend the cost curve and leads to significant improvement in patient outcomes. Research has also confirmed the critical role that pharmacists play in providing patients with the assistance necessary to maintain high levels of medication adherence, especially through in person interventions.

Community pharmacists are uniquely positioned to positively influence medication adherence due to frequent communications with patients regarding medications. It's rare for people to only make one trip a month to the pharmacy. They're often there weekly, if not even two or three times a week. We see patients often. Through services such as medication reconciliation, medication therapy management, pharmacists are assisting patients to correctly use, adhere to, and gain control of their medication regiment. We help patients understand why they are taking these medications. NCPA believes that the proposed nonprescription cost of drugs has the potential to increase patient access to medications and reduce barriers to medication adherence. With their extensive training and expertise with medication counseling, community pharmacists are poised to ensure conditions of safe use associated with a new nonprescription class of drugs and subsequently save health care dollars through improved medication adherence.

Related to a new nonprescription class, it is essential to address the importance of documentation of conditions to ensure safe use. Community pharmacists currently have access to electronic systems that can document care processes and also have mechanisms to transmit this information to other providers. As electronic health records become more prevalent, pharmacists can increase electronic communications with physicians and other providers.

Regarding this proposed new class, NCPA believes that all involved parties should have all the information necessary to make quality, informed, collaborative decisions regarding a patient's current and future health. Neither a pharmacist nor physician currently has access to a comprehensive patient profile. Patients often fail to report medications, vitamin, supplements that they've added or discontinued in their regimen, leaving gaps in the medication history. Therefore, NCPA proposes that products with conditions of save use be made available in pharmacies settings only. This will ensure that patients safely and effectively integrate the medications into their regimen, that pharmacists ensure proper documentation for each patient and communicate with the patient's physician if necessary. Furthermore, documentation will allow pharmacists to conduct studies to evaluate the effects of conditions of safe use on the safety and efficacy of particular drugs and on behavior and health outcomes such as labeling comprehension and adherence to medications.

Pharmacists are currently ready and willing to support and integrate a new class of nonprescription medications into their practice. They would not need additional certification or specialized knowledge to do so. However, standard algorithms developed for dispensing the nonprescription products should be put in place. Execution of the new drug class should not be dependent on a specific location to prevent consumer confusion. Patients should feel confident in knowing that they can expect a continuum of safe and effective use of non prescription product no matter which pharmacy a patient selects to obtain the drug.

Reimbursement for pharmacists services related to a new class must be addressed. However, the challenges of proper reimbursement can be overcome with strategic coordination between all involved parties. For example, as a practitioner in the state of Washington, I am engaged in multiple state authorized collaborative practice agreements for the management of patients. Through these collaborative practice agreements I'm able to bill and be compensated for the services I provide including administering medications, dispensing medications, performing CLIA waive lab tests, counseling, among other services. Payers include the federal government through Medicare part B and D, Washington State Medicaid programs, private insurers and the patients themselves. All of these entities have already recognized the value of providing patient care by a pharmacist in a pharmacy setting.

Overall, NCPA members fully support a nonprescription class of drugs with a condition of safe use. We believe such a class will have a positive impact in enhancing public health if used appropriately with pharmacist intervention. Benefits of the class include increased access to health care, improved utilization of health care resources, decreased overall health care costs and improved collaboration between members of the health care team.

Standard algorithms will be necessary to enable smooth and uniform integration of the proposed paradigm across all pharmacy settings and NCPA is committed to working closely with the FDA and other key stakeholders as this process involves. Thank you for your time and the opportunity for us share the viewpoints of independent community pharmacy on this incredibly important issue and I would be happy to address some of your concerns regarding collaborative practice agreements and payment issues.

Jane Axelrad:
Thank you. Mary?

Mary Kremzner:
Hi. Thank you for that presentation. So, community pharmacies are very busy; we know that. What barriers do you see at the store level for community pharmacists that are in place that would make this paradigm more difficult to adopt? Is it space? Is it time? Do you foresee any major hurdles?

Beverly Schaefer:
Certainly time is a factor in every pharmacy, regardless of what kind of setting you're in. I think possibly patient expectations would be another issue to manage.

Diane Maloney:
We're hearing a lot today about these collaborative practice agreements and I'm curious how widespread they are, if patients are aware when they're engaging with the physician or the pharmacist that that arrangement exists? And I guess, what role -- I mean, are over the counter products being used in the context of those agreements as well?

Beverly Schaefer:
Sure. We first became involved with collaborative practice agreements in the state of Washington with immunizations. Our pharmacy was one of the first in the entire country that did immunizations. Currently that is a huge part of our business. We do ten to 15 immunizations on a daily basis year round and during flu season we do hundreds of immunizations. Ours is a 5,300 square foot pharmacy; it's not a huge entity, but we still manage to do this as part of our patient care practice.

So that was our first foray into cooperative practice agreements. We also did emergency contraception before Plan B was available without a prescription so that was a prescription drug that was available through pharmacist's supervision and we again had an algorithm set up that would allow us to yes or no dispense that the patient would have to fill out and then consult with a pharmacist.

It was interesting that the expectations of how that would go turned out to be unpredictable and it was entirely different than people predicted. So I would predict that use of a nonprescription category of drugs would be different than what we could possibly expect right now.

Jane Axelrad:
Andrea?

Andrea Leonard-Segal:
So, based upon what you just said, could you -- do you have any thoughts on the kind of testing that we might want to do before approval related to that, to address some of those expectations and --

Beverly Schaefer:
So I guess one of the things that would be incumbent upon, if we were looking at monitoring some chronic condition would be, what are the goals of treatment? And does that mean measuring in some way, some results of treatment? Does that mean measuring before treatment starts and treatment ends? Or does treatment end but maybe measuring some consequence of using the products? Pharmacists certainly can perform some of the most basic tests of measuring certain vitals for patients.

Jane Axelrad:
Any more questions?

Andrea Leonard-Segal:
Yes. And one other question I have, which I guess relates to that some way: I was interested in your write-up here that you say that pharmacists would not need additional certification or specialized knowledge to engage in this new paradigm that we are contemplating here today. And -- but you say standard algorithms developed for dispensing nonprescription products should be put into place. So you don't feel that there is any additional formalized educational process that pharmacists would need to expand into this role? Is that what I'm understanding from this?

Beverly Schaefer:
That's correct.

Andrea Leonard-Segal:
And what would they need in terms of the algorithm execution? Is there -- it sounds like this becomes a pro forma thing. I do this, then I do that but the basic knowledge behind it is sufficient? Is that what I'm hearing?

Beverly Schaefer:
Correct. Pharmacists are clinically trained. They spend a year doing clinical rotations in various settings in looking at and interpreting patient data. So as far as being able to look at existing patient data, they would certainly be able to do that and determine, yes or no, if they would fall into a category suitable for -- this new category of drug.

Jane Axelrad:
One more, but we really are -- we're way behind, though. If you want to ask one more, go ahead.

Andrea Leonard-Segal:
So, would you recommend that we actually try to assess that as part of our process in terms of the knowledge base and how that goes forward with some of these algorithms? Or is that

something that the agency would not need be looking at in terms of the clinical development programs for these products?

Beverly Schaefer:
I would say that the pharmacists are clinically trained through their six year program where they come out with a doctorate of pharmacy, that they have the skills and training necessary for this.

Jane Axelrad:
Okay, thank you very much. Okay, well, we're ending little bit late. I've been sitting here trying to figure out whether I should have everybody come back a 1:00 or 1:15. I don't know. If I -- I'm thinking 1:15 for -- all the panelists have to go check offices and things like that. So we'll resume at 1:15 and if that -- if anybody has an issue in terms of their schedule, in terms of where they're supposed be speaking and they have to leave or something, please see either me or Lee and we'll work it out.

[break]

Session 3

Jane Axelrad:
Okay, we're going to start. I think the majority of the panelists are here. Elizabeth Russell?

Elizabeth Scott Russell:
Good afternoon and thank you for the opportunity to provide comments on the proposed new paradigm in which certain prescription drugs could potentially have nonprescription status under appropriate medications -- appropriate preconditions of safe use. I'm Scottie Russell, Government Affairs Manager with the National Association of Boards of Pharmacy, or NABP. Founded in 1904, NABP is the impartial professional organization that supports the state boards of pharmacy in protecting the public health. NABP aims to ensure public health and safety through its pharmacists' license transfer and competence assessment programs as well as through its accreditation programs.

NABP's active members include the boards of pharmacy of all 50 U.S. states, District of Columbia, Guam, Puerto Rico and the Virgin Islands. And we also have associate members that include eight Canadian provinces, Australia and New Zealand.

NABP recognizes and supports pharmacists serving as the health care professionals responsible for providing patient care that ensures optional medication therapy outcomes. NABP also recognizes the ongoing and critical need for pharmacists to conduct drug utilization review and provide patients with counseling and therapy management services and for state regulatory agencies to aggressively enforce standards of care.

Since as early as 1993, NABP's member boards to pharmacy have passed three separate resolutions seeking increased access for consumers to certain medication under safe, non prescription dispensing scenarios as determined by FDA. NABP applauds FDA for considering this new paradigm that would allow specific prescription medications for certain diseases or conditions to be made available without a prescription under conditions of safe use. We would encourage FDA to seek this new authority in broad in general terms, leaving the specific conditions of safe use and the details of implementation to regulation or to the approval process for each application for nonprescription status of a particular drug. While standardization of conditions of safe use is desired where possible, we recognize that there may be necessary differences for different drug products.

Additionally, we support this new concept with the understanding that FDA's authority remains related to the drug manufacturer for approval of OTC status and the conditions for such approval and that the states retain the authority to regulate the practice of pharmacy. And we offer the following comments: NABP believes that pharmacists are uniquely qualified by extensive training and experience to provide quality care under this new paradigm. As pharmacists in all states may already dispense both prescription and OTC products, by using these existing classes of drugs to accommodate this new concept, it is not anticipated that changes in state law or regulation will be required for pharmacists and pharmacies to participate.

In trying to respond to a few of the questions that were framed in the Federal Register Section A, Types of Technology and Conditions of Safe Use, Question Number 3, what other types of conditions of safe use could be used? Requiring pharmacists counseling and monitoring is a logical condition of safe use for safe and effective nonprescription dispensing of certain drug products. Pharmacists are also uniquely positioned and readily accessible for ongoing, post marketing data collection that could assist in monitoring and assuring safe and effective use of any product addressed by FDA's proposed paradigm. Pharmacy computerized patient dispensing systems could automate and consolidate patient monitoring which will provide for effective implementation through counseling and medication therapy management services.

In Section B, Question One, would this new paradigm increase consumer access to necessary medical care? NABP and the literature contend that the pharmacist has traditionally been and continues to be an accessible and underutilized health care provider. The new paradigm would indeed increase consumer access to necessary medical care by making certain products more available to patients under well defined and controlled conditions. Patient use of certain products within the new paradigm would be significantly increased due to eliminating current barriers and would be more effectively monitored than is currently possible. Under the new paradigm, pharmacists would be able to provide more direct medication management and care which will positively impact patients' compliance. The increased access and availability may also assist patients who would otherwise forego treatment thereby ultimately improving patient care and patient safety.

The third question in that section, would a lack of oversight from a practitioner including involvement in diagnosing the condition be a concern and, if so, how could these concerns be addressed? We assert that pharmacists' extensive training and knowledge places him or her in a unique position to assist with the coordination of care by managing the safety and benefits of all the patients' medication. In fact, pharmacists are legally required and do monitor for drug interactions another drug effects. Within the new paradigm, it's our understanding that the designation of products into this new category would take into consideration the need for practitioner oversight and define diagnosis as the basis for assignment into this new OTC category.

Using conditions of safe use as the baseline, the pharmacists' expertise and training would provide for the provision of care in recognition of when to advise the patient to consult a practitioner. Additionally, we believe the pharmacists will use the opportunity this new paradigm affords to increase communication and collaboration with primary care providers and other health care professionals where appropriate or where required as a specific condition of safe use.

Currently, the structure of the health care system and the laws and rules addressing the prescribing of prescription medications often results in the prescribing practitioner interfacing with the patient or inquiring with other health care providers about the patient only once a year. This new paradigm, however, will allow for pharmacists' monitoring throughout the year which will result in increased communications with prescribing practitioners throughout the year, resulting in greater practitioner oversight of the patient. With additional Question Number 7 -- with respect to would additional specialized training be needed for pharmacists if this paradigm

were adopted? We assert that the extensive training and knowledge of today's pharmacists would not require any additional specialized training if the new paradigm is adopted. Specific conditions of safe use for a particular product could be managed through existing continuing education and professional development programs.

NABP thanks you for the opportunity to provide these comments and we look forward to continuing to work with the agency on this important issue.

Jane Axelrad:
Thank you very much. I'll start with a question. What role can FDA expect the state pharmacy boards to play if we were to adopt this paradigm in ensuring that the pharmacies have the appropriate qualifications to perform whatever role they would be expected to play if the drug were approved with conditions of safe use that included pharmacist involvement? And how would they -- what role might they play in ensuring that the pharmacists are doing with they're supposed to be doing?

Elizabeth Scott Russell:
Well again, we contend that the pharmacists graduating from an approved college of pharmacy and I think ACP will talk to the education component, that they are have the skills and training necessary to play a part in this new paradigm. Boards of pharmacy do inspect pharmacies and we do have -- all boards of pharmacy do have complaint handling processes to, through the inspection process, hopefully we would proactively ensure that pharmacists are practicing in accordance with standards. And there's -- boards have complaint processes to deal with issues where something falls below standard and disciplinary processes to deal with that already.

Jeffrey Kelman:
Do you think that the application of this new paradigm will be available to smaller pharmacies as well as larger pharmacies?

Elizabeth Scott Russell:
I do. I think -- of course the devil is always in the details and it will depend on what the conditions of safe use but I don't see where it would be a barrier to small pharmacies, no.
I think -- I heard a lot about the work flow this morning and I think that as technology and the use of automation increases within pharmacies and pharmacy technicians are -- education for them becomes more standardized and they become accredited, I think we'll use technology and technicians more in the distributive function and fee pharmacists up to participate in additional medication therapy management and be able to better participate in this paradigm as well.

Peter Beckerman:
Do you have anything to tell us about any liability concerns? Specifically, I'm interested and what the state -- what a pharmacy perspective is on whether existing malpractice insurance typical policies would cover the actions that pharmacists could be taking under a new paradigm like this?

Elizabeth Scott Russell:

Honestly, that's a little bit out of my purview. State boards don't really get involved with malpractice liability insurance.

Jane Axelrad:
Any other panel questions? Okay, we'll move to our next speaker. Thank you very much. Cynthia Riley.

Cynthia Riley:
Good afternoon. I am Cynthia Riley. I'm a pharmacist and Director of the Practice Development Division at the American Society of Health System Pharmacists or ASHP. ASHP represents approximately 35,000 pharmacists who practice in hospitals and health system settings, including outpatient pharmacies and ambulatory care clinics. Pharmacy practice in these settings is characterized by collaboration with multi disciplinary patient care teams, pharmacists' access to patient health care records and compliance with safety and quality enhancing standards such as those of the Joint Commission. Pharmacists and hospitals and health systems use pharmacy technicians and computer technology extensively to increase their productivity and give them more time for patient care. More than half of larger hospitals have an outpatient pharmacy and pharmacists practice in ambulatory care -- in ambulatory or primary care clinics in approximately 20 percent of all hospitals. These practice sites dispense billions of prescriptions per year. Pharmacists in these settings are in an ideal position to contribute to the public success of the paradigm currently considered by agency and the subject of this public meeting. And we appreciate this opportunity to share our views on this issue.

ASHP believes that expanding availability of certain medications that are currently prescription only and that have the unmet potential for improving health status would be in the public interest. Studies have shown that integrating pharmacists into the multi disciplinary care models has positively impacted patient outcomes and appropriate medication use. As our comments will demonstrate, pharmacists, especially those in hospitals and health systems are uniquely positioned to help patients optimize appropriate medication use, reduce medication related problems and errors and improve health outcomes through the delivery of patient care services that include health promotion and education and disease prevention and mitigation strategies. For example, studies have shown that the pharmacist-provided care can reduce drug expenditures, hospital readmissions, length of hospital stay and emergency department visits.

Pharmacists reduce medication related adverse events and help patients better manage multiple chronic conditions through medication therapy management services, or MTM. MTM can be provided to patients in the outpatient pharmacy setting as well as to hospitalized patients and those patients visiting an outpatient clinic or primary care physician office. Under the proposed paradigm, pharmacists could select or recommend additional medication therapy, review patients' current therapies and recommend any medication changes to the patients' physicians. Pharmacists would counsel patients on their new medication regimens, implement strategies to improve adherence and be available to answer patients' questions. Pharmacists already provide these and additional services via established collaborative practice agreements in 43 states, through which they manage complex therapies, including anticoagulants. ASHP supports the establishment of a paradigm in which certain prescription drug products may be obtained without a prescription subject to certain conditions, including availability from a pharmacist following

appropriate patient assessment and professional consultation. Drug products appropriate for this category should be identified through the advice of pharmacists, physicians, and other licensed health professionals who are authorized to prescribe medications, and on the basis of the medical conditions to be treated by and potential adverse effects of these drug products. Licensed health professionals with prescribing authority would continue to have authority to prescribe these medications.

If structured appropriately, this paradigm would significantly increase public access to important therapies, particularly in rural and under-served areas where patient's access to physicians may be geographically or financially limited. Pharmacists are present in a wide variety of settings, including health system-based clinics, hospital outpatient pharmacies, independent and chain pharmacies, grocery stores, and federally qualified community health centers. As stated previously, hospital pharmacists play a prominent role in providing outpatient care. Consumers have greater access to pharmacists than any other health care practitioner. Pharmacists are well respected by consumers and the patient's comfort level with his or her pharmacist is well established. While compensation would be required for the pharmacist services necessary to support the proposed paradigm, direct patient calls should be similar to or less than the fees associated with a physician visit.

From a safety perspective, some medications may not be appropriate for traditional, nonprescription status because of the complexity of use, need for laboratory monitoring, and over safety concerns. For such medications, consumers would be able to draw on the education, training, and experience of pharmacists to help them assess their need for the medication and if use is appropriate to learn how to take it and monitor its effects. Proposals to reclassify prescription drug products that could provide important public health benefits if more widely available have sometimes been rejected because of concerns about safety and whether patients would be capable of determining if they were suitable candidates for treatment.

For example, the FDA has three times decided against making lovastatin available without a prescription, although the predicted public health benefit was significant. ASHP also opposed this switch because of the lack of safeguards and oversight associated with the medication's use under existing models for nonprescription use and because dosing for the proposed product was insufficient for disease management.

However, the paradigm the agency is now proposing could provide the oversight and safety measures needed to support HMG-CoA reductase inhibitor or statin as one drug that could be available without a prescription subject to certain conditions of safe use. Other drug products that might be considered for nonprescription access via this paradigm include inhaled corticosteroids and beta-2 agonists used in the treatment of asthma, select therapies for hypertension, osteoporosis, and diabetes, and vaccines.

We do, however, support the FDAs proposal to make these determinations on a drug-by-drug basis and not by drug class. The purpose of our statement today is to describe the criteria that could be used to identify prescription drug products that would be appropriate for nonprescription use under safe use conditions and to provide an overview of practice implications of such a system. While the impact of overall costs on patients, health systems, and

health insurers, and models for reimbursement for pharmacist services are beyond the scope of this statement, ASHP would note that pharmacist involvement in the proposed paradigm would assist in addressing the estimated 50 percent of all patients who are nonadherent to therapy resulting in an estimated $100 billion spent annually on avoidable hospitalizations. Pharmacoeconomic analyses that consider the many variables that affect overall health care costs and development of alternative reimbursement models for these products are encouraged.

The criteria used to identify drug products for inclusion in the paradigm should address the concerns associated with a substantial self-care role for patients while taking into consideration the benefits of pharmacist oversight of these therapies. Those benefits include assessing for contraindications and precautions and monitoring for adverse drug events, drug interactions, and therapeutic response. In addition, ASHP believes that any drug considered for both prescription and nonprescription usage should 1) meet many of the criteria currently used to reclassify prescription drugs to nonprescription status, such as a drug product has a well-established benefit to risk ratio, a wide safety margin, and is not a systemic or other anti-infective agent to which emergence of resistance is a concern; 2) have been marketed as a prescription product for a sufficient length of time and been used in sufficiently large numbers of patients to detect serious adverse effects; 3) have evidence of effectiveness in safety at the dosing regimen that would be available without a prescription; and 4) be used to treat a disease symptom or condition that can be readily detected or diagnosed by the patient, pharmacist, or health care provider. Further, if the drug is used for a condition that requires laboratory or other medical monitoring, the pharmacist should be able to perform or obtain the results of monitoring.

Cost effective tests that are easily administered are becoming increasingly available and this will facilitate pharmacist identification of signs and symptoms of deterioration in health, as well as evidence of the effectiveness of the drug. If the drug has the potential to cause toxicity that can result in death or serious harm, there should be reliable early warning signs that can be readily detected and interpreted by the pharmacist or patient. In applying these criteria to determine if a prescription should be also available without a prescription, an independent decision must be made about each individual chemical entity, dosage form, and drug product because of differences among various members of a drug class and different dosage forms and drug products.

Because drug information is continually evolving, drug products once designated as available without a prescription should continually be assessed as new effectiveness and safety information becomes available. For example, omeprazole and other acid suppression therapies were once considered highly safe for nonprescription use; however, there is growing evidence of safety concerns, especially with extended use. Therapies such as these might be safer if included under this new paradigm of pharmacist-provided access. The post-marketing surveillance of these medications through collaboration of the FDA and product manufacturers should be supported by information reported by pharmacists and patients to an established surveillance system, such as MedWatch. A complete discussion of the pharmacy practice impact of allowing access to prescription drugs without a prescription is beyond the scope of this statement today. However, some important implications of this approach can be described. Optimization of this practice would require that an ongoing relationship be established and maintained between the

pharmacist and the patient, and that documentation of the care provided be available to the patient's other health care providers.

The role of the pharmacist in providing a drug to a patient would include an initial assessment of the patient to determine appropriateness for the treatment, counseling about proper use, ongoing monitoring for effectiveness, side effects, and drug interactions, and documentation of the care provided. Because of this expanded role, and the expertise involved in appropriately managing a medication, pharmacists must be paid for the services provided in conjunction with furnishing the drug product itself.

In addition, other conditions and procedures would be necessary to ensure the safety and effectiveness of these therapies, including 1) if the drug is part of multimodal therapy, such as in conjunction with diet and exercise, information about those adjunct therapies should be readily available to the patient from the pharmacist or other sources; 2) pharmacies should adopt standardized processes for triage, treatment, and referral of patients treated with these medications. The expertise offered by clinical practice guidelines should serve as the basis for these protocols; 3) pharmacies should adhere to quality measures that would be developed to assess this care and engage in ongoing quality improvement activities to assess and improve the quality and safety of services provided.

As FDA further examines the potential utilization of prescription drugs without a prescription, some important questions about appropriateness and practicality may well go unanswered. ASHP encourages the FDA to engage in pilot studies to assess the safety and viability of the concept in process. Among other study designs, pilot studies evaluating specific therapies should assess disease management using a proposed model compared to disease management under the current system. To ensure the safety of individual agents, label comprehension and actual use studies should be required for all therapies that are potential candidates for prescription and nonprescription access, just as these studies are required for products moving from prescription to nonprescription status. Among the setting selected for such demonstration projects, should be outpatient pharmacies and hospitals and health systems that are well integrated with patient's overall health care services. ASHP and our members would welcome the opportunity to help design and participate in such a study.

Finally, innovative reimbursement and payment models are needed to ensure the success of the proposed paradigm. Insurance and prescription benefit providers must not transfer the cost of these therapies entirely to patients by designating these therapies with nonformulary status. This approach to previous prescription to nonprescription status, including nonsedating antihistamines, led to increased out-of-pocket costs for consumers and prescribing shifts to agents covered by insurance plans; these actions may have limited patient access and negated a potential for overall cost savings. If patients are overly burdened financially, it is less likely that they will have the incentive to seek treatment.

In conclusion, expanded access to prescription drugs by allowing for certain products to be available without a prescription subject to certain criteria, could increase patient access to and public health benefit from drug products without compromising safety. Proper criteria for identifying appropriate drugs in this category will address many of these safety concerns.

Further, it would tap the expertise of pharmacists who are well prepared to help people make the best use of medications in this category. Thank you.

Jane Axelrad:
Thank you. Questions?

Mary Kremzner:
Thank you. You mentioned MTM, medication therapy management. So I know, you know, this has been -- MTM has been around for decades and there's a lot of different organizations involved in MTM, but is there a standard system for compensation or -- I mean, how is this working in terms of compensation for pharmacists now and would it be sustainable if this paradigm were adopted?

Cynthia Reilly:
Well, you know, currently there is -- and I may not be the best person to speak on this, but there is compensation that has been developed under Part D for medication therapy management, as well as under the Affordable Care Act, there was specific criteria of what MTM should include. And so those systems and what the reimbursement for it have already been established and can serve as a model for extending this to these types of products.

Alberto Gutierrez:
I appreciate the suggestion that we develop a pilot and see if it works, but it occurs to me that there are some significant barriers to doing that. We currently, of course, have a statutory mandate and drugs have to be classified as over-the-counter or prescription, so I was wondering if you have any concrete suggestions about how we might go about structuring a pilot or if there are any alternative mechanisms that could effectively function as a pilot.

Cynthia Reilly:
It's a great question. I think one approach, noting that those agents are not currently available without a prescription, would be to look at some of those products that are already available in not really a dual system, but say omeprazole that is available as a prescription versus nonprescription. I mean, one of the things that I mentioned in my comments is that we know that there is over-prescribing these therapies and extended use where there should not be and I think that may provide some good models to show improvement of how these therapies could be used.

Jane Axelrad:
I was wondering if you could talk a little bit about how we should consider the differences between a pharmacy and pharmacists who are in an integrated health care system as opposed to how the paradigm would work in an independent pharmacy or chain pharmacies and whether we would have to take into account different factors or issues in one setting or the other.

Cynthia Reilly:
You know, I think certainly pharmacists that practice in health systems are fortunate to have some benefits in terms of the integration of health technology, but that's also a really recent paradigm. Even physicians up until recently in hospitals were ordering drugs here, but checking lab data over here and so I think ambulatory-based -- ambulatory care clinic-based pharmacists

would have some advantages in terms of exchanging that information, but realistically health care professionals have always been overcoming these barriers through facts and other types of, I guess really archaic mechanisms at this point, but they've managed to work and so I think that there would be more challenges to do it in settings that have less technology, but I think in general that they could be overcome.

Alberto Gutierrez:
Along those same lines I was just wondering whether pharmacies that are associated with the health care system use CLIA waiver testing or do they actually just use the central laboratory.

Cynthia Reilly:
Yes they do. I mean, it depends on what their access would be to the facility's laboratories, but in general anything that's CLIA waived they would probably be conducting right in the facility just because of the ease obviously of using those tests.

Alberto Gutierrez:
But the laboratory is not involved in the process at all in any way? Or seeing the waiver? For example, seeing the CLIA waiver testing?

Cynthia Reilly:
You know, I think the pharmacy would probably have its own license for that and the CLIA waivers for those specific tests. So there may be like for pharmacogenetic tests, I think, which increasingly will be seen with drug therapies, you might find those types of tests being done by the hospital-based laboratory as opposed to the pharmacy.

Jane Axelrad:
Okay, thank you. Our next speaker is Jan Towers.

Jan Towers:
Good afternoon. I am here representing the American Academy of Nurse Practitioners. We represent the 148,000 prescribing nurse practitioners out there in our communities. We do work closely with pharmacists, so we have an understanding of some of what is desired here and what we did was look at this situation from the perspective of us as clinicians and in relation to how this impacts our patients. As we look at it, the issue that comes to mind for us is 1) the issue of providing -- making over-the-counter drugs -- more over-the-counter drugs in relation -- instead of having some prescriptive drugs -- I'm sorry I'm stumbling around there a little bit, but the one thing that we see as an issue here that we haven't heard talked about too much in the previous discussions is related to a third tier, which would be something that would be behind the counter framework. And so we have some concerns and questions about that and then the other is on the other end extending to prescribing so that prescriptions that have been made can be prescribed again by pharmacists.

So as we look at this, our framework is that we feel that it's very clear that moving certain drugs to over-the-counter status has been proven to be not harmful and in many instances helpful in the comfort, health, and well-being of the general public. One of the things we feel that is that steps are being considered for examining additional drugs for this purpose. The standards for selection

would have to be developed that would clarify the processes to be undertaken to determine which drugs could be converted and how these drugs would be dispensed and monitored. The following factors we feel would need to be considered for these drugs under consideration.

In terms of access, the questions we had was -- and we feel need to be addressed always in relation to this are, you know, does the condition for which the drug is being taken require clinician oversight? And if yes, how much, what kind, and how often? We wondered how the drug would be dispensed. How much could be dispensed at a time? How often? At what point would a patient be denied access to the drug if we moved in this direction? And what kind of documentation of purchase would be required, if any? How much and what kind of monitoring would be necessary? In the areas of oversight, we are asking how would the need for clinical assessment and appropriate diagnostic undertaking be undertaken? What kind of follow-up needs to be undertaken -- would be undertaken for patients requiring a given drug?

How will dispensing this drug be communicated to the clinician providing health care to the individual? Will it be needed? A distinction we feel will need to be made regarding drugs that may be used for a specific set of symptoms for which a clinical diagnosis would need to be sought and those that would not.

In the area of extension of prescription drug refills by pharmacists, the question is which drugs would be selected to allow refills without consultation with the prescribing clinicians? Under what circumstances would such an extension be safe? What would be the limits of such an extension? Would it be the same drug -- same for all drugs or would there be a dispensing guideline used for each drug? How would such an extension be communicated to the prescribing clinician? And how would such extensions be documented?

As we look at this, we feel that the concept would work best where there's a closed system of care and we think of course of things like the HMO model or retail clinics where you have a closed system that's allows the pharmacists and clinicians to interact directly. So this raises other questions, then, for models that would not be in a closed system and even within the closed system, is there a common electronic record system accessible to both clinicians and pharmacists that could be utilized for this kind of communication? What kind of alert system is developed to allow for open communication between the pharmacist and the clinician? And what kind of record would be established for patients not under the care of a network clinician? How would confusion be minimized with the variety of options that might be available? And how would individualize patient care be maintained? How would needed diagnostic tests and follow-up laboratory needs be determined and implemented? And in the area of payment, would there be a charge for this service? And who would pay? And how would the medications be covered by insurance carriers or the service?

Our conclusion in relation to raising these questions, these are all things that we feel really need to be determined in order for something like this to be successful, that assigning additional drugs to nonprescription status if done carefully has merit. However, such an assignment must be done carefully to protect patient safety and health care provider liability. Uniform standards for making these changes need to be developed and implemented in order to provide for those protections. Likewise, pharmacy extensions of prescription drugs beyond the expiration dates of

the prescribed drug need to be considered carefully. Adequate communication systems need to developed and implemented so that the clinicians and pharmacists can work cooperatively in the best interest of the patients. Development of standards should be undertaken by a cross section of providers who prescribe and dispense drugs to patients and we feel this should include people like nurse practitioners.

I think our concerns with all of this as you move forward in relation to it are related to safety, related to maintaining the continuity of care, keeping clinicians informed and maintaining an ability for comprehensive assessments and management to be a part of whatever takes place with these patients and perhaps most of all, preventing patients from falling through the slats because there are too many people doing different things unless there's good communication established. So it's more than just the rules, it's the process and the way the communication would be maintained by the team in relation to these things.

Jane Axelrad:
Thank you.

Robert Temple:
The -- you talked a lot about the kinds of operating paradigms you think would be useful. And some of what you were describing sounded reasonably intense. There would be very clear instructions for exactly what to do. And I guess I wonder how well you think those things would work. If you had, for example, a hypertension algorithm you could have a sequence of drugs; you could have the tests that need to be done to decide when someone needs to switch a drug; you could have pertinent questions to ask at all visits. Are these things practically implementable, do you think?

Jan Towers:
When nurse practitioners first started to prescribe, we used algorithms. And then we found that you had many patients that didn't fit the pattern so they're not the end all and be all. And you do have to -- and I think the representative from AMA allude to that as well -- there are things besides the things that are in those algorithms which means there must be some clinician input within this framework. Now it wouldn't have to be probably every encounter; there could be ways of using that algorithm to determine if this is somebody that needs to get back to the clinician, or you can go ahead and do something here and then there would be some framework set for that. But you do have to be careful about algorithms because they don't -- not everybody fits the mold and what we find many times is maybe more people don't fit the mold than do.

Robert Temple:
So they need escape clauses, or --

Jan Towers:
Yes. Right.

Jane Axelrad:
I was wondering if whether there are lessons to be learned from experience with shifting some prescribing responsibilities to nurse practitioners that could be useful in setting up a new

paradigm here where someone other than the physician would be involved in helping the patient select or take the appropriate medication or for follow-up monitoring. We have postulated that, you know, pharmacists would play a role but conceivably other health care practitioners could also play a role. And are there lessons learned from the experience that you had when they shifted to nurse practitioners doing some prescribing?

Jan Towers:
What's interesting about our role, when we first developed our role which was -- it's been about 40 years now that we've been doing this and we're finally at a point where we're really able to function at our full scope. But I think one of the things that we found is we were studied and studied and studied so lots of pilots and lots of studies first to demonstrate that this is going to work and getting the cooperation of other health care providers in the process can go a long way to facilitating something like this so that you really can make the best of what are really opportunities to help get people involved in the care patients and still make sure it's safe for the patients. It's clear there are not enough of any of us to go around, especially pharmacists, and so trying to find a way that we can all team up and work together is going to be very important. But communication is going to be a very, very big part of this.

Jane Axelrad:
Okay, thank you. Now I'm not going to let you all take a break after only 45 minutes. Since we started late, we're going to try and fit and a couple more speakers, I think, before the break if we can. So, Marissa Schlaifer.

Marissa Schlaifer:
Threw me off there. Thank you. The Academy of Managed Care Pharmacy is pleased to provide comments to the Food and Drug Administration on using innovative technologies and other conditions of safe use to expand which drug products can be considered nonprescription.

AMCP is the national pharmacy Association up pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's 6,000 members develop and provide a diversified range of clinical, educational and business strategies and business management services and strategies on behalf of the more than 200 million Americans covered by managed care pharmacy in benefits.

The Academy is pleased that the FDA is exploring the public health benefit of approving certain drugs that would otherwise require a prescription for nonprescription use under conditions of safe use. AMCP is in favor of expanding the availability of certain over-the-counter medications when conditions of safe use are provided and applauds the FDA for raising this possibility. These conditions must be specific to the drug product and might include assistance with self selection of an appropriate medication or provide follow-up monitoring during continued use. Other conditions could include requiring pharmacist interventions to ensure appropriate nonprescription use and the use of innovative technologies.

Medication selected for a status must provide a benefit to the public. Many individuals, especially those without health insurance coverage may not schedule appointments with their

physician for health issues that they perceive to be minor and therefore may not have ready access to prescription drugs for these conditions. Making certain drugs available without the need for prescription would provide access to treatment regimens that those patients might not otherwise obtain.

Decisions on which drugs are selected for this status must be based on clinical effectiveness and safety. Products that can be identified as appropriate for treatment based on indications that require limited physical assessment, or easily interpreted lab tests to diagnose and monitor would be a candidate. General criteria for this over-the-counter status would include products with low risk when appropriately used, products with sufficient testing and experience to ensure safety and effectiveness and products with uncomplicated instructions for use.

Standardized processes for ordering and dispensing of these over-the-counter drugs must be established. Pharmacies will need to further development documentation and reporting systems for the ordering and dispensing of such drugs. It will be important for pharmacists to add information on these medications into the patients' medical records.

Pharmacy management systems are being developed to have the functionality to store the patient information necessary to monitor the safe and effective use of drugs. It is in this arena that electronic health records can be a great benefit. Electronic health records will contain this information and will be accessible to pharmacists. A joint working group with representatives from both Health Level 7 or HL 7 and the National Council for Prescription Drug Programs or NCPDP, both standards development organizations, recently completed development of the Pharmacist Pharmacy Provider Electronic Health Record PPEHR functional profile. The standard, when implemented, will provide a pharmacist with a fully functional EHR that is capable of providing bidirectional communication with the prescriber EHR. Additional functionality will allow the pharmacist to document patient progress and exchange that information with the prescriber. The EHR can be the ideal tool to foster the team based approach to health care delivery that benefits patients.

Pharmacists must be required to perform clinical evaluations and interventions before dispensing these drugs. Pharmacists would conduct the initial screening for clinical lab test results and contra indications or drug interactions. If a drug is determined to be appropriate for the patient the pharmacist should counsel the patient on safe use and would monitor the drug for safe and effective use for an appropriate amount time which may vary by product.

Pharmacist training requirements must be based on knowledge and skills required to interpret objective clinical data and to apply selection criteria in order to dispense these products.
As you will hear from ACPE, the educational requirements to become a pharmacist are extensive. Upon completion pharmacists are uniquely qualified to assist patients in the selection of appropriate medications and the monitoring of treatments. Pharmacists today complete a minimum of two years of pre professional coursework followed by four years of professional education leading to the doctor of pharmacy degree and eligibility for licensure. Many go on to complete postgraduate training that may include certificate training programs, one or two years of accredited residency training and/or board certification in a specialty area. Depending on the medication being dispensed, and on the condition being treated, pharmacists may need additional

training to differentiate diseases treated by these types of drugs in order to accurately identify those that are treated by these types of drugs. In order to identify those that are treatable by over-the-counter drugs and those that are more serious and require referral to the appropriate health care practitioner for additional medical attention.

Patient health information must be protected. Standards for the use and disclosure of personal -- patient personal health information or PHI must meet existing requirements. Standards should restrict the unauthorized use and disclosure of individually identifiable health information but permit the use of personal health information in those instances where the information is related to the treatment of the patient's medical condition.

As previously stated, many individuals, especially those without health insurance may not schedule needed appointments with their primary care physician for health issues that they perceive as minor and may not have ready access to prescription medications. Making certain drugs available without the need for a prescription under certain circumstances may serve as the primary entry point into the health care system for many patients and would foster a pharmacist patient relationship. Pharmacists would refer patients who need more in depth assistance to physicians and other health care professionals as appropriate.

The availability of over-the-counter drugs under conditions of safe use could lead to increased diseases awareness by patients and greater participation in his or her health treatment. Patients with greater participation in their health care typically have more positive outcomes.

Making certain drugs available over-the-counter could also lead to a reduction of burden on hospital emergency departments as patients may seek treatment at a pharmacy instead of hospital emergency room. Given the sheer number pharmacies and their extended hours, many of which are open round the clock, patients will have greater access to the treatments afforded by these over-the-counter medications.

In conclusion, the Academy is in favor of the FDA's proposal to make certain drugs that would otherwise require a prescription available for nonprescription use under conditions of safe use. While many questions on specific aspects of the program still need to be answered, the benefits to the health of all patients should guide the FDA as it pursues this initiative. The Academy thanks the FDA for the opportunity to provide comments to the Food and Drug Administration on using innovative technologies and other conditions of safe use to expand which drug products can be considered nonprescription. These and additional comments from the Academy will be submitted to the topic.

But as I finish planned comments, I'd like to provide an example that I think addresses some of the questions raised earlier today about CDTM and collaborative drug therapy management. This wasn't part of our planned comments by I think a specific example will help address most of the questions that have been asked today.

So specifically, coming from an example, Scott & White health plan, which is a health plan in Temple, Texas, implemented collaborative drug therapy management programs for members meeting certain criteria. This program initially focused on diabetes and heart failure, CHF, and

now includes asthma. In this program, Scott & White health plan members meet with a pharmacist monthly and are then eligible for co-payment waivers of medications and supplies for the identified disease state. The care is provided in Scott & White retail pharmacies and the pharmacists are working under a collaborative practice agreement with Scott & White physicians. The pharmacies are billing for pharmacist services.

A study was conducted to evaluate the impact of the pharmacist run medication management program on medical utilization and glycemic control. In a preliminary analysis of results, patients in the intervention group demonstrated an improvement in medication adherence and a trend of greater decline in hemoglobin A1C compared to controls after 12 month of enrollment in the medication management program. In a 2011 update, Scott & White indicated that the program still operational for diabetes for the fourth year and for asthmatic patients and patients with refractory hypertension.

A clinical and economic evaluation was completed for the diabetes group with the intervention group showing a 58 percent greater sustained reduction in hemoglobin A1C over a two year period compared to matched controls. The health economic outcomes associated with the diabetic program showed a significant reduction in inpatient medical costs in the intervention group while the medication costs and the outpatient costs were greater in the intervention group. The average reduction in total medical costs during the second year of management in the intervention group versus the control group reflected a reduction of $1,800 per enrolled diabetic patient per year over their matched controls. For the 400 patients currently enrolled in the program, that reflects an annual savings of $720,000 per year for the intervention group. Savings are inclusive of all costs associated with administering the program including both co-pay waivers and visit charges for the monthly pharmacist visits.

Although this is a very specific example, it does demonstrate a health plan and medical group's reliance on the expertise of pharmacists. The FDA's proposed new paradigm, OTC with safe use, would apply this expertise in a far more broader -- far broader fashion. Thank you.

Jane Axelrad:
Thank you very much.

Robert Temple:
Is the Scott White thing all written up someplace?

Marissa Schlaifer
It is. It's in an -- it's an ACP document that I can forward.

Robert Temple:
Yes, that's good. And was this randomized or were they assigned?

Marissa Schlaifer:
From my understanding they were matched controls, so yes, they were patients that were enrolled as the program and then there were matched controls. I only have the information that we received from Scott & White.

Robert Temple:
It doesn't sound randomized, but...

Marissa Schlaifer:
I'm sorry?

Robert Temple:
It doesn't sound quite randomized but it might be okay.

Marissa Schlaifer:
No.

Jane Axelrad:
Dr. Gutierrez?

Alberto Gutierrez:
On the same vein, do you know if they were trained to do diabetes care, the pharmacists?

Marissa Schlaifer:
I don't have more specifics about that program. In general though, just speaking about programs in general, pharmacists, as they graduate from pharmacy school and become licensed do have training in diabetes care. There are additional certificate programs that are available the pharmacists can complete and specifically to the area of diabetes. Whether these particular pharmacists had completed that certificate training program or not I can't answer but I can find out that information and share it.

Jeffrey Kelman:
Marissa, in general, how do you think this new paradigm will interact with plans' coverage of these drugs and coverage of enhanced pharmacy services under the new program?

Marissa Schlaifer:
I think -- first I definitely have to qualify everything I say by an understanding that every health plan, every managed care organization will make their own decision on what to cover and what not to cover both on the prescription drug side and on the pharmacist services side. And I think it will vary based by product. I think you'll see a lot of variation that this is what we would expect, not necessarily what all plans would do. But there would be variation based on product.

I think all decisions made by managed care organizations will look at the value, both the value of the product and the value of the pharmacist services, whether a product prevents hospitalizations, whether it prevents further development of diseases. I think when we look at products -- it's been mentioned several times today about products that have gone over-the-counter that managed care organizations have chosen not to cover. Some of those have been the non-sedating antihistamines and although I don't want to discuss the value of a specific medication class, I think we can see by those medications not being covered how health plans perceived their value as far as preventing further medical conditions.

I think one example, if we look specifically in the Medicare part D situation, when the benefit began in 2006 there's no coverage and the benefit dictated no coverage for over-the-counter medications. Several years into the benefits, CMS gave plans the authority to cover certain OTC medications as part of step therapy but if plans chose to do that they had to do that out of their own administrative costs to cover those medications. One of the drug classes I didn't -- one of the drugs the plans have chosen to cover in some situations -- and like I mentioned, it varies from plan to plan -- is the over-the-counter PPIs or proton pump inhibitors. And so when plans perceive the ability to cover a medication to prevent future medical, both medical events and medical expenditures, they'll make the choice to do that coverage. So I think that's what we'll see across drug classes and across pharmacist services. When plans can see the value, there will be reimbursement and when they don't see the value, there may not be reimbursement.

Jane Axelrad:
Dr. Leonard-Segal?

Andrea Leonard-Segal:
I wanted to explore that Texas program just a little bit more if I could. So was there an algorithm that the pharmacists were following for the diabetic care? How did in the intervention group, how did they communicate -- this is the theme of the day so far -- how did they communicate with the physicians that had primary care for the diabetes patients? Was there a communication paradigm written into the algorithm? How did this work?

Marissa Schlaifer:
I think -- I'm going to answer a little more generally because the information I have on that specific program really is just what I shared today. I wasn't expecting to talk about collaborative drug therapy management. But I think in general the big thing under collaborative drug therapy management is it's always based on an agreement between a physician or a set of physicians with a pharmacist or a set of pharmacists. And everything about what is done in that relationship is dictated in that it's a written agreement. So a physician can say I want you to do all these things and I'm comfortable with what you're doing and you don't need to report back to me on a daily basis. Or a physician could write into a collaborative drug therapy management agreement, you have the authority to see these patients. I want you to report back to me daily after you see the patient and let me know what you've done. That's completely within -- I think some of the struggles around answers today have been because there are so many different types of collaborate drug therapy management agreements and it's strictly dependent on the relationship between a physician and pharmacist.

In many small towns, the physician and pharmacist may routinely talk daily. In a large setting like a Kaiser or Scott & White health plan, it goes into the electronic health record and the physician may have access to the record. It completely varies from situation to situation. So I can't talk specifics on the Scott & White situation, to your question, but I think there's an understanding in most pharmacists that are involved in collaborative drug therapy management that there's those a need -- if we're talking about managing a chronic medication that there's a need for physicians to have that information.

Marta Wosinska:
If you are aware, or for that matter if anybody else is aware of any data that might be out there about what role insurers' health plans have played in this and to what extent they're participating, how they're responding to these kinds of collaborative agreements, we would very much welcome that information.

Marissa Schlaifer:
In this document which I'll forward on, it's in a members only section of our website right now because it is -- it is trying to train people on how they can use collaborative drug therapy management -- we've got two specific examples: The Scott & White example and then another example which I can read if you want to or we can just forward it on to you, is with Fairview, a medical clinic in Minnesota that does have agreements with Prime Therapeutics of PBM and the Minnesota Blue Cross/Blue Shield plan and that's also covered in here and I can share that information. And there is documentation to further articles about these programs. And we can probably, if it's of interest, we can go back to the actual plans and get that information and share it with you.

Marta Wosinska:
That would be helpful.

Marissa Schlaifer:
Okay.

Jane Axelrad:
Okay, one more speaker before the break. Dr. Soller?

R. R. William Soller:
Thank you very much. Good afternoon. I'm Dr. Bill Soller. I'm professor and executive director in the Center for Self Care at the University of California, San Francisco and I'm here [inaudible] we looked at ESL residents in San Francisco who are Vietnamese and Chinese ethnicity. They had never received drug information in any of their Western prescription medicines in the last five years. When they saw the information printed in their language and then saw it printed in more or less the OTC drug facts label, they wanted it. They wanted it in that form. It's a little bit along the lines of, if you have it you don't necessarily think you need it or use it but if you've never seen it before, you realize its great value. And again, this is an area where I think it needs to be -- we think it needs to be more closely looked at so we're not leaving people behind.

The OTC drug facts label is considered important for consumer product self selection, dose and dose regimen selection and in use of monitoring. It's also true many people do not read the OTC drug facts label as we recently summarized in the journal "Self Care" at added some new information to that scope of knowledge. And it is also fortunate in this regard that most OTC medicines have a relatively wide margin of safety. So under certain circumstances, a learned accessible intermediary with accountability may be the preferred choice to expanded self care. And I will use learned intermediary in the context of the community pharmacists because, as I will point out in a moment, to consider the pharmacist not a learned intermediary is not keeping up with what's happening in the field of medication therapy management.

For example, learned a new meteor's such as the pharmacist may be preferred choice when the algorithm for product selection is too complex, benefit risk decisions are not narrowly defined, requiring judgment at times of selection and/or monitoring. Referral to primary care physician is an important step in the selection algorithm and in monitoring. Interpretation of diagnostic findings from nonprescription device such as a borderline result requires professional judgment and understanding the label information is essential to safe use. And I would add here, when documentation that's important, if it's deemed essential to have post-marketing surveillance follow-up looking at this as an iterative process.

Today pharmacists are recognized as important partners in the patient's health care team for providing MTM services. As I say, we have experience in MTM and it reflects the experience that you've heard from other practitioners today. I would refer you to Chisholm Burns' Systematic Review and Med analysis. It's the most recent one that is out and it provides a fully comprehensive view of the clinic benefit of having the pharmacist on the MTM team. Most notably, the 2007 Medicare Modernization Act identified pharmacists as MTM providers and, of course, they're providing that on a broad scale with Part D. We just finished providing motivational counseling instruction to the Kaiser MTM pharmacists in Northern California and I calculated out earlier that they are doing on the order of hundreds of thousands of hours of MTM counseling to the Northern California Kaiser members.

So the situation has changed very dramatically since the previous reviews by FDA and the Government Accounting Office looking at behind-the-counter access to non-prescription medicines and I'd like to also add in a comment about the Royal Pharmaceutical Society in this regard as they have been dealing with a similar revolution in MTM in the U.K. But they've also had this very strong NHS strategy of opening access to reduce costs, reduce ED visits and help out a shortage of GP's.

Here for generic medicines, now the brand name company will provide it for the innovator product but when it becomes generic, the Royal Pharmaceutical Society plays a partnering role and they have standardized materials to support the diagnosis product selection and referral components of pharmacy class non-prescription medicines. So for the U.S., novel conditions of use involving pharmacists as intermediaries, we think professional support is essential and has the potential to ensure consistency in counseling across community pharmacy and practitioners as well as across pharmacies and I'd be happy to comment in the Q&A on how we handled that with Blue Shield and Raley's Pharmacies.

These are examples of the practice guides and practice points quick reference guides patient information pharmacists and support staff training that is for Tamsulosin, which is used for benign prosthetic hypertrophy in the U.K. and including on the blue the pharmacy support staff training. I didn't include the survey, which is a 22 point question survey that is filled out by the consumer and then reviewed by the pharmacists and there are unique ways to have documentation of what is going on and that diagnostic process with that particular view. It's a unique paradigm because the consumer can come in and get a prescription for about four weeks. They don't get a refill unless they see a physician.

This is the poster child. One of the proposed Mevacor labels that demonstrated that if we get too complex with the consumer, an advisory committee really won't go for it. And I think this issue as I'll talk about in terms of simplicity is important but it doesn't mean that it could not be done in a pure self-care consumer setting. But our experience to date and what the U.K. is doing is that they're seeing that there needs to be an intermediary support for this.

Now, as always switch should of course be evidence-based. The FDA has established that actually use studies and label comprehension studies may be pivotal to decisions of RX to OTC switch. New types of studies may be needed in order to support novel drugs specific conditions of use. This may include diagnostic device comprehension studies such as the instruction manual, videos are great. We use them in our clinical service. Re-design of the actual use study to accommodate a learned intermediary, such as a pharmacist or a proposed IT solution to self-selection and/or monitoring, validation studies of the consumer required self-selection surveys similar to what I mentioned on Tamsulosin which might be undertaken with community pharmacists, validation of an FDA approval of technology through kiosks, smartphone apps if there's going to be a diagnosis that is involved as was done recently with well doc and usability of integrated foreign language components to self-selection. Certainly the IT world allows us English plus other languages. And finally post marketing surveillance of pharmacist-documented self-selection diagnosis, et cetera.

Novel approaches to drug-specific conditions of use should also focus on the process of self-care and be driven by a principle of simplicity in design. Certain approaches to risk mitigation have been less than successful. I'll put up one of the versions of the Mevacor label as an example and from our most recent experience in assessing what was going on in 84 comprehensive cancer centers in relation to REMS, that from a practitioner process side to us has had a profound negative effect in terms of how they report their experience.

So the positive public health impact of an approval for non-prescription drugs with novel conditions of use may be hindered by lack of consumer and practitioner acceptance of complex risk mitigation strategies. The implication here is that actual use studies might be designed with greater emphasis on consumer patient and practitioner satisfaction with the process of self-care. Here, too, simplicity is important to help ensure equity in self-care. We urge close attention to this concept of simplicity as it relates to labeling, practitioner-mediated self-selection, consumer self-selection, documentation, post-marketing surveillance. In other words, simplicity in the process is extremely important.

With novel conditions of use, consumer mediated self-selection, pharmacist as intermediaries, new approaches to most post-marketing surveillance may be needed from diagnosis to product selection self-monitoring adverse experience surveillance. The pharmacy is set up with IT systems, particularly if there is documentation on the selection and documentation side to address novel ways to do this. And the reprogramming, although it can be costly but it is feasible because the systems are in place.

Finally, on economic considerations, Rx and OTC drug approvals are not based on economic data. We think that doing this could potentially stifle drug development. In the end, we also think it's up to the company to decide if they're going to get a return on investment and determine

their own particular marketing plan. But the inquiry that you have is cast much more broadly to consider potential public health ramifications of changing channels of drug distribution for improved access in the context of associated cost changes and how sensitive is that system. You know most recently in the U.K., although it has not been a large trend with the downturn in the economy, as much as consumers have moved to OTC, for those products that were moved, there is and now, I won't call it a resurgence but there is a trend back to the emergency department because of economic considerations. So if you were to bring economics at least at this stage of the game into a consideration would a product be switched or not, you would be forecasting in an unpredictable way across future changes in the economic climate that could affect it. So, as important as this might be, our view collectively is that it should be pursued on a separate track and not tied as economic determinant of a specific drug approval.

For novel conditions of use there should be a very clear national strategy, defined expectations as to the data set necessary to support switch using conditions of use as a criterion and follow-up guidance to help industry sort through the drug and device development passed to new conditions of non-prescription use. And of course this is your paradigm. This is how you do it. The benefit here, just to emphasize that, is predictability. It aids companies in forecasting development costs and potential return on investment but from the group I'm representing, what it does is it is of great interest to understand what the predictability is in the process from an advisory committee member standpoint and from the standpoint of other stakeholders because then we're more able to provide informed input.

So, in conclusion, as a group we feel it's impressive the list of questions that you've put together. Clearly a great deal of thought has been put into this by you. We support exploring new regulatory frameworks for non-prescription conditions of use. It if can be OTC it should be OTC. If it can be non-prescription because of conditions of use it should be that, too. But in either case, it can only be successful if it is data-driven on a case-by-case basis. If it addresses self-care equity and uses new study designs to address specific conditions of use and has documentation to support post-marketing surveillance and address through that, as well, liability concerns.

And I'd add a fifth point that we haven't addressed and that is clearly it has to have an economic sustainability. It's likely that it's not going to be one-size-fits-all, that Janet Woodcock had it right: it's important to be flexible. You can approach this from the OTC side and think of simply an IT solution that might be very workable in the pharmacy or you can think about this from the prescription side and think about EpiPen and how that might be done in relation to how plans allow for some co-pay but the person doesn't have to see or talk with the physician each time they use it. So, retain a case-by-case approach, we urge. Keep an open mind and apply flexibility.

Thank you.

Jane Axelrad:
Thank you. Panelists? Bob.

Robert Temple:

Do I judge from your last comment if it can be OTC it should be OTC, if it can be whatever this is called, that you think this should be thought of as class conclusions. I mean it wouldn't be true that we always make all members of a class over-the-counter when perhaps they could be. We generally wait for the labs--

R. R. William Soller:
This sounds like it's touching on one of your earlier comments and questions today. I think I can speak for the group in saying that we would not, if there was a novel set of conditions of use that have not been used before, to say that an entire class would now have those same conditions of use might take an awful lot of study. And it is probably more of a step-by-step approach as was done with some of the OTC switches where ultimately it became essentially we don't need to see any studies, we'll just do it. So I think in the conizals [spelled phonetically] the azoles, the example of that. So I don't advocate taking say all diuretics and putting them into this class, as an example. I don't think that's the way to go at this point in your health policy and regulatory decision-making.

Robert Temple:
Okay.

Andrea Leonard-Segal:
A couple of questions I guess related to -- I was interested in your slide about examples of new types of studies to look at these products and these paradigms and I wonder if you have some comments on the notion of a pilot setting, a more long-term pilot setting in certain parts of the country to test out some of these new paradigms maybe after an actual use study is conducted so that we really get a living sense of how some of this may work? Have you thought about that kind of a thing and--

R. R. William Soller:
That's-- that's not a new issue. I remember when I was working on aspirin heart attack we thought about something that might be uniquely done in Hawaii to explore what that would look like. I guess one comment I have is I think the geographical area, how that would be done would be important. So in the Poison Control Center, Salt Lake City was an ideal kind of thing. Hawaii. Alaska. So that you have a containment on what is going on within the health systems geographically.

Philosophically, well, as a researcher, I see a lot of interest in that because you like to do a pilot, you like to learn interavally and move forward. The question I would have for FDA is whether you can sustain that in the context of remarks that have come in from critics of this at past meetings and ask whether you can experiment on the American public. So, just as an academic researcher looking in, I know that has been the criticism of the agency in thinking in that area, notwithstanding the potential value that you would have of what might be a pilot to regional rollout, I guess, is what you're thinking of. So, honestly I've of mixed mind on that. I think there's a certain criticism that might not be able to be sustained. Yeah.

Andrea Leonard-Segal:

Can I follow-up Jane? Okay. The question I guess, so when we look at these different, the way the different states are conducting certain programs like Washington state with the emergency contraception.

R. R. William Soller:
Could you speak up just a little bit?

Andrea Leonard-Segal:
Yeah, I'm sorry. How the different states are conducting these different, their different programs historically with the Washington State emergency contraception, the thing we just learned about going on in Texas with diabetes, et cetera. Those are almost pilot entities to themselves even though they're not nationally looked at and I wonder if there's a way to think about this. You know if there's a way that we as a national body could sort of take advantage of some of that. Can you think of --

R. R. William Soller:
Well, I think you bring up a really interesting point. It sort of mitigates my second comment, my prior answer to you about this question of experimentation. Of course those were state-driven so that was a population of people that basically, in a sense, agreed to have that happen in the state. If that could be done in that context, then I think you're fitting kind of our national psyche about how we look at these kinds of health policy issues. I think if you just came out of the blue and said suddenly without preparing the field, "California, you're going to do this." Given my eight years in California I think the population might not want to be handled that way. I think it's in how you handle it Andrea, that you can probably swing something like this, but as with anything, it's population-centered care as patient-centered care. You have to bring them in as stake-holders in the process and believers in the process. So I think it can't be directed. It would have to really have a grass roots support for it.

Jane Axelrad:
Dr. Gutierrez.

Alberto Gutierrez:
Yeah, I was interested in your new approaches for post-marketing surveillance. You have among the, well the first bullet there is actual diagnosis. I think that refers to diagnostic testing that would be part of getting the accurate diagnosis.

R. R. William Soller:
Which slide are you on?

Alberto Gutierrez:
It's 17.

R. R. William Soller:
Seventeen?

Alberto Gutierrez:

No. It was that one but it was the second part of it. I have it as 17. One more. Next part, there you go. And new approaches to post-marketing surveillance may be needed. Accurate diagnosis.

R. R. William Soller:
Well, what I was thinking of was the Tamsulosin example in the U.K. where they have the 22 questions that are used as part of the inclusion/exclusion criteria for a decision on diagnosis as well as self-selection. That is not, I think, being used as it could be in a post-marketing construct because all of that can be put into an electronic database and now think about being able to look at an entire region if it's going to be a pilot study or to look across the country over time to see how the system is working. So I think there's a very valuable data set that could be afforded to these sorts of considerations by virtue of how the IT system is already set up in community pharmacies today. That's really the point I was getting at here. And as an aside on this, the whole drug safety or the history of drug safety in this country is iterative and to be sure that as we go forward to recognize that there may be changes. That it's a decision today but as new information comes in it could be modified improved with more information. So in this age of information technology, in this area, our group believes that there should be a strong emphasis on post-marketing surveillance.

Jane Axelrad:
Diane?

Diane Maloney:
Okay. I had a question just with regard to the documentation on I think it was the previous slide. You talk about simplicity and design regarding the documentation. I think I've heard other people as well talk about recordkeeping or putting the information in the electronic health record. I don't know how critical people feel that is but I'm curious in particular about this simplicity.

R. R. William Soller:
Well, as much as say, the U.K. has that the electronic medical record is up and well and working in all parts of the country, that's not necessarily the case nor necessarily a case in pharmacy-only distribution. But let me just talk about the documentation if I could in relation to our own MTM services. The best, absolute best MTM program is linked at the hip with the EMR of the physician's office or the clinic. There's no question about that and we run medication therapy management services in diabetes in that kind of paradigm. We also have a program that's ongoing now with California Blue Shield and Raley's pharmacists where it is in the community pharmacy and where there is no linkage with the physician and there is reticence on the part of physicians to be willing to open up and understand the value that the pharmacist actually brings as a member of the team, not subverting the physician, but as a member of the team and time savings.

What we have done is we've taken the SOP note, the subjective-objective assessment plan note and we've recast that as a structured interview. So, for diabetes and hypertension, we have a structured set of questions that the patient fills out and then this is reviewed by the pharmacist. It's much similar to the Tamsulosin survey although we were doing this sort of years before in the clinic setting. And that works very well because it's very easy to put into the IT system or we

can do it off an I-Pad. So, there are ways to both have a paper approach as well as an electronic approach allowing it to be used in different systems or if the IT system goes down. And that flexibility and that redundancy is what we've always built into our systems. So those questions then have been reviewed by a clinical team and reviewed by Raley's, UCSF and California Blue Shield physicians, pharmacists, nurses and lawyers, and has worked well to really populate the SOP note which represents sort of a mini electronic record or populate what would be similar to a very much cut down version of that. I don't always think in every situation that there needs to be an EMR link for some of the things that are considered and those that are in pharmacy-only in the U.K. because its working over there, you know, depending upon who you talk to, it's working well or it's not. I mean, depending upon how they view the situation. But that is going to be true I think of every decision.

Jane Axelrad:
We can take one more if there is one, Dr. Ganley.

Charles Ganley:
Yeah, Bill. I just have a question. Under your construct, could an insurance company partner with a pharmaceutical company to create a paradigm that they could use nationally for themselves to have a non-prescription product?

R. R. William Soller:
Well, I think that that would be a really interesting construct, Charlie. I can tell you that in discussions with different insurance providers that it is a steep hill to climb to create change in a new system where it's a system actuarial that's built on prediction in terms of return on investment. So that is a -- I won't call it a barrier -- but it is a very large hurdle that has to be overcome and it's not an easy one in our experience. But I do think as an example, I don't know what the cost of an EpiPen is, but I told some people here earlier I carry an EpiPen as a result of a severe allergic reaction last year. I had occasion to need to get a refill. So I went back and forth with the physician, who I know as a friend, and he was out of town, he wasn't, then it was back and forth and I didn't mind that because we were dealing with family business in the emails. But I did have to think about if I was not in the system, what would that mean? And I think the EpiPen as a person that knows a lot about it right now, would be absolutely a perfect choice in this regard for something like this. Some other change and where a person is not now really penalized because you don't think about what your monthly insurance is for your pharmacy plan. You think about what's out of pocket. That's what drives you. And I think figuring out the kind of system where it's fair against the risk is a magic equation. I don't mean it's, you know, but it is one that you know you've got the right price point that's perfect for accessibility and for companies being able to make a business. And I think the insurance plans would benefit by trying to think how that might be shared.

Jane Axelrad:
Okay, thank you. I think that will be a good segue because we're going to hear from the allergy and asthma community and people after the break. So we'll break for 15 minutes and we'll resume no later than ten after 3:00.

[break]

Session 4

So since everybody got quiet in a lot less than two minutes, we may as well begin early. Dr. Lanier?

Bobby Quentin Lanier:
Well, for any discussion to be complete it should feature some polar viewpoints. My name is Bob Lanier. I'm the physician allergist and represent the 5,000 members of the oldest allergy and asthma organization in the country, the American College of Allergy, Asthma and Immunology. I have practiced for about 42 years and am now its Executive Director. All our fellows have primary care certification in pediatrics or internal medicine with sub-specialty training in allergy and immunology. That's a 13 to 14 year track. A great majority of us are community-based. We're in the trenches.

I examine a minimum of 10 to 15 asthmatics every day and all varieties of severities and I've done so for over 40 years. The college has an intense interest in adherence and compliance. It's a crucial topic for those of us who deal almost entirely with chronic disease of genetic origin. We became aware of the proceedings via the Laya Press on February the 28th when reviewing the press releases and the docket description. We realized the importance of the concepts being discussed today, that patients with asthma may be able to receive short-acting beta-agonists medications without direct supervision of a physician and clinician, perhaps substituting the clinical examination with dialogue either by a computer or by a pharmacist. Now that will be my focus today. It's our expert area, our area of expertise and a concern of the college and I'll focus it to albuterol OTC and secondarily epinephrine by auto-injector.

Now let me say we're not Luddites. We know change is inevitable. But we want the change to be better. And what we envision with hearing some of the issues today is chaos. Let me also assure you that the College of Allergies is well aware that over-the-counter status of epinephrine-based asthma inhalers for many years and we understand there's considerable pressure to make albuterol available over-the-counter at least as a minimum some new behind-the-counter item. But just being simple folk, allergists are a little confused and perhaps you can help us on that. On one hand, one branch of the FDA is warning us, and patients, about the same drug class in question: that's vitagenis, that they're incredibly dangerous.

By reading the black box warnings and the product insert of some, you'd think there were people laying in the beltway out there as we speak, dead, holding little purple disks in their hands. These inhaler warnings are so vivid we have people sign consents before prescribing. Each year the warnings get worse. We receive Dear Doctor letters about how bad they are. Manufacturers had to send us warning letters. The cost on these drugs has gone through the roof and then new folks and another branch of the FDA begin to discuss how you want to make this drug class easier to get. We're just flat-out confused.

Now I'm not a pharmacist, although I do play one in the office sometimes. I actually go over the product insert with patients. I know we're talking about short-acting beta-agonists in one case and long-acting in another, but even a country doctor knows that two nickels equal a dime and

two shorts make a long. Same. Same. The message is very inconsistent about the risk and benefits of beta-agonists.

Now most of the pressure for the switch is economic. And the proposal gains some traction with reference to reducing the clinical encounters and the cost in this new world of medicine that we face. Penny wise, pound foolish. Accessibility. Every doctor employs trained nurses with medical records in hand to query patients and assist in refills without seeing them necessarily after consultation with the doctors. There's no charge for that. I did it many times today with my office. Now we do it 24/7 for people with emergencies. I cannot envision telling them to go to Walgreen's in asthma crisis. Can any program you project match those free services? I challenge you. I accept this as a part of my overhead. And is access a true issue particularly as we move to universal health and compliance, specifically Albuterol. In the case of Albuterol, I cannot tell you once in 40 years of taking care of asthmatics full-time that I ever shook my finger in a patient's face and said, "You've got to take more Albuterol or more Primatene." That's really not the issue. There's no compliance issue with this drug. Overuse, sure. Compliance, no. To change the status of the basic compliance is just not supported factually.

Since Primatene has been removed from the market, we've seen asthmatics emerge from the underground of poor control like raccoons after dark. They're mad. They want their drug. And now you'd think we'd see a lot of poor folk. But that's not necessarily the case. That was underscored to me last weekend. A social friend of mine called me in a panic because he couldn't buy Primatene. He had heard there was something wrong with it last year and he made a point of hoarding it. He bought 12 Primatene inhalers last October. Do the math on the doses. Now he runs out and it's pretty obvious over the phone what's happened. Now this gentleman is a 72-year-old retired banker. He's immensely wealthy. But he's used Primatene for 20 years despite cardiac, arrhythmia occurring requiring a pacemaker. I told him I wanted to see him and then he dropped on me. He said, "Bob, I don't need your advice. I just need the drug."

Now it's the same conversation that we're having today on a larger scale. It took me the better part of an hour on the phone to convince him to come in: first time in eight years. He dutifully filled out his little ACT questionnaire, great validating questionnaire, scored a 20 out of 25, which is very acceptable. When I listened to him I was a little stunned. I mean, he was breathing real short breaths so he didn't sound like much. When I made him expire, though, his wheezing was enormous. His lung functions showed poor flow rates, significant volume loss. He said it was nothing. Just a cold. Stats are when your FEB-1 is 60 percent or less like his were though you're going to be in trouble real soon. Now how is a pharmacist supposed to know that?

Long story short, I intervened with steroids and everything but the kitchen sink and he slowly got better, much better. When I followed up with him last Friday, I asked him how do you fill out that validated questionnaire and he said, "Hey, I'm no dummy. I know how to take quizzes. I was afraid you were going to put me in the hospital. I had a golf tournament this week." Well, alrighty, now. A one hour visit cost him nothing. He was Medicare and I accepted it. Except that he complained that the Albuterol cost him $50. He wasn't happy about that. He would have eventually presented but he and many people need a clinical examination and the judgment born of experience and training. This is a lethal disease. And the phenomenon of frequent flyers --

that's people who hit the emergency room sick, has not been stopped by OTC medications and providing a replacement OTC is just not the answer at all.

Now on the surface the new proposal being discussed here are chilling and a little scary. Carrying this forward, I can see a kiosk in a 7-11 connected to a vending machine. You push the right buttons and you get an Albuterol inhaler pop out like a bag of chips. Now inadvertently, you're facilitating bad behavior on the part of patients by not having them talk with a clinician.

I came here for the American College of Allergy, Asthma, and Immunology on a fact-finding mission. We want to know where the data is that makes patient care better, proves outcomes, reduces hospitalization with OTC Albuterol when self-managed or managed by a non-clinician. In our mind there's just not a substitute for a clinician. We're not only convinced that patients won't gain the system with questionnaires and data collections as my patient did, and we just don't want to be a part of giving sick people more rope to hang themselves with. This is just different from liver drugs. The American College of Allergy, Asthma, and Immunology is supportive of any innovation you come up with that will improve patient care and we want to be a part of it. But we're worried that the unintended consequences of good intentions and we would humbly suggest that you be careful to implement the changes that look good in these collaborative studies to independent prescriptive practice and extrapolating that data to OTC Albuterol, and if you do, that you build in a measure to demand that these patients see a clinician every once in a while. We could back that and anything else that truly benefits the asthmatic and allergic patient.

At this point I feel a strange kinship to General Custer, particularly about the FDA vending machine. But, I'm ready for questions.

Jane Axelrad:
Panelists? Come on, John. No? Okay.

Robert Temple:
We have to get our pulmonologist here but I take it from the last thing you said that if something were made so that it was easier for someone who already had a prescription for this to get it on a bad day when the doctor wasn't around or he was maybe even off someplace else, that wouldn't trouble you so much as long as he was part of the system.

Bobby Quentin Lanier:
Well, you know what? When I signed on, I do calls 24/7, seven days a week and done it 40 years. I don't know too many people that don't do that. I mean, are you aware that that people don't answer their phones at night?

Robert Temple:
Oh, I think some doctors aren't available on weekends but what do I know, you know? My doctors aren't always available on weekends. No, you're right. There's somebody at the office handling any emergency.

Bobby Quentin Lanier:

That's right. We have that and they have patient records in hand and they know this patient. You don't always have that with a pharmacist. They do different shifts. They do, you know, different pharmacies. People come and go. We're the same.

Robert Temple:
But if there were some people who had difficulty with access on a weekend and were people who were already getting it, that sounds like it's less trouble for you than--

Bobby Quentin Lanier:
Well, yeah, on a limited basis. I mean, we do it, too. Just like I refilled this fellow's Albuterol. A measure of good faith. Would you come in? He said yeah. I'll refill it for you, sure.

Robert Temple:
Okay, and your worry, I mean, given the persistence of Primatene for what 40 years, 50 years, do you think that was on the whole a bad thing? Was that troublesome? Were a lot of people who should have been seeing a doctor, not? Or were people just filling in, you know, between their regular medicines with that.

Bobby Quentin Lanier:
Well, we just don't really know, do we?

Robert Temple:
I don't but I wondered if you did.

Bobby Quentin Lanier:
Yeah. No. I have no special knowledge but, you know, when you look at data for asthma deaths around the country that have been, you know, skyrocketing in the last 40 years, I mean, I just don't know. I don't think anybody can say that for certain but we do know this: it's not good. I mean, you would not suggest that as a pulmonologist to your patient to treat them with the only agent available. Particularly somebody that had moderate asthma.

Robert Temple:
No. I would say we all wondered why it persisted but that's a different question.

John Jenkins:
You focused on asthma here, which is appropriate because there's been a lot of debate over the years about bronchodilators. What about other chronic conditions that allergists see, like say, allergic rhinitis and nasal steroids and what you're thinking there about making them more broadly available where it's not really a life-threatening situation. So do your concerns carry over from asthma to all other chronic conditions or are they unique to asthma and bronchodilators?

Bobby Quentin Lanier:
Well, the asthma, the American College of Allergy, Asthma, and Immunology has a position statement on over-the-counter steroids, nasal steroids particularly. It was last done in 2008 and it's being reviewed now because we thought that was really what you were going to be talking

about now and I never heard that. I did hear a pharmacist earlier say that she wanted to use nasal steroids for sinus infections, which was, you know, unique thought. The over-the-counter nasal steroids are a separate issue, but we're concerned about anything that now has a product insert that says that it's problematic. And the product insert on nasal steroids all include growth warnings and they include chronic long-term use. They also carry the risk of nasal septic perforation. So while I'm not particularly in my office, I'm vehement about somebody coming in for a nasal steroid spray is different than Albuterol because that's my one index that somebody's in trouble. If you take that away from me and people just get away and get sick. Nasal steroids -- that may be different. We're examining that right now.

Jane Axelrad:
Anybody else? Okay. Thank you.

Bobby Quentin Lanier:
Thank you for your time and patience.

Jane Axelrad:
Nancy Sandler?

Nancy Sandler:
Following Dr. Lanier's presentation. It's not going to be quite as entertaining but I'll do my best. I'm Nancy Sandler. I'm president and founder of Allergy & Asthma Network Mothers of Asthmatics. We're an organization founded in 1985, to help families and to eliminate deaths and suffering due to asthma, allergies, anaphylaxis, and related conditions. I'm here to make the case that asthma and anaphylaxis medications do not meet the criteria of OTC status, or modified OTC status, as described in the docket.

We talked a lot today about information and information technologies and how important it is but information does not equal understanding or appropriate use. Asthma is a complex condition. All the wheezes, coughs, or makes a person short of breath is not asthma. Sometimes it's nerves. [laughs] But self-differentiation and self-diagnosis and self-treatment for asthma it's impossible and dangerous at best.

There's the NHLBI asthma guidelines, the GINA guidelines, the global initiative guidelines, and the Blue Book all demonstrating that you can have better outcomes at lower costs by actually doing the right things. The right care, the coordinated care, the very patient-centered care, as described in these documents saves lives, it keeps kids in school, it keeps parents at work, it eliminates repeat hospitalizations and emergency department visits, and it's cost effective. But guess what it also does? It reduces need for medication because when you know why you have the asthma and you know what the contributing factors are you can actually prevent those episodes that keep you running back to the pharmacy for more medications.

My daughter was born with a very severe disease. First six years of her life she lived in and out of hospitals. It was only when we got into a drug study program at Georgetown University Hospital that we got the care, the coordinated care that was needed and she never needed to go back to a hospital again. How does that happen? It's not by do-it-yourself medicine.

All asthma is serious and I really want to stress this because most people don't understand the simple fact, asthma is serious. If someone came in right now and held a plastic bag over your head for a few moments and then ran out of the room, you would consider that serious. Anything that impacts your breathing, even if it's momentary, is serious.

In this slide I'd like you to take a look at the charts to the right hand side and remember that all asthma symptoms are serious and have the potential to become deadly whether a person has been diagnosed with mild, moderate, or severe disease. Research shows that among children and adults who died of asthma the diagnosis was just as likely to be mild as it was to be moderate or severe. Excuse me, I'm sorry.

Vicky Modica [spelled phonetically] is Mikey's mom and she didn't know that asthma could kill until it happened to her son. He'd been hospitalized many times. Emergency rooms many times. Always told her son had mild disease. She had the right equipment, the right drugs. She was doing what she thought she was supposed to do and then one day he died. She said, I thought asthma was a way of life until it was the way of my son's death. She was the inspiration for that book and it talks all about the underlying component of asthma, the part of asthma that you don't feel. It's always present but not always noticed and it's called inflammation.

She was also a Medicaid mom and she said, you know, I was poor but I was not stupid. Someone could have told me that mild asthma was serious, could have treated the underlying component of asthma and he would be here today. This is a young father and this video is on our website at aanma.org, but he spoke at Asthma Awareness Day, the first Asthma Awareness Day that we had on Capitol Hill. And he talked about his two-year-old daughter who was wheezing and so he took her to the pediatrician. She was sent home with breathing treatments and told if it got worse take her across the street to the hospital, because they lived across the street from the hospital. Well she did get worse. They went to the hospital and then she was sent home again to more breathing treatments. He was giving her next breathing treatment, holding her in his arms. She looked up at him and he said she whispered, I love you, and she looked at me and looked at me and looked at me and then I realized she was dead. Asthma doesn't always look so bad.

We're all familiar with the, you know, the talented, dynamic New York Times journalist, Anthony Shadid. A man who sustained a bullet to his shoulder, kidnapping, and beating but he succumbed to progressively worsening asthma symptoms triggered by horses.

You know there's more than 3,600 stories like this that happen every single year and in each of these, or at least with the stories that we hear through the organization, they said it just didn't look that bad. I didn't know asthma could kill. Even under the best of circumstances asthma is a deceptive and elusive disease. So perception is reality, right? But asthma does something to the brain that actually alters our perceptions of reality. Repeat asthma exposures, excuse me, episodes affect brain gray matter thus the patient's ability to perceive, assess, or communicate symptom severity and risk. So it actually doesn't feel all that bad in the early stages. That's the silent part of asthma. The noisy part of asthma is the wheezing, choking, and gasping that most people associate with the disease of asthma. Oh, he's wheezing again, he's coughing again.

Medical literature is replete with examples where patients and families and/or medical care providers underestimated severity and symptoms. This is a YouTube video. You can see the title right there. I hope you look it up but it's about 16 seconds long. This looks like a very happy, healthy little girl, doesn't it? When you listen to the video you will hear her wheezing and wonder why her parents are not whisking her to the hospital.

This man here his [unintelligible] is titled, "My Near-Death Experience Asthma Attack." He describes his asthma in this video as being mild with only a few episodes a year but in this video he details the current attack which at 4:30 that morning nearly killed him. As he speaks from the beginning of this video and to the last word he is wheezing and you want him to go back to the hospital. But what happened with him is he used his nebulizer during the middle of the night but his airways were so clogged and swollen that the medication didn't make it into his airways. It made it into his bloodstream and his heart, his heart started beating faster and he needed more, he needed more oxygen than his lungs could provide. Even though his parents were in the next room he couldn't get up and call for their help. He called 9-1-1 instead. So not only is asthma serious, the diagnosis is complex, and self-assessment entirely subjective, entirely subjective.

Too little or too much medication administered at the wrong time is also associated with increased symptoms, emergency visits, hospitalizations, missed work and school days, poor performance, higher health care cost, and oh, yes, death 3,600 times a year.

So I want to talk about some prime myths out there right now and some of them appear in the document. And the first is that patients have to see a doctor if they want a prescription refilled. Well when bronchodilators are prescribed patients are given a specific number of refills that should last until the next scheduled doctor's visit. If they don't that's a sign of worsening asthma and it's a sign that you need to be seen and reevaluated and your treatment plan, your written asthma action plan should be adjusted. Bronchodilators should travel with the patient everywhere they go every single day but they should rarely need to use it. So if they need to use more than has been prescribed something is wrong. So please remember that.

More medication is better and cheaper than going to the doctor. This is a fallacy that we run into when families -- when they're first trying to figure out how to get asthma under control. It's just like if I could get more medication and if I could get cheaper medication I'd be doing well. Well this is where patients often get in trouble. They become actually comfortable and the familiarity of their discomfort and then they get upset when a request is denied. Okay? I'm going to repeat that. Patients often become comfortable in the familiarity of their discomfort and get upset when a refill is denied. A lot of the denials happen at the pharmacy. Well, I don't know. I really don't know because the patient is not without options at the pharmacy. The pharmacist or the patient can contact the doctor directly to obtain the refill. We all have 24 hour access to our doctors. If you have a prescription for a bronchodilator, you have a doctor. So you have access to someone who can refill that prescription for you and take the information necessary to see whether or not that refill should be conditional. Oh, I already said that so I'm not going to say that again.

All right, so the patients. Another fallacy is patients who use OTC medications cannot afford to go to the doctor. Well this also is simply not true. All of us use a lot of OTC medications and we also use a lot of prescription medications. So, but if someone is suffering heart symptoms or

their face starts to droop on one side or if they've suffered a gunshot wound to the leg or they have a broken leg, they're going to find their way to a hospital to get it fixed because they perceive that the situation is very, very bad and they need help. The problem with asthma is it happens from the inside. We can't see it and if we could, it would be ugly and people would be going for help.

There's the argument that patients who use OTC medications cannot afford prescription drugs. Well, again, a lot of people who use OTC medications are also using prescription drugs. And if people don't have financial resources or health insurance and we talk to these families every single day, we help them find resources and pharmacists and kiosks can help in these areas. I'm getting a high sign over here and I didn't realize it was going to happen that fast so sorry about that. There are ways to get free medications and pharmaceutical companies are definitely great at having coupons and other types of services. I am going to jump. Could I ask for a few more minutes please?

Jane Axelrad:
Yes, take a few more.

Nancy Sandler:
Okay, thank you very much because I would like to, you know, patients do need a voice here. OTC medications are fallacies that OTC medications are good for patients in emergency situations and it is in a true asthma or anaphylaxis emergency it's prudent to head to the emergency department not to the pharmacy. And I'm going to jump to the next slide here and this is an important part of my talk today as well.

In the document and in prior presentations people have referred to inhaled bronchodilators as rescue medications and I want to be clear with everyone here. You don't need to be rescued if you're using your bronchodilator at the appropriate time and that's at the first hint of symptoms. It's before exercise and it's also during an episode. It's not just in rescue situations. In fact the term rescue is interpreted by one-third of patients as a bronchodilator is only needed if you're going to call 911, or if you're dying, and if you are the inhaler is going to inflate your airway. They interpret the word controller often used to talk about inhaled corticoid steroids they interpret this mean, that this, this name, this pet name as something that can -- is going to stop wheezing. It's going to stop the shortness of breath and you're supposed to take it when you are wheezing, you know, when you want it to stop. This could not be more wrong. Inhaled corticoid steroids should be used daily, broncho daily, bronchodilators should be use rarely. And it's my hope that FDA will take that terminology and everyone in this room will take that terminology away as NIH and NHLBI and CBC haven't in their language.

Okay, so there's a lot of bronchodilators and inhaled anti-inflammatories and combination medications out on the market and I don't know how you would begin to choose which ones would, you know, be accessible and which way but our biggest problem with access to medications is that our doctors prescribe one medication and they teach us how to use it in the doctor's office and then we go to the pharmacy, pick up the bag, we take it home, we open it up, and it's a different something-or-other. What we would really like is for our prescriptions to be filled the way our doctors and our training have been provided. I mean after all why do health

insurance companies reimburse for office visits and allergist consultations if someone else gets to decide the medications we get. And I'm not saying that the pharmacist is always the one who's deciding the medication that we get but there's too many other people that are in that game.

This shows the differences between the various medications and these are education points that should be discussed with patients. So one size does not fit all.

I'm going to talk about epinephrine and I'm going to clarify one thing really quickly. Dr. Woodcock said earlier today about EpiPens that may be lost, broken, or malfunction. I think she was referring, I hope she was referring to EpiPen as the term Kleenex is often used to describe, you know, tissues. But we have done an awful lot of research with Twinject and with EpiPen and I can assure you only EpiPen has never, ever, ever had a malfunction. And so I do want to make that clarification.

Also Dr. Soller if you're still here, you said you carry your one EpiPen. Please carry two because in 33 percent of the cases the first one isn't enough and also please don't call a friend when you need a refill. If you call your doctor you'll get one faster. So, but epinephrine is not recommended for treatment in any guidelines for asthma that's inhaled, however, auto injectable epinephrine is a lifesaver for people with anaphylaxis.

The case against OTC medications for asthma also applies to auto injectable epinephrine. Anaphylaxis is not a do-it-yourself disease. People do not understand that it's serious or that it kills. These are two young girls whose lives were lost due to anaphylaxis, accidental exposures and two faces of many -- I'm trying to do this really fast here but I don't want to overlook anything here.

And that is in 2003, there were almost no laws protecting students' rights to carry auto injectable epinephrine at school and you see as of 2011, they're allowed to do that as well as their prescription inhalers. These are prescription devices that laws have been wrapped around as prescription devices. Eleven states right now are looking at entity prescribing so that schools can have these devices on premises for situations where the first anaphylactic accident happens or reaction happens at the school. We need to be careful that when we're looking at OTC types of paradigms that we take these things into consideration to see severity and also what work is going on in the rest of the world.

I want you to know that our ACEs program, it's called Anaphylaxis Community Experts, this is an unbranded program but by way of disclosure I'm recognizing sponsorship through Mylan and working with the American College of Allergy, Asthma, and Immunology. Our volunteers and college volunteers are working with pharmacists. They're working with teachers and community members, school nurses, doing education programs because you can't treat anaphylaxis on the fly. Anaphylaxis is serious. Asthma is serious. Ay, yay, yay...

I'm going to close with these comments. Although the Healthcare Bill is going before the Supreme Court next week it presently has an individual mandate requiring every American to pay for insurance. However if FDA moves medications for chronic diseases such as asthma and

anaphylaxis and others to OTC status because the Agency believes we can self-diagnose or ask a kiosk to select the best medicines to treat our symptoms, what will our insurance premiums cover? If only the sickest of the sick are seen by doctors, what happens to preventive care and patient-centered care? And I can tell you in asthma we'll just get sicker.

NHLBI guidelines, NIAID food allergy guidelines, GINA, Blue Book, our organization and others, NIAID, EPA, CDC, we're all working together. All working together for patient-centered care, true patient-centered care coordinated so that we can achieve our personal goal without depending on medication. Thank you very much.

Jane Axelrad:
Thank you. Mary?

Mary Kremzner:
So you mentioned -- I understand your concerns about these particular products going over-the-counter, but you mentioned increased hospitalization, increased death, increased emergency room visits. Do you see a role pharmacists can play in mitigating some of these situations?

Nancy Sandler:
I tell you I've enjoyed working with pharmacists for nearly 30 years now professionally and, you know, while my daughter was very young and very sick really depended an awful lot on our local pharmacist. Pharmacists play an important role. Unfortunately and in the last, greater than a decade, we've seen more and more, excuse me, less and less of our pharmacist and more and more of technicians or people who are going to ring your purchase up at the counter but not really provide any education.

When that paradigm began to happen my pharmacist contacts were very concerned that the profession of pharmacy was losing that patient contact. And I agree it did get lost. And I would like to see a world where our pharmacists are more engaged and they're more knowledgeable about who we are when we come in. But I have to tell you for people with asthma, and maybe so with anaphylaxis too, because so many others with asthma also have anaphylaxis. We're avoid going into the pharmacy anymore because of germs and they trigger, they trigger, you know, we're already getting enough exposure at the doctor's office and then go in and pick up more in the pharmacy. You know, that is a concern for us and so we do prefer, tend to prefer the drive-through window. But yes I do see pharmacists as being part of our community of care but not in a diagnostic way, not in a way where we go there to pick up our medication because the pharmacist says this is what we should have.

Jane Axelrad:
Okay.

Nancy Sandler:
I do thank you for the additional time and we will be submitting additional comments, too.

Jane Axelrad:
Okay, thank you.

Nancy Sandler:
Thank you.

Jane Axelrad:
Peter Vlasses.

Peter Vlasses:
Good afternoon. I'll try and make up some time in that I need to make a flight so there'll be urgency to my comments. I'm here because I appreciate the opportunity to provide input on aspects of the pharmacists' education that's pertinent to the proposed new paradigm for OTC drugs under the conditions of safe use. I will clarify one correction on the agenda and that is that I'm not a professor of clinical pharmacy in that when I took my position 13 years ago I had to give up all academic affiliations because of the potential for conflict of interest.

Our Agency has been around since 1932. We accredit the professional degree programs in pharmacy which is currently the Pharm.D degree. We're recognized by the U.S. Department of Education for meeting their criteria and we also meet the criteria of the Council on Higher Education Accreditation. We also are -- accredit the providers of continuing pharmacy education for the physicians on the panel if you think of LCME and ACCME and put them together, that's our mission.

We -- accreditation is required for graduates to be able to sit for the national licensing exam and continuing education offered by ACPE accredited providers is accepted for mandatory license renewal requirements by all state boards of pharmacy in all states and territories. I'm here specifically to address the question under Section B, would additional specialized training be needed for pharmacists if this paradigm were adopted? Earlier today you saw a diagram proposed by the American Pharmacists Association that tries to look at these various combinations of where average risk of the drug increases. To the far right being the RMS, to the far left being the OTC medications, prescription drugs being there and then now this new paradigm being proposed. It is clear that our education covers extensively prescription drugs, over-the-counter drugs, and now RMS medications and any movement towards changing this OTC under safe use would, likewise, then be accommodated in our educational procedures both for the colleges and schools as well as the continuing education world.

We belong to a group of 11 pharmacy organizations that a number of years ago put out a vision about what we believe pharmacists need to be to better serve society. And that is to provide patient-centered and population-based care to manage the health care system resources including drug products, technicians, robots, and other devices and to promote health improvement, wellness, and disease prevention. This vision is inherent as the basis of our standards both for the degree programs and our continuing education providers. And I think you'll agree that these three competency areas are very germane to the topic at hand about OTC safe drug use.

Since about the 1970s, our educational process has been undergoing a major metamorphoses from an emphasis on the drug product to a very patient-focused emphasis where what is the role of the drug product in the patient's care. And we have, starting in the year 2000, have moved

thoroughly to the doctor pharmacy degree as the entry level degree. We've had a big expansion, a lot of interest in the student world to become pharmacists and the profession through market forces has expanded primarily because of the baby boomers, like myself, coming through the system. When we expand the number of schools and the number of branch campuses, we have a growing number of graduates now that are Pharm.D prepared and then you'll see that by the year 2014 we're projecting almost a doubling of the number of graduated pharmacists.

What does our curriculum look like? We want to make sure that pharmacists know things that they need to know, that they can do things that they need to do, and that they also have attitudes and professional behaviors that allow them to be professionals. They have pre-professional requirements, a minimum of two years, but usually now three- and four-year graduates entering programs. We have four basic sciences that we look at: biomedical, pharmaceutical, behavioral/social administrative and clinical sciences. So we look at the integration of these sciences to better understand drug products, where they fit into therapy, where they don't fit. We have experiential education early in this introductory pharmacy practice experiences or the IPPEs, which now are mandatory to be at least 300 hours. We have simulations that are part of our curriculum, and then the last year is entirely experiential where students are mandated to spend time in community pharmacies, hospital pharmacies, and ambulatory clinics where they learn about, from, and with physicians, nurses, and other health professionals. And again, our curriculum has a strong emphasis on chronic disease management.

Germaine to today's discussion is that, again, prescription and over-the-counter medications are extensively covered and even when drugs switch from Rx to OTC, the rationale for that is part of the curriculum. We extensively cover things about adverse drug reactions, drug interactions, assessments as they relate to medications, technologies and tests for monitoring, and many of these are now available in pharmacies, effective communication with patients, families, partners, and colleagues in other health professions, and methods to encourage patient adherence to medication and other therapies. Specifically, we're training people to be coaches to patients so that they better adhere to their medication. Compliance is not a one and done, but rather an ongoing relationship.

We have economic issues that we address in our curriculum and there's a strong emphasis on team-based education and my colleagues at LCME and CCNE have been meeting to talk about how do we harmonize the inter-professional education expectations in our professions.

In the world of continuing education we have 270,000 licensed pharmacists. As I mentioned, it's now required for re-licensure in all states and territories and that we have, as an example, that the boards may request specific content for the continuing education and currently we have -- I have 150,000 pharmacists here. I think this morning you heard 170,000. I think that's probably a more accurate figure where people have been certified to be immunizers and have accepted this role and it's now a role that's accepted by all states and territories.

In the world of continuing education we have many different providers. There's 358 that are currently accredited and they come from a different arena of both academic and nonacademic, and we have identified three different types of continuing education, strictly knowledge transfer, application where you take information and you have to apply it to a particular case, but more

importantly, practice-based continuing education leading to a certificate program that demonstrates with hands-on workplace experience in many cases, the ability to perform certain clinical functions.

Now, we're very committed to working with colleagues in a collaborative way and providing better health care as a team and one of these efforts we've been working with is with our continuing education providers in medicine and nursing, we have focused on engaging providers of CE to provide programming for health care teams and in so doing we've tried to incentivize them by decreasing the burden for team-based education.

So for the last several years we've now offered by the team, for the team, continuing education where we jointly accredit, meaning medicine, nursing, and pharmacy will review and in one accreditation procedure review and approve people. The criteria here for who qualifies is listed and we're even expanding those criteria to include now the state accrediting bodies in addition to the national accrediting bodies and the criteria here is that about 25 percent of their activities need to be team-based.

We have the following organizations that have gone through and gone through the interdisciplinary or inter-professional accreditation procedure and there's four additional applications that will be in the review this year.

Another aspect of how we're trying to be collaborative in the arena of public health and safety is the collaboration that we're enjoying right now with the FDA and even members of this panel with the industry working group and our accreditor colleagues and providers of continuing education as it relates to the extended-release and long-acting opioid REMS education. And again, we're looking for systems in place to support documentation of the required elements, a congruous approach to fulfill FDA's expectations and hopefully create a model for addressing other public health problems. In that regard, we've partnered with the National Association of Boards of Pharmacy, who you heard from earlier today, and we've developed a system where now all the continuing education taken by pharmacists that we accredit the providers of will now be in a central database. This process has been -- is being implemented as we speak with full implementation that has to occur by December 31, 2012. So at some point in time we'll be able to address practitioner level continuing education and specific activities undertaken for re-licensure.

In conclusion, a recent report on improving patient and health system outcomes through advanced pharmacy practice, a report for the surgeon general that was produced by the Office of the Chief Pharmacists of the Public Health Service, and was publically supported by the surgeon general, had the following quote:

"Because pharmacy practice has already shifted to allow more clinical services, the nation's colleges and schools of pharmacy have followed suit with appropriate education and training to support these roles."

I agree with the FDA's view that increasing the number of people who are able to obtain for the first time and those who continue on necessary drug therapy under the proposed paradigm for

OTCs would provide improved health outcomes. I hope I've provided you with information that supports the fact that the current education of pharmacists, both degree preparation and post-licensure continuing education, would appropriately support the change of the new paradigm of OTC products under conditions of safe use, and I'd be happy to answer any questions.

Jane Axelrad:
Thank you very much. Mary.

Mary Kremzner:
Hi. Thank you. So you mentioned that the school curriculum has extensive chronic disease management. So, does that mean a pharmacist upon graduation is capable of performing clinical assessments for products that perhaps would become OTC or that are not traditionally OTC?

Paul Vlasses:
The current curriculum, for instance, for diabetics, would include hemoglobin A1c monitoring and what that does and when it is appropriate to do something? When is it appropriate to refer? In certain situations we're taught limited physical assessments as it relates to the monitoring of the therapy in terms of whether somebody is wheezing or not wheezing, and other physical findings that may lead to referral. We obviously have done things like take blood pressures or measure cholesterols as part of the training, and that's all part of initially classroom and then real world on a limited basis simulation, and then eventually wholesale in the entire last year. So the answer to your question is I believe today's graduates, under proper circumstances of adequate time and adequate information, can do what I think you're looking for in this paradigm.

Jane Axelrad:
What about people who are not so recent graduates? People who have been out practicing, you know, for 15, 20, 30 years. What kind of efforts would need to be made to reach out to that community if we were to shift the paradigm?

Paul Vlasses:
I mentioned the immunization as an example of how new aspects of education that preceded somebody's education in a program can then be brought into the practice arena. It can be monitored. It can be requested by somebody looking for a particular credential and that has worked very successfully and I think the people at the Centers for Disease Control have actually come at the state level and testified on behalf of having pharmacists do this because of the public health improvement that would come out of enhanced immunizations.

Jane Axelrad:
So, just to carry that thought a little further, I mean, it would be very complicated if we were to decide that you wanted to have pharmacy involvement in dispensing or deciding whether to use a drug with conditions of safe use. Would you be expecting each pharmacist to become certified in the use of that as a pre-condition to being able to dispense that drug?

Paul Vlasses:
You know, I think as professionals, pharmacists are taught to do what you think you're capable of doing and not exceeding those capabilities. So, I think in the immunization world the

pharmacists went out and sought some of this certification to be capable of doing this safely and effectively for patients if they weren't taught to do that in school. Now our students are taught to do that as part of their educational programs. So, I think there's a professional component here that they're not going to expose themselves to tremendous liability for something they don't know how to do. I think that's part of being a health professional.

Jane Axelrad:
Okay, thank you very much.

Paul Vlasses:
Thank you.

Jane Axelrad:
And our last speaker today, Daniel Hussar.

Daniel Hussar:
Thank you for the opportunity to participate in the hearing. I'm Dan Hussar. I'm a pharmacist and I'm on the faculty at the Philadelphia College of Pharmacy. Among my responsibilities there is teaching the required nonprescription therapeutics course and my experiences also have provided expertise relative to prescription medications and discussions I present on the topic of new drugs.

I feel that the Food and Drug Administration has an exceptional opportunity to extend and improve health care for millions more Americans than are well-served now. As stated in the federal register announcement for this public hearing, and I quote, "Under-treatment of many common diseases or conditions in the United States is a well-recognized public health problem." Millions of Americans do not see a physician or other prescriber now unless they are experiencing symptoms that they are no longer able to tolerate. Millions of Americans use unregulated herbal products, natural products, dietary supplements that have not been evaluated, either for efficacy or safety, or even the composition of the products. These situations represent every day experiences for millions of Americans who are currently not served by our health care system. I feel the opportunity exists by addressing the topics that you've identified for consideration in this hearing to extend the involvement of pharmacists in a way that will contribute significantly to further extension of health care benefits. I think this can be done in an efficient manner. I think it can be done in a manner that will relieve and ease the burden on emergency rooms, as well as many physicians.

Currently, pharmacists in the local community pharmacy setting, and many ambulatory care settings of hospitals and health systems, are providing assessments for individuals and making a determination as to whether the symptoms or other complaints voiced by a patient, voiced by a consumer are ones that require referral to a physician or other prescriber, perhaps to an emergency department of a hospital or whether they are of a relatively minor severity that can be appropriately managed with nonprescription medications. Pharmacists are doing that right now. They are prepared to do more. They have the knowledge, as well as the accessibility to assume a greatly expanded role for what I would suggest is a large number of medications that currently require a prescription.

As the previous speaker mentioned, I think that the topics being addressed here are particularly important and timely with respect to the relationship to the report that was just provided to the surgeon general that addresses in a comprehensive fashion the role that the pharmacist can assume for many of these responsibilities.

My remaining comments will focus primarily on my identification of certain medications that I consider to be strong candidates for availability without a prescription in a pharmacy with the consultation of the pharmacist. I realize that some of these medications have already been mentioned in previous presentations, and I'll try not to be redundant other than to mention several of them. The first three that I have included in my written comments are medications that are needed on, literally, a life or death basis for emergency situations. Urgent or emergency situations rarely occur at convenient times and convenient locations, like right across the street from a hospital.

I feel that medications, such as epinephrine auto-injectors for severe allergic reactions, albuterol for oral inhalation for acute asthma attacks, and naloxone for narcotic over-dosage. These medications are often needed on an urgent basis and the greater that we can -- the greater the extent to which we can make them available from health professionals will be a lifesaving intervention for some individuals.

The triptans for migraine headache: Anyone who has suffered a migraine attack recognizes the importance of prompt use of a medication that will help to relieve those symptoms. Oseltamivir, Tamiflu for influenza. Pharmacists are positioned to distinguish between symptoms that represent influenza or the common cold or allergic rhinitis. With oseltamivir it is important that treatment be initiated as soon as possible if that drug is to be of value in controlling the symptoms and heading off a more serious influenza infection. The statins have received quite a bit of attention and I realize there is a debate relative to increasing the extent to which these agents are available, but there are many individuals out in society rather than seeing a physician on any sort of regular basis or even at all, are taking medications available without a prescription. No, I shouldn't have used the word medication, dietary supplements, herbal products. Red yeast rice has a reputation of being of value in reducing cholesterol concentrations. It's available as a dietary supplement. What does it contain? Lovastatin, among other things.

Here's a situation in which many individuals are treating themselves without the benefit of a physician, a pharmacist, or any health professional. One of the strongest reasons for which I think statins should be available from a pharmacist is that and, again, this would be on a selective basis within given parameters, is that there are many individuals who are now using unregulated, unstandardized products that have not been evaluated for their efficacy and safety. Wouldn't it be better to have these individuals obtaining a product from a health professional recommending a product with known composition, with known efficacy, with known safety and risk factors? And again, I'm not suggesting that pharmacists be acting unilaterally. I anticipate that the expanded role of the pharmacist in providing medications that currently require a prescription will have the effect of stronger and more comprehensive communication between the pharmacist with physicians, greater collaboration, greater referrals as pharmacists identify individuals who should not be treating themselves, even with the consultation of the pharmacist, whose

symptoms are of a severity or of a complexity that requires a more thorough evaluation that the physician can provide.

There are a number of other prescription medications that I've noted in my written comments. Just to mention several of these, cyclobenzaprine to help relieve certain musculoskeletal symptoms. Ramelteon is a drug that has been approved following the completion of clinical studies for insomnia characterized by difficulty in falling asleep. Ramelteon is a melatonin receptor stimulant or agonist. There are dozens of melatonin-containing products available in health food stores and many other retail outlets that have never been considered by the FDA, do not come under FDA regulation, and yet are out there with so little known about them. Wouldn't it be better to have a product that has undergone clinical studies, has been considered and approved by the Food and Drug Administration as a better alternative to the dietary supplements that utilize melatonin?

The last agents I would specifically mention are agents that are used for smoking cessation. Right now there are three nicotine replacement therapy formulations available without a prescription: the gum, the lozenge, and the patch. There are two other nicotine replacement therapy formulations, a nasal spray and a formulation for oral inhalation. There is also a drug, varenicline Chantix, which is widely prescribed for use to help individuals stop smoking. In my opinion, it should not be more difficult to obtain a product that will help individuals stop smoking when a product as dangerous as cigarettes is widely available requiring only proof of age to purchase. I think this is an unacceptable irony. I was impressed with the signs all around the FDA campus as we arrived here today, a smoke-free facility, and I think we can do so much more. There are many current smokers who would like to stop who will not see a physician for a prescription for the medications that could help them stop smoking. Pharmacists are well positioned to assist in those circumstances.

In addition to these examples, I think there are other medications that will also be strong candidates for a switch to status that they could be available from a pharmacist. The increase in a number of prescriptions that are available from a pharmacist will not only increase patient access to these medications, but will also make them more available on a cost-effective basis. As I mentioned earlier, I anticipate that there will also be increased communication, collaboration, and referrals with this greater involvement of pharmacists as they have occasion to communicate information that they have obtained from patients to a physician to whom they might refer the patient.

I anticipate that there's a potential for some turf wars between health professions as these issues are considered. With all of the health professions working together or separately, however it may exist in a particular community, we as health professionals are not doing the job now that needs to be done in providing the highest quality health care and preventing drug-related problems. There are too many drug-related problems relating to prescribing, dispensing, and administration. I think to the extent that we can expand the involvement of health professionals. In this case I can speak with the expertise only for the pharmacist, but I feel that this would be a very positive step. I also feel, and the economics have been brought up on several occasions. I don't think that insurance companies and others who are paying for these products as they get switched to a nonprescription availability should be enabled to experience a financial windfall. I

think this will be resolved in a competitive marketplace as these insurance companies and others have to be competitive in the programs they offer. But I think there should be a continued coverage of the products that are switched to nonprescription status. Thanks very much for your attention.

Jane Axelrad:
Thank you. Questions? Dr. Jenkins first.

John Jenkins:
As often happens at these meetings and our work at FDA, we hear people who have very different views on the same issue, so we just heard a couple of presentations earlier about albuterol and epinephrine adamantly opposed to the idea of them being more widely available without a prescription. They're number one and number two on your list. Can you address some of the concerns we heard earlier from Dr. Lanier and Ms. Sandler about why they shouldn't be available and how you have a different view?

Daniel Hussar:
Yes, I'll be happy to respond to those. My brother carries an EpiPen. We vacation in northern New York. I think the closest pharmacy even is 25 miles away. I'm not aware of another health care facility. When emergencies occur there needs to be the availability of that product. In his case it was a bee sting and I just feel this is -- I don't look at the EpiPen as a product that is going to be misused or abused. I feel that it's accessibility to the extent that we can make that possible from a health professional; and I would contend that in many situations the local pharmacy will be more accessible than a hospital emergency department or a physician.

Just with regard to the consideration of epinephrine, that is the situation in which I'm advocating availability from a pharmacist, not in the inhalation products that have been available over the years.

With regard to albuterol, for many individuals with asthma, there is the use of albuterol on a regular basis. My recommendation addresses the emergency use of albuterol. The term rescue has been identified and some have suggested maybe there are other terms that would be appropriate also. It's the emergency situation in which I'm recommending the availability of albuterol from a pharmacist. I realize that for many of these agents there are issues that will support and issues that will oppose. I tried to give careful -- I'm actually pleasantly surprised that I could come up quickly with as many examples as I did that I feel, in general, are safe for the general population to use. I think this is a responsibility that pharmacists will take very seriously and will want to make sure that the services, the advice, the selection or recommendation of a product is consistent with the highest quality standards and the follow-up monitoring that may be necessary.

Jane Axelrad:
Dr. Leonard-Segal.

Andrea Leonard Segal:

So, I also was looking at your list and as I look over some of the products that are on it, I wonder if in fact, if they were to be available without a prescription they in fact would all belong in the category where pharmacists needed to be involved. Could you foresee that any of these could be available under other conditions of safe use? Or even just OTC under our current paradigm?

Daniel Hussar:
I missed the first part. Was there a specific medication that you mentioned?

Andrea Leonard Segal:
Well, no. I'm looking across some of these and I see a nonsteroidal anti-inflammatory drug for pain. You've added the inflammation indication, so are you implying that there would be new indications that the product would be used in higher doses to treat inflammatory arthritic conditions that are currently not OTC? Or are you looking at the pain indication -- that pharmacists could diagnose or are you looking at the current indication? I noticed some -- the intranasal allergic rhinitis product that came up in the last conversation. Is there -- we have allergic rhinitis as an indication currently now OTC. Is there something about this that requires a pharmacist to intervene or could there be other conditions of safe use? The algorithms? The technologies we were discussing earlier? Could a product like that maybe just be OTC under the current paradigm? I'm -- we've got nicotine products currently OTC now.

So I'm just looking at your list and I'm trying to understand whether we're hearing a discussion from a pharmacist's point of view that is not also looking at other possible OTC paradigms that we're considering here today? Or whether there are very significant safety concerns that you have about these you think need the health care provider intervention.

Daniel Hussar:
I think there are important roles for technology and although I wasn't here earlier when some of those comments were made, I respect and value discussion that will lead to the more effective incorporation of technology into some of these circumstances. Having said that, I don't think that there is anything that replaces the judgment and the experience of health professionals whether it's a pharmacist, a physician, a nurse practitioner, a physician assistant; and therefore, I just feel very strongly that to the extent that the dialogue with the patient can be extended to bring out the information that will enable a personalized recommendation that may be consistent with that patient's lifestyle and activities.

But with regard to so many of these products, there is no medication that is completely without risk. And I think the experience with so many nonprescription medications, the recent experiences, relatively recent experiences of switching products like Claritin and Zyrtec and Prilosec OTC, I think those steps -- or those actions have had major benefit for many individuals with relatively little risk. Now maybe some of the medications we're considering today, I heard suggestions that intranasal use of corticosteroids might be associated with some risk. Personally I think that is extremely unlikely when those products are used as intended. As I consider allergic rhinitis with my students and I talk about the medications like the antihistamines and some of the other products that are currently available without a prescription, in the same discussion I identify the intranasal corticosteroids as, in my opinion, being the most effective treatment for allergic rhinitis so that when the nonprescription possibilities are exhausted, yes

there is that alternative that can be prescribed. I think a pharmacist is well positioned to make that recommendation and to guide the patient in the appropriate use so that the risks can be minimized to the extent needed.

Jane Axelrad:
Any other questions? Thank you very much for sharing.

Daniel Hussar:
Thank you.

Jane Axelrad:
I think we had a very full and informative day today and we'll adjourn today and reconvene tomorrow at 9:00. I hope that you'll all be able to come back for the second day. Thank you.

[end of transcript]

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