

**PROTECTING SENIORS FROM MEDICATION  
LABELING MISTAKES**

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**HEARING**  
BEFORE THE  
**SPECIAL COMMITTEE ON AGING**  
**UNITED STATES SENATE**  
ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

WASHINGTON, DC

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## **PROTECTING SENIORS FROM MEDICATION LABELING MISTAKES**

**WEDNESDAY, DECEMBER 11, 2013**

U.S. SENATE,  
SPECIAL COMMITTEE ON AGING,  
*Washington, DC.*

The Committee met, pursuant to notice, at 3:48 p.m., in Room 562, Dirksen Senate Office Building, Hon. Bill Nelson presiding.  
Present: Senators Nelson, Gillibrand, Warren and Collins.

### **OPENING STATEMENT OF SENATOR BILL NELSON, CHAIRMAN**

The CHAIRMAN. Good afternoon.

I want to thank the witnesses.

This is a topic that is a true consumer protection issue. It ensures—the issue is to ensure that every senior receives the right information at the right time for every prescription.

I want to especially thank our colleague, Senator Kirsten Gillibrand for bringing this issue to the Committee's attention and for her many years of tireless work to try to ensure that people are given the correct information that they need as they consume prescription drugs.

Naturally, when we find out about this, all of us are shocked.

Adding to that shock is the fact that, knowing my own habits: I receive the prescription in a bag. It has got a label on the outside. It may or may not have all kinds of papers on the inside. And, if I really want to get into the detail, which some of the providers need, there is another piece of information that is about that thick, and it is wrapped around the bottle.

And so, if you are like me, I get it from the drugstore; I just rip open the bag, take out the little box, open the box and take the medicine and stick it in my toiletries kit.

And, of course, there are four different patient leaflets to say different things with one prescription.

That the one piece of information written for the consumer for every drug—it has not been approved by the FDA—a simple description.

So we are here to bring light in this Committee on what is not working and to come up with recommendations on what can work.

Consumer Reports surveys five different pharmacies and finds that the information provided to consumers on the same drug, in four of the five cases, omitted a warning that violated an FDA violation.

And the strategy is less than optimal when the FDA says that only 75 percent of patient medication—the information, when actu-

ally provided to the patients, even meets the minimum criteria for use—75 percent.

So the situation that we have here is unacceptable; it is dangerous; it is not transparent, especially for seniors who, as we know, have to take an awful lot of drugs at once.

And so we need to do better, and we are looking forward to the course of this hearing, of having you all advise us how we can make the process better.

Now our panel is star-studded.

We have Dr. Janet Woodcock. She is the Director of the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration.

We have Dr. Doris Peter, the Associate Director for Consumer Reports Health Rating Center.

We have Richard Scholz, an experienced pharmacist and a litigator.

And then we will hear from Dr. Gerald McEvoy, the Editor in Chief of the AHFS Drug Information and Consumer Medication Information with the American Society of Health-Systems Pharmacists.

I am going to turn the meeting over to my co-leader, Senator Collins, and she is going to run the meeting until I get back because there is a big colloquy going on, on the floor of the Senate, that I tried to get started, but Senators can be awfully long-winded—

[Laughter.]

The CHAIRMAN. [continuing]. On the floor of the Senate, and I could not get a word in edgewise.

So I will go over there and make my statement and immediately return. In the meantime, you will be in the tender, loving care of Senator Collins.

#### **OPENING STATEMENT OF SENATOR SUSAN M. COLLINS**

Senator COLLINS. [Presiding.] Thank you, Mr. Chairman. I promise to take good care of the gavel while you are gone.

I do very much appreciate the Chairman calling this hearing to examine ways to ensure that the written information given to patients with their prescription medications is clear, accurate, easy to read and up-to-date.

In an ideal world, all patients would receive extensive counseling about the risks, benefits and safe administration of their prescription drugs from their physicians and pharmacists. In the real world, however, these conversations are often limited and sometimes nonexistent.

It is all too easy for us in the rush of everyday life not to engage our health care providers about the details of the medications that they are prescribing or to take the time at the pharmacy for consultation with the pharmacist. As a consequence, we often rely on the written information we receive with our medications, either on the drug labels or in package inserts.

Even when we have been counseled by our physician or pharmacist, the written information can reinforce our knowledge of our prescription medications.

Ensuring that patients have access to accurate, up-to-date and consumer-friendly information is, therefore, an important compo-

ment of drug safety. This is particularly true for older patients who may be taking multiple medications and who may be experiencing vision or cognitive problems.

Most pharmacies send patients home with complex instructions and warnings about their medications. Unfortunately, too often, this literature simply is not helpful enough. Patients may receive several different types of information developed by different sources that may be inconsistent and are often difficult to read and understand.

A 2008 FDA study found that while 94 percent of consumers receive information leaflets with their new prescriptions, as the Chairman pointed out, only 75 percent of these leaflets meet even the minimum criteria for usefulness. It is no wonder that the Institute of Medicine has identified poor labeling as a critical source of the medication errors that injure at least 1.5 million Americans every year.

Improving the written information that accompanies prescription drugs is one way that we can help to improve patient safety.

My friend and colleague, Senator Gillibrand, has had a long-standing interest in this issue since her days in the House, and I want to recognize the fact that she suggested this hearing to our Committee.

Again, I am grateful to the Chairman for calling this hearing, and I look forward to hearing the testimony from our panel of witnesses.

Before we do turn to our witnesses, however, I do want to give Senator Gillibrand the opportunity to make any opening remarks that she wishes to deliver.

#### **OPENING STATEMENT OF SENATOR KIRSTEN E. GILLIBRAND**

Senator GILLIBRAND. Thank you, Madam Chairwoman. I am so grateful to you and Chairman Nelson for holding this hearing, for your leadership on the Aging Committee and for your steadfast resolve to really help our seniors. I really appreciate it.

The issue before us is of grave concern to our seniors, to our families, to families with children, and it is something that all Americans have a right to know:

What is the medication I am taking?

What are the effects?

What are the side effects?

Can this medication be combined with other medications?

What the risks to my health?

And, if that information is not provided in a simple way that is standardized and approved, for many, many people, that information may be lacking. It may actually not be there, or it may be limited in some way or inaccurate in some way. And that is what really matters.

So I am extremely grateful for this hearing. As we will hear today, the guidelines at the Department of Health and Human Services in 1996 regarding the information that should be provided to patients is very outdated. The FDA has been studying how best to streamline this information that patients received for the past five years.

But I am concerned that if FDA continues to provide only guidelines and is not given new oversight authority over the content of leaflets, we will continue to see patients struggle with inadequate information or lack of understanding of all they need to know for their drug regimes. It can lead to deadly mistakes.

So I am grateful that we are looking at this issue. This bill that I have drafted, that is one of the issues of today's hearing, has been endorsed by the AARP and the Consumers Union, who are both represented here today.

And I encourage them and other witnesses to help us thoroughly understand this topic and suggest steps that we can do and take to ensure that patients receive all the scientifically accurate, up-to-date information that is consistent for all identical or similar products.

Thank you very much.

Senator COLLINS. Dr. Woodcock, we are going to begin with you if you would proceed, please.

**STATEMENT OF JANET WOODCOCK, M.D., DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION**

Dr. WOODCOCK. Thank you, and I thank the members of this Committee for having the hearing.

I am Janet Woodcock. I am the Director of the Center for Drug Evaluation and Research at the FDA.

This is a very important issue to patients, as you have already said, particularly seniors, and I really appreciate the opportunity to discuss patient medication information and what we are doing.

It is common practice in many, if not most, developed countries to provide a leaflet containing patient-centric information when a prescription is dispensed. And the FDA has long tried to establish a similar system in the United States, but these efforts have been thwarted for several decades by various challenges.

Most recently, in the late 1990s, the agency was instructed to evaluate the private sector's ability to provide such information. Several evaluations, which were contracted out to independent groups, showed that the information provided did not meet key minimum criteria for things like legibility, readability and so forth.

FDA presented these findings at a public advisory committee meeting, and the FDA advisors recommended that the agency explore other mechanisms to get this information patients and that we collapse other existing mechanisms called Med Guides and patient package information and so forth, prescribing information, into a single leaflet.

Since that time, FDA has been conducting research on the content and format of such patient medication information, or PMI, and has held extensive stakeholder consultations, public meetings and workshops. And we have learned, among other things:

Number one, the standard format and content is very important, similar to what has been adopted for food labels and for OTC drugs. This standardization helps people navigate the information and find out more easily what they want to know and locate that in the information.

And, second, user testing is very important. Experts, by definition, know too much, and they cannot predict what a nonexpert—how a nonexpert will interpret certain information.

For example, use of a circle with a slash through it, that was used over a symbol of a pregnant woman, to say do not use, was taken by some people to mean the drug was a contraceptive and, therefore—the drug was a teratogen, causing birth defects. It should never be used by pregnant women.

As you can see, the experts and what they think consumers will walk away with may not be true. We have to have consumer testing, we think.

As a result of the research and stakeholder input, we plan to institute rule-making about a patient medication information leaflet.

I understand that there are additional issues that members have raised. And some, including people testifying today, have asserted that PMI should be the responsibility of a single private entity to ensure uniformity.

We suggest that information about a manufacturer's product is best produced and tested by that manufacturer. Certainly, many pharmaceutical manufacturers may choose to contract out the design and testing of patient information about their drug to a third party. But, particularly in the early years after approval of a drug, when there is a rapid pace of change around information of safety and efficacy, the drug manufacturer is the entity most up-to-date on these changes.

Finally, concern has been raised about the currency of the physician package insert. That is what Senator Nelson was referring to—the very thick document in there, which is for prescribers.

FDA completed a regulation years ago, requiring a new format for this document, but we were constrained by economic considerations from dealing with inserts earlier than, I believe, 2003, unless there was new clinical information submitted.

And, as a result, all new labels have this new format, all the physician-prescribing, but that is only 15 percent of all labels that have been updated.

I am happy to tell you today that we now have in place a program to update and maintain all drug labels. It is a big project. It is going to take a while, but we have a contract in place. We are conducting a pilot phase, and we have secured the cooperation of a number of major manufacturers.

Obviously, the physician insert information is what PMI will be based on, and it must be up-to-date if the patient information is going to be meaningful.

In closing, I thank you for your interest in this issue that is important to patients, particularly our senior citizens who rely on medication to sustain their health, and I look forward to the discussion.

Senator COLLINS. Thank you.  
Dr. Peter.

**STATEMENT OF DORIS PETER, PH.D., ASSOCIATE DIRECTOR,  
CONSUMER REPORTS HEALTH RATINGS CENTER**

Ms. PETER. Good afternoon. Thank you very much.

So I work at Consumer Reports, and I really appreciate the chance to be here today to bring you the consumer's perspective on how to improve prescription drug information that is given to consumers, often referred to, as was here, that stuff stapled to your bag when you leave the pharmacy, with the aim to address the more than 1 million people who experience preventable adverse events each year and the 100,000 people over the age of 65 who are hospitalized each year.

So I bring you this from the perspective of: I am a mother of three, also a caregiver of my mother, who recently died and a consumer myself of this information, but also the perspective of my work in this area through the Consumer Reports Best Buy Drug Project.

It is a grant-funded project that has been going on for about 10 years, where we provide millions of consumers with free, unbiased, evidence-based comparisons of drugs, in terms of their effectiveness, safety and cost. So we have a lot of experience in designing this information for consumers.

So I am here to advocate a somewhat different point, relating more to the actual content of the patient information, and I am here to advocate that consumers can be provided with—that they need to be provided with—the type of information in the right format so they can make informed decisions. And that is not possible today, and it is also not possible given the current plans for patient medication information.

Consumer information about drugs has to be evidence-based, patient-centered and transparent, and this is a chance for FDA to make a big impact in the ability of consumers to participate in their health care and play an active role in decision-making.

So, specifically, consumers need—and there is proof they can understand—quantitative information about the benefits and risks of a drug. And, without that quantitative information, consumers are not able to weigh those benefits and risks, and determine whether the drug is the right choice for them or not.

So there is an evidence-based approach to present this information, called the Drug Facts Box, and there is an example in the testimony I submitted that has been developed by Drs. Lisa Schwartz and Steve Woloshin. And it is a one-page table that summarizes the benefits and harms for each use of a drug. This approach has been carefully studied, including through national randomized trials, and has shown that most consumers can understand this information and that it improves decision-making.

FDA, in their own work in this area, identified that consumers are afraid of side effects, and that is the single greatest deterrent from filling and taking prescription drugs.

But one of the reasons they are afraid of it is because it is presented in a long list that does not put the benefits and the harms in balance with each other. And that is what this quantitative presentation can do. It can let them weigh that information.

In addition, the results from FDA focus groups underscore the point that consumers feel they want to be involved in this process of weighing the benefits and harms. They do not want it to be the physician that does it for them. They want to be involved. The only way they can do that is if they have the same information.

So withholding this information from consumers is not transparent, and it does not allow them to participate in their own decision-making of their care.

So, in relation to that, another piece of information that is not currently presented in PMI is the dosing information—standard dosing information—of the drug. This is really important. The consumers need to know what the standard use is and the standard way these drugs are used.

In a database that we collected of consumer-reported harm related to drugs, 40 percent of the reports were related to dosing errors alone.

And, in other countries, these usual dosages can be found as part of the patient leaflets, but not the consumer medical information that is here in the United States.

So I think we need to have a level playing field where consumers know what this information is. They can use this to alert the possibility of a prescribing error or possibly an off-label use of a drug that may not be in their best interest.

So it is really important to have this content available.

Our third recommendation for going forward and developing a new PMI is that the package insert not be used as the source of the information for consumer information for all the same reasons that were brought up before about the package inserts containing errors and not being up-to-date and inconsistent.

It is interesting to hear that there is a process for keeping the package inserts up-to-date, but the track record shows there can be even decades before new safety information gets into labels.

And we have our own case of a patient—one example, a patient who took a medication in 2007, and 2003 was when the safety information was known but not in the package label, and the package labels were only updated in 2013. So that is the reality right now.

The final recommendation is that manufacturers not author PMI. FDA's own work in this area has shown that consumers mistrust the pharmaceutical industry because they feel the industry is more concerned with profits than with safety. To ensure the generation of objective, unbiased PMI and ensure consumer confidence and trust in the content, the PMI should be delegated to an independent, unbiased third party other than that of the drug manufacturers.

Thank you for your attention. I am happy to answer any questions.

Senator COLLINS. Thank you.

Mr. Scholz.

**STATEMENT OF RICHARD SCHOLZ, JACOBS SCHOLZ  
AND ASSOCIATES, LLC**

Mr. SCHOLZ. Thank you, Madam Chairman, Senator Gillibrand. We appreciate the opportunity to be here today.

I am Richard Scholz. I am a registered pharmacist and also a member of the Florida bar and a practicing attorney, and I am a managing member of Jacob Scholz and Associates, LLC.

I am here today to share with you some of my experiences over 36 years as a pharmacist and being in the pharmacy industry and

being in the PBM industry, which is the industry that acts as an intermediary between insurers and employer groups as well as patients.

But I really come to you from a perspective as a pharmacist and to share with you some of the experiences I have had dealing with individuals who have struggled with their medication management, as well as in the most vulnerable population, which is our seniors, and it is because of their multitude of health issues as well as the volume of prescriptions that they have to consume to manage their health care.

The perspective that I use is that—and I like to keep it kind of simple because I am a simple farm boy. I grew up in Ohio on a farm, and my mother still lives on the farm where I grew up. She is 83 years old, and she struggles with this on a regular basis.

I mean, she has to manage medications. Fortunately, she calls me or whatever, and we can go through them. But other people do not have that opportunity.

I want to try to impress upon you the myriad of information that is going on out there, and the influences.

My mother is a patient. She is in the center of this paradigm.

She has got the physician who is getting information from the FDA through the package insert, which should always be there with the medication at all times, also getting drug manufacturers doing advertising to the physician. So that is a source of information that skews that particular input.

That information from the physician trickles down to my mother, occasionally, not always. Most of the time there is no counseling at the physician's office when there is a prescription issued.

Pharmacists, quite frankly, do not have time to counsel and, quite often, do not take time.

There is no standard document that is given to her with her prescriptions.

She gets information from her insurance company, who is trying to influence her to change her medication because it does not fit the formulary or it is on a three-tier formulary—so, another influencer for these senior citizens trying to balance all this information coming to them.

What they really need is they need unified, concise, FDA-approved, manufacturer-printed, manufacturer-distributed, pharmacy-dispensed—mandatory pharmacy-dispensed, like it is in the EU—concise patient information so that they have a fighting chance.

This document could be a reference document for all patients, all seniors. This is a generation that grew up with communicating on paper and verbal communication. They like to take notes on things. It allows a reference document.

If we can get a proper PMI, it would be a wonderful reference document so that when the senior goes back to the physician, they could ask questions off of the reference document.

The goal is to get a PMI that is in the marketplace with every prescription. And, in the United States, the GAO report that just came out said that there were 3.8 billion prescriptions in the retail market dispensed in 2011. That is 3.8 billion opportunities to educate a patient on their health care.

We have been on this track since 1979, when the patient package insert initiative was proposed and then shelved in 1982. That is my entire career that this population has been without this information.

And, quite frankly, we have had too many stakeholder meetings, too many studies, too many of these things.

The only real stakeholder when my mother opens that bottle in the morning and takes that medication is her, and that is what we have to focus on here—getting this information to every patient, about their medication, so that they can have a full understanding.

They can be empowered with enough information to enter the dialogue with health care providers so that they can actually empower them to improve their health.

In a moment, on the professional insert—very important for me as a pharmacist. Throughout my career, anytime I needed information, it was always written information accompanying the product no matter where it was in the distribution system. That is under siege today.

There is a—and I have it in your packet. In the record is an OIRA packet on their dashboard. There is a proposed rule to eliminate this, detach this, and have nothing with the package other than this label.

And then, to have to go find this somewhere else, this information—from a pharmacist's perspective, that is catastrophic. Of those 3.8 million, this information is accessed 12 times for every 1,000 prescriptions by pharmacists, that they fill—to check that information to see if the dosage is right, see if there is a contraindication.

Information that I would never propose to memorize, or commit to memory, changes too fast. It is important to have it here. That information is critical—that it never gets decoupled from this distribution of the product.

Thank you.

Senator COLLINS. Thank you.

Dr. McEvoy.

**STATEMENT OF GERALD McEVOY, PHARM.D., EDITOR IN CHIEF, AHFS DRUG INFORMATION AND CONSUMER MEDICATION INFORMATION, AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS**

Mr. McEVOY. Good afternoon, Ranking Member Collins.

And I also want to thank Senator Gillibrand for her leadership on this issue.

My name is Gerald McEvoy, and I serve as Assistant Vice President of Drug Information for the American Society of Health-System Pharmacists.

ASHP is the national not-for-profit professional and scientific society representing over 42,000 pharmacists and technicians who practice in hospitals and health systems.

ASHP has a nearly 40-year history of providing patients with meaningful information about medication. Our patient medication information is provided electronically, free of charge to consumers, through the National Library of Medicine and our own SafeMedication.com web site.

I am here today to provide ASHP's perspective on the issue of patient medication information, or PMI.

It is critical that patients receive the necessary information along with their prescription that will ensure optimally safe and effective medication use. FDA has proposed achieving this goal by putting manufacturers in charge of authoring the patient information for each of their products. Although we agree with the goal of streamlining and enhancing the usefulness of PMI, we strongly disagree with FDA's plan.

The FDA approach fails to ensure that patients will receive timely, accurate, consistent and impartial information. Under their proposal, FDA would replace the existing system that relies on independent publishers with manufacturer-authored information. More than 800 manufacturers would be charged with authoring PMI without any central editorial oversight.

First, we are concerned the FDA's proposal to allow manufacturers to develop their own PMI will result in inconsistent information across tens of thousands of drug products, creating confusion and possible harm for patients. There is no mechanism to ensure that PMI for identical products would be identical or that similar information would be included in every relevant medication within a drug class.

For example, Zocor's professional label first included a warning about the increased risk of myopathy in patients of Chinese descent in early 2010. Yet, almost four years later, the label for some generic products still does not include this critical risk information.

If a patient were switched from an innovator product to a generic, or from a generic to another, what safeguards would be in place to ensure the patient information is consistent regardless of whose product the patient is taking?

Second, we have concerns with the timeliness in which this information would be updated for all related products. FDA's proposal to tie PMI to professional labeling is troubling due to the lag times we currently see with respect to changes in this labeling. Information that is critical to safe, effective medication use must be made available to the patient as soon as it is known and must be available consistently and at the same time for all affected PMI.

For example, when Viagra was approved in 1998, the professional label included an appropriate alert that it should not be taken with a nitrate product, a potentially fatal interaction. And, yet, almost 15 years later, we found that 29 of 30 nitroglycerin products still do not include the same complete class-wide contraindication about Viagra and other ED products in their professional labels.

Third, FDA maintains they lack the resources to review and approve manufacturer-authored PMI. FDA claims approval is not necessary because manufacturers will base their patient information off of the FDA-approved professional label. Yet, as I have described, this claim clearly is not valid.

Given these concerns, ASHP continues to urge FDA to consider alternative models. ASHP believes that PMI developed by a single entity is the best pathway to ensure that timely, accurate PMI gets into the hands of patients to ensure safe, effective medication use.

FDA would be responsible for developing the standards against which this PMI would be judged.

We strongly support Senator Gillibrand's Cody Miller Initiative for Safer Prescriptions Act, which would permit the Secretary of HHS to pursue this alternative pathway.

As detailed in my written statement, FDA has never shown that the current system of PMI authorship by independent publishers has failed. Instead, FDA only has been able to show that what patients receive at the point of dispensing failed because of substantial downstream alteration of both the content and format of PMI.

Notable in the 2008 final report is the finding that independent publisher-authored PMI that was least altered at the point of dispensing actually exceeded FDA's content usefulness standards by over 20 percentage points. Thus, FDA is focusing on addressing concerns with authorship quality that simply do not exist.

Again, thank you for inviting me to testify today, and I, too, am happy to address your questions.

The CHAIRMAN. [Presiding.] Thanks to all of you.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Mr. Scholz, I want to follow up on an issue that you raised when you held up the bottle that had the prescription drug information insert for providers and pharmacists attached to it.

As you mentioned, the FDA is considering issuing a proposed rule that would require just electronic information for prescription drug products in lieu of these paper inserts, including the one that you just demonstrated.

As the Chairman is well aware, when I was the Chairman of the Homeland Security Committee and we did an in-depth investigation into Hurricane Katrina, we learned during the course of that investigation that there are times when electronic technologies are simply not available, whether it is due to temporary power outages or a catastrophic natural disaster or terrorist attack.

In addition, as a representative of a largely rural state, I know of many patients and health care providers that still reside in areas that have limited access to the internet.

As a practicing pharmacist, do you think that such a switch from paper to only electronic information would be in the best interest of health care providers and their patients?

Mr. SCHOLZ. Thank you, Senator Collins. Thank you for that question.

Certainly, this is an area that I am very passionate about because of the need to have this information available and have it readily available.

You brought up several important factors, and that is when the internet is not available and there would be a question about the information that is in this packet and how it affects that practitioner's decision as to how they dispense or whether they dispense or what directions they give the patient regarding this information.

That is clearly problematic in natural disasters.

It is clearly problematic in rural areas where there is difficult internet reception.

Also, it is difficult for Department of Defense pharmacists and health care professionals when they are in a forward operating

base that does not have that type of internet or they are not able to use the internet based upon some security issues.

So there are a number of different practice settings that this information would be totally unavailable to those practitioners at that time.

So that is incredibly important.

Then you go the next step, which is the fact that if you look—and, unfortunately there is a lot—oftentimes, when we look at health care policy, it is inside-the-Beltway thought processes. And sometimes we have to go out and think of what happens on the front line and outside the Beltway.

If you are a practicing pharmacist and you are working really diligently to fill 400 or 500 prescriptions, sometimes 800 prescriptions a day, your focus is right medication, right patient, right directions.

If something comes up as to a conflict or a question or a dosage that you need to make an interpretation based upon the fact that your patient has impaired renal function and this is metabolized through the kidneys—those kinds of issues. That information is here. It has always been here. It has been a lifeline for pharmacists.

And the GAO, in 2006, when the FDA actually passed a rule as to justify the financial significance of the rule, they cited the fact that to increase the information that is in this insert and increase the formatting, that would have significant effect on adverse drug events and hospitalizations. We do not disagree with that.

I think they were exactly right and this information needs to be very robust; it needs to be available.

When you look at a normal pharmacy with a high volume, they may have internet connectivity in their region, but from a workflow standpoint, they are not out surfing the internet for this information.

And there has been no study to my knowledge that has ever determined—and again, if I go back to GAO and I go back to the 2006 FDA economic significant analysis for expanding this professional insert, what we have is 12 times for every 1,000 prescriptions, this is accessed for information by the pharmacist. That is a significant amount of inquiries into this information that would not be available.

You cannot stop your workflow and go out and search the internet to go get this because that internet—and these are closed systems. They are closed operating systems, and they do not actually go out and surf the internet because of obvious HIPAA reasons and all the kinds of hacking reasons that would go on.

So having this information readily available so I can turn around, pick this up off the shelf and have this information is absolutely critical.

Senator COLLINS. Thank you.

Dr. Woodcock, I am going to ask you whether the FDA is still pursuing this idea in light of what Mr. Scholz has said.

The GAO also came out with a study in July that talked about a number of disadvantages that could offset any potential public health benefit of making that switch.

Dr. McEvoy, I have read, has this wonderful line when he talks about that if you have the guide in print that it always has power, it is immune from computer viruses and tampering, it does not freeze, and you know it is from a reliable source.

What is the status of the proposed rule-making?

Dr. WOODCOCK. We are still pursuing it. Keep in mind this is a proposal, and we would seek public comment.

I think, although I recognize people are very aligned with what has happened, you know, over time and the way we have always done things, I think we have to consider that sometime in the future electronic information is going to be how we get information. Actually, it is how many, many people get information now.

These inserts cannot be changed rapidly. And we have had situations where we have had new safety information, and the insert that is out there, okay, is in paper, and it cannot be rapidly revised. To modify that, we have to call all the product back and change the information, which takes it then out of the hands of patients and availability.

So there are liabilities to doing this. In addition, having one of these inserts per every unit means that there are millions of them produced for every product at a cost of over a million dollars per product line to fold these up and stick them into every package.

So there are tradeoffs here.

I understand the concern. We have discussed this for a long time, about the desire to have written information available for pharmacists.

So I think that is what will be discussed in the proposed rule, and we will get comments from everyone about the viability of this proposal at this point in time.

Senator COLLINS. Well, count me as one who thinks that it is not a good idea.

And I also am concerned, as the Chairman and I were discussing, if it extends to the patient insert, that there are a lot of seniors who just do not use the internet, and that would be a real problem as well.

But I think the many examples that Mr. Scholz gave, including those of our soldiers in a forward operating base, who may not, for security reasons, be able to get on the internet. I think that is an excellent point.

So I hope that the FDA will not proceed. I think it would lead—I understand your concern about updated information, but surely, there is a more effective way to deal with that.

Dr. WOODCOCK. Well, there are also work-arounds for some of the specific situations you have mentioned.

And, as far as patient information, we recognize that different people want their information in different formats. Some of the younger generation, as you well know, will throw away a piece of paper, but they want to be able to swipe their phone over 2D bar code and have the information available to them.

So we would contemplate doing it both ways.

Senator COLLINS. Before I have to go back to the Chairman, I would just respectfully suggest to you that if you did a demographic study of who is taking prescription drugs, it is far more

likely to be an older person than a younger person, particularly multiple medications.

Thank you.

The CHAIRMAN. In the last couple of years, I have had occasion to go to that detailed pharmaceutical information once.

And I have asked myself, as Susan and I have discussed this, would I have gone—and I am computer-literate. Would I have gone to the computer and tried to look this up? And I think the answer would be no.

Now there are a lot of senior citizens, which is the subject matter of this Committee—that we are trying to protect their interest. So we want to have you consider—heavy consideration—our concern.

Senator Gillibrand.

Senator GILLIBRAND. Thank you, Mr. Chairman, and thank you again for holding this really important hearing. I am very grateful.

To Dr. Peter, given your understanding of the needs for drug information by consumers, what do you propose the FDA should do in terms of proceeding in the development and testing of patient medication information?

What would you propose—because we have heard several concerns about, for example, not using the information from the drug manufacturer, not using even the information from the pamphlet that the FDA has approved because it can out of date.

What is your best recommendation?

Ms. PETER. Thank you, yes.

I think one of the key things is that there be attention to some of the issues surrounding the evidence behind the content itself, not just the format. There has been a lot of discussion and testing of where things go, but I think there has been not enough attention paid to the consumer needs for elements that have not been presented in the PMI drafts from FDA.

So the first thing I would ask is that we go back to the evidence base for what content, in terms of the specific elements, consumers need and to show them all the possible options of what could be in there because surveys of patients in other countries, outside the United States, have shown that consumers rank that dosing information just second to the information about the intended uses of the drug.

So consumers need that other information that is there, but the FDA testing and process had not, at least to my knowledge, uncovered that yet.

We would also like the whole process to be more transparent with a defined timeline. I was originally brought in to discuss this back in 2010, now again in 2013, and nothing really—there has not been much that has happened, and it was hard for us to figure out what had happened in the interim—so, a very transparent process with a defined timeline.

When it comes to the issue of, I already mentioned, manufacturer authorship, that we would—based on our own studies and those of others, the consumers do not trust the manufacturers, and we would urge FDA to reconsider manufacturer authoring of it.

And, finally, I do not know if this is even a possibility, but many groups, including some Federal agencies, are including consumers, not as stakeholders as a larger group, but as consumers actually

on the group that is working on the actual medication information itself.

Senator GILLIBRAND. Who do you recommend should author it?

Ms. PETER. I would say a third party. I do not have an individual group in mind.

But the manufacturer, for us—

Senator GILLIBRAND. Is there any group that is qualified to do it?

Ms. PETER. I would guess there are. I mean, there are currently other authors of this information now.

If the FDA has evidence-based standards to follow and those standards have been developed in a proper way, then those standards can be followed, I guess, by a number of organizations.

We would not propose to be one of those groups. I think we are an independent organization, but there are others that could follow that—follow the standards.

Senator GILLIBRAND. Dr. Woodcock, could you comment a little bit on some of the concerns that you have heard here today?

Even the FDA has admitted in a quote in 2008 by John Jenkins, the Director of the FDA's Office of New Drugs, who said it is "a false assumption that the FDA-approved labeling is fully accurate and up-to-date . . . we know that many current approved drug labels are out of date and in many cases contain incorrect information."

And we have heard that today through testimony.

If the professional labels are not accurate and up-to-date, why would the FDA propose using those labels as the foundation for the patient medication information?

Dr. WOODCOCK. Well, we think it is an unacceptable situation that the professional labels are not up-to-date, and as I said, we are launching an initiative that we have already started to bring those labels into currency and maintain them current.

I think it would be difficult to do patient medication information without having a current label, a professional label, to base it on because much of that information is highly technical. And we want to translate it for the patient, but drug interaction information and so forth is fairly technical, whether there is a meaningful interaction or not.

So we do believe that the professional labels must be updated. We have a new format, and many of the labels have been—current new labels have been done in that format. However, the older labels and many of the generic labels, as some of the other panelists have alluded to, are not up-to-date.

And Congress passed a user fee program for generics last year, and this has provided us the resources to oversee this industry more broadly.

Senator GILLIBRAND. Thank you.

I would also like to echo the concerns of Senator Collins, that I do hope you maintain a focus on actually having a paper pamphlet because for rural areas—

Dr. WOODCOCK. Certainly.

Senator GILLIBRAND. [continuing]. For the most at-risk, at-need, who do not have access to computers, for those communities, we have to make sure it is easily and readily accessible.

Dr. WOODCOCK. For the patients, we want to provide it in a format that they are going to use and that they most prefer. So we totally agree with you there.

Senator GILLIBRAND. Thank you so much.

Thank you, Madam Chairwoman. Thank you, Mr. Chairman.

The CHAIRMAN. I want to ask you all to comment.

To make this a lot more simple for the consumer, can we get a one-page other than your detailed pharmaceutical information?

Can this be boiled down to a one-page for the consumer to understand the purpose of the drug, the dosage—well, they can read their specific dosage by the doctor on the label, but—an understanding of what are the caveats, what are the side effects; such as, Dr. McEvoy, the example that you gave, don't dare take any of the following products if you are taking this drug, you gave of the nitrates?

Can we boil it down to a single page, Dr. Woodcock?

And then as you discuss that, can you also discuss—we are in a world of generics. And I finally understand what a drug is, and then I see the bottle of pills that I got is some long name that I have never heard of, and then I have to go and do my search to find out what it is in place of. So talk about that, too.

Dr. WOODCOCK. Certainly. In our testing, consumers overwhelmingly prefer a standardized, formatted, single-page leaflet, okay, at least as the starting point, with the key information, the kind of information you are talking about. That is what they really want.

And people are used to the food label. You know where to find whatever you are interested in—how many carbs, how much fat. Whatever you want to know, you know where to find it in the food label, all right.

The same with the OTC label that we have for OTC drugs—there is a box you can look at.

So the consumers would really like that. The patients would like that. And I believe that we can do that, all right.

And I agree; the generic names are very confusing. They are technical. They are kind of made-up names for chemists to look at. And we really need to explain to people kind of what they are getting so that they can make sure they did not get the wrong drug.

My husband came home last week with the wrong drug. He had a Schedule II narcotic for some unknown reason put in his prescription bag instead of what he was supposed to get.

So this happens all the time, and we need to help patients guard against this.

The CHAIRMAN. What about Spanish-speaking consumers?

Dr. WOODCOCK. We are very sensitive to the language issues. And we, for example, put our drug safety alerts out; we translate them all into Spanish so that patients can have the latest safety information.

I think that is one of the things we would have to talk about—is language issues.

The CHAIRMAN. Many moons ago, when I was a young Congressman, President Carter published a proposed regulation regarding this kind of information.

And then President Reagan—the pharmaceutical convinced the FDA that they could accomplish the same thing on a voluntary

basis, without a mandate, and the FDA withdrew the final regulations. But that was 30 years ago, or more.

So you want to comment on that?

Dr. WOODCOCK. Well, as I said in my oral statement, we have been thwarted for a long time. We have been trying for decades to get a leaflet which most other countries have for their patients and that is given to every patient when a prescription is dispensed.

We did a test recently, in the last decade. Relatively recently, we had an independent party test the quality of the voluntary what has been provided, and we found that it has not met the minimum standards.

Now, as was said by Dr. McEvoy, some of that is that the pharmacies altered that in many ways after the information was assembled, and that is a problem that we have to mutually address—how do we get a leaflet handed out, right? How do we make sure that happens, and it is not altered in different ways?

The CHAIRMAN. What interaction do you have with patients as you consider what you want to be labeled?

Dr. WOODCOCK. We have been doing a lot of research that involves patients and what their preferences are and how they interpret.

And what we have concluded is that each of these inserts, or whatever you want to call them—leaflets—should have consumer testing. That is sort of the best way to do this, to test whether the information is in there and that the people actually walk away with the right idea, with what we are trying to communicate.

And social science has taught us that the best way to figure that out is to test it because experts are very bad at communicating information to nonexperts.

The CHAIRMAN. And, yet, you are talking about taking all consumer information off the professional label; isn't that what you are discussing?

Dr. WOODCOCK. What we are discussing is the following: A proposal to have a single type of leaflet that is given to every patient every time they fill—every time a prescription is dispensed to a patient.

And you would—that would—right now, they get several kinds of information.

They get this voluntary information that is often printed on the white bag, that you were talking about, that people sort of tear off and throw away.

They may get a Med Guide if there is a serious issue, which is a long document that has some liabilities; that actually has to be approved by the FDA.

And they may get patient information that is part of a drug label, which we do for certain drugs where the consumer has to understand how to use it.

So they may get any one of these types, or several types, of information. That is very confusing.

And what the advisory committee and many other people have recommended is that that be put into one leaflet, a single document that people can expect.

The CHAIRMAN. Dr. McEvoy, when you write patient medication, do you consult patients?

Mr. MCEVOY. Do we consult patients?

The CHAIRMAN. Yes.

Mr. MCEVOY. We have engaged. In fact, there is a piece of active research that is going on now, evaluating the content of patient information from a concision basis. And so, yes, it is something that is periodically done.

We get feedback through the National Library of Medicine itself directly from consumers about that information as well.

What we are proposing is that FDA actually have the oversight for a new process but that that process not be run by the manufacturers themselves, but that instead—just as Dr. Woodcock has just mentioned, that they have a huge backlog of outdated information.

And for generic drugs, for example, 90 percent of those labels are older than 2001. And, yet, 80 percent of the drugs that get dispensed are generic medications. And that was a failure because the manufacturers did not voluntarily update their information and put it into the format.

And the path that FDA has chosen to correct that is not to go back to the manufacturers but to, instead, find a qualified outside contractor to actually develop it.

So what we are suggesting is a similar path to be pursued, to really create this information centrally. And we think that the only way that you can address the issues that I have described—inconsistency across labels, timeliness issues that currently exist with those labels—is to have a centralized process.

And we feel confident that if the FDA were to issue an RFP that there would be a number of highly qualified organizations, scientifically based and independent, who would step up and actually respond to such a proposal.

And it is ASHP's belief that that is the preferred path as opposed to having manufacturers author it independently.

The CHAIRMAN. Do you agree with that, Dr. Woodcock?

Dr. WOODCOCK. Well, let's think this through, all right.

It is true that we are doing a contract to get a version of the other labels, but for us to regulate the package insert, which is what Dr. McEvoy is talking about—that modified package insert—the manufacturer must submit it to us. So there has to be a step where the manufacturer adopts that as, or modifies it as, their updated label, right.

Now what we are—as a result of our research, we think there should be consumer testing of these labels. The actual leaflet should have consumer testing to make sure that people walk away with the right idea, okay; they do not have wrong ideas about that specific label.

Now for FDA to do an RFP, that means we would pay for all that testing, for every single label that would exist.

And, as far as I understand, for us to do any kind of surveys or testing, we need to get a lot of clearances and different things, as you are probably aware. So I think there is difficulty in making that workable.

We believe that we should regulate these leaflets to ensure that they are consistent, that they are consistent across classes, that their format—and so forth, that they are correct, that they are not promotional in nature, and so forth. But it is unclear that we

should be responsible for having all that patient medication information generated.

The CHAIRMAN. In regulating this, you would include having the correct, up-to-date information.

Dr. WOODCOCK. Absolutely. We—

The CHAIRMAN. What is your power? What is the stick of the FDA to require the pharmaceutical companies to do that?

Dr. WOODCOCK. Well, as you know, clarity on our authorities is always appreciated. As I said, we propose—we are contemplating rule-making to establish this currently.

The CHAIRMAN. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Dr. Peter, I am very intrigued by this drug facts sheet that was included with your testimony because as a consumer, to me, this is the kind of information that truly would be useful. It is so clear—what is the drug for, who might consider taking it, recommended monitoring, other things to consider, how long it has been in use, then the comparison between the drug and a sugar pill.

But I do not know what this drug facts paper comes from. Is this something you are recommending as a patient insert? Is it something that Consumer Reports does as part of its Best Buys?

Explain to me what this is.

Ms. PETER. Sure, definitely.

Senator COLLINS. I love it, but I do not know what it is.

Ms. PETER. Yes, we love it, too, and we cannot take credit for developing it. Drs. Schwartz and Woloshin at Dartmouth University developed the facts box.

We have been promoting it, and we have been working with them to create more of them because they do not have the funding to create them for all drugs.

So they have been thoroughly tested that consumers can understand them and make better decisions.

And, believe it or not, you know, even physicians would benefit from this because even the professional package insert does not lay out the information in a way that even a physician can weigh benefits and harms.

So I would—I mean, I would recommend it for both.

But for consumers, I would say this would go along with additional information, like the dosing, administration, things that are the standard information that is already part of the PMI.

This helps with the decision-making part—should I take this drug? Should I not take it? Am I experiencing a side effect because of the drug? Am I not? What are the risks and benefits?

So we see that it would go along with additional information. It could be on the back side of a two-page document or a one-page document, two-sided, if you are holding to the one-page limit.

But I really think this helps patients. Patients are more and more asked to participate in the decision-making, and this is a tool that can help them do this. And it makes the information transparent and available to them.

We have all this information. Why should they not have it?

Senator COLLINS. Thank you.

Dr. Woodcock, just one final question for you.

You mentioned that one reason the FDA is pursuing electronic drug labeling is that it would allow a faster turnaround if there is a new adverse consequence from the drug.

I do not know whether you are familiar with GAO's recent study from the summer on electronic drug labeling, but the GAO specifically addresses that issue and says that at least one manufacturer said that they could provide revised labeling for distribution within 24 hours.

The GAO also notes—and, goodness knows, I have found this to be true of my own pharmacy—that pharmacies are not carrying large inventories of drugs these days. They have moved more to a just-in-time-inventory. So it is not like they are going to have to replace a large quantity of drugs with new labeling.

GAO points out that it is much more likely that fewer drugs are kept in stock at any one point of time as businesses operate in a more just-in-time economy. So, with fewer drugs in stock, it is possible that there are fewer drugs with out-of-date labeling in circulation.

This seems to be contrary to, or at least answers, your concern to some extent about the timeliness if we moved away from the paper insert.

Dr. WOODCOCK. Well, first of all, I would say we have had issues where a drug label out in circulation did not match a new safety problem and people were very unhappy about that.

Second, FDA has tremendous experience with recalls and trying to get a drug pulled, a certain drug out of circulation, right.

And I do not know what the pharmaceutical company told the GAO, right, but I know even with tainted Heparin, if you recall that, we were still finding old Heparin that was contaminated on crash carts, and so forth, months and months after everyone knew that there was a problem with that Heparin.

So it is, by no means, trivial to extract those units out of the drug supply. There is a long supply chain now with intermediate, you know, suppliers and so forth.

So I understand your issue about the paper insert, and that is heard.

Senator COLLINS. Well, I would suggest a tainted drug is very different from a drug labeling issue. A tainted drug needs to be recalled regardless of what the labeling has on it.

Dr. WOODCOCK. Sure. What I meant was there was a tremendous effort to find that Heparin and get it out of the drug supply, and we were not entirely successful.

Senator COLLINS. And I understand that, but that is different from a labeling issue is my point.

Mr. Chairman, I have a few more questions, but I am going to submit them for the record. And I thank you very much for holding this very interesting hearing.

The CHAIRMAN. Thank you, Senator Collins, and as usual, thank you for your excellent cooperation as the co-leader of this Committee.

Dr. McEvoy, how frequently would you say that you see the inaccuracies between labels of the same drug on two different manufacturers?

Mr. McEVOY. I cannot give you a precise number. I have been looking at labels for over 30 years in my capacity, and I can tell you it is not uncommon occurrence.

I think where it is most common is across drug classes, where relevant information that appears, let's say to every statin, should appear.

We provided in our written testimony a study that looked black box warnings, which are the most serious warnings, and it took somewhere between 2 months and 14 years for some of those black box warnings to appear on all affected products.

So, you know, it is not an insignificant problem.

The other area where it is common is in drug-drug interactions, where the initial drug interaction will appear in a given label, but the other drug with which it interacts is not consistently updated.

We, as a publisher of drug information, then take it very serious to harmonize the information and to harmonize it at the same time. And what we are proposing is that FDA look at alternative models that can accomplish that.

Dr. Woodcock believes that regulation through their proposal is the only way to do that. We believe that FDA actually could have far greater control through a contract basis, where they establish specific metrics against which the contractor would be judged for their work.

The requirements for testing—in terms of the pharmaceutical industry, the overall cost of this is probably far less if that money were tied into additional PDUFA funding the next time that that is revisited than it is going to be for the entire industry to do this independently.

All we are asking is that the agency sit down and talk to people that have alternative models, that they be thoroughly thought through to see if, in fact, there are ways to accomplish this because, at the end of the day, we do not want seniors to be confused when they pick up a prescription this month, and three months from now they get a generic version of that, and the information that they receive is different because the professional label for that manufacturer's product is different. And that is our big concern.

The CHAIRMAN. If there were a simplified description of the drug, like Senator Collins had shown here in this one for Lunesta and showing it compared to taking a sugar pill, would this have averted the disaster that Senator Gillibrand brought up about Cody Miller?

Mr. McEVOY. I doubt that it would have because in the case of the Cody Miller disaster, which is a very unfortunate one, the information really had not emerged to a level to alert people. If you look at when FDA actually issued their first alert on that, it was some months after that particular tragedy. So I am not sure that would have specifically avoided that unfortunate situation.

But I think that the basis of what Senator Gillibrand is focusing on, beyond that, is making sure that the information gets into the hands of patients and their family members that they care for as quickly as it becomes available.

And had that information been available and not been available in the professional label upon which PMI was developed, then it would have been an avoidable tragedy.

So, you know, I think that would not have necessarily avoided it.

But I think that what that piece really shows is we need to test. We need to determine what essential information the patient needs, and we need to do that as the first.

And that is not the path that FDA has gone down. They have made an assumption that one page is adequate. We do not know that is the case. We do not know that it will contain all of the essential information that a patient needs to safely and effectively use that drug.

Dr. Woodcock mentioned the experience in Europe, for example. And at one of their meetings at Brookings, they had invited someone who is very active in creating labeling in Europe. And he commented specifically on the prototype that FDA had developed, that was limited to a single page, and looked at what they had established in Europe through good consumer testing as the required level of information the patients needed for safe and effective use of their drugs, and that was four or five pages.

So all we are saying is we want a science-driven process to establish that information. We do agree that what is out there now is far too long, but it is far too long because the standards that created that have not been revised since 1996.

The CHAIRMAN. Senator Warren.

Senator WARREN. Thank you very much, Mr. Chairman and Ranking Member. As always, you put together terrific and important hearings.

I want to apologize for being late. We are doing flood insurance on the floor and have a Banking hearing going on simultaneously.

But, when I was doing my homework for this hearing and reading all the materials that we got together and reading your testimony, I was struck by something I really wanted to come here today to ask about.

I understand from reading all this that the FDA does regulate drug information, but the trick is it is only for doctors, not for patients, and that patient information, like how to take a medication or the risks associated with the medication, are left largely unregulated.

And so this made me think of the Consumer Financial Protection Bureau, and it seems to me this is like saying that what the Consumer Financial Protection Bureau should do is make sure that mortgage brokers and credit lawyers understand the terms and conditions of mortgages and credit cards but not so much for making sure that consumers understand, when they are signing on the dotted line, what it really means.

So what I came today to try to understand is why consumers are not guaranteed the basic information they need to keep themselves safe and to keep their families safe.

So here is where I want to start this. In 2010 alone, the CDC found that over 15,000 people died from unintentional prescription pharmaceutical drug overdose. Unintentional—which means that some of them were not clear about how they should be taking their medications.

Now certainly some of these cases result from prescription drug abuse, but the FDA's own web site says that the readability of the labels is a major problem, particularly for older Americans.

Ten years ago, the FDA required over-the-counter medications to contain a consumer-friendly label for exactly this reason, but still, there is nothing in place for prescription drugs, which are significantly more dangerous.

So, Dr. Woodcock, we have, so far as I know, only the one study from 2010. But, is there anything particularly unusual about 2010, or is it fair to assume that thousands and thousands of people die every year from unintentional drug overdoses?

Dr. WOODCOCK. I think that is fair. I do not think we know the exact numbers, but it is fair to assume.

Senator WARREN. Fair to assume, okay.

Is it safe to assume that better information would have saved some of those people?

Dr. WOODCOCK. That is very likely.

Senator WARREN. All right. So when does the FDA plan to use its regulatory authority to implement effective, standardized patient information for prescription drugs?

Dr. WOODCOCK. Well, we have tried, as I said in my oral testimony, multiple times and have been thwarted, but we plan to engage in rule-making soon and try again to establish a patient leaflet that would be dispensed with every prescription given to a patient in the United States.

Senator WARREN. I am glad to hear that you want to aim in that direction, but I really am asking a when question. What is your timeline for when we are going to get these identifications, this information, into the hands of consumers?

Dr. WOODCOCK. Well, putting in place regulations in time-consuming—

Senator WARREN. Yes.

Dr. WOODCOCK. [continuing]. And is frustrating. So it usually take a number of years for us to get a regulation in place if we are successful.

And, as you probably read, we have tried multiple times to do this and have been thwarted in our efforts. So we plan to try again.

We have done quite a bit of research. We think it is necessary. Other countries have this. And we think it would be very desirable for the patients.

Senator WARREN. So, Dr. Woodcock, I actually—remember, I actually worked at one of these regulatory agencies and got this process started.

So let me ask it in smaller pieces. When are you starting the regulatory process? When are you going to put it in place?

Dr. WOODCOCK. We have had a Part 15 hearing. We have done a lot of research. You know, we have to have a lot of supporting information and documentation when we do put a rule forward.

So I cannot tell you when FDA will put that rule forward, but that is what we plan to do.

Senator WARREN. I do not want to hear the plan that you are going to start this. Is the plan—have you already started?

Dr. WOODCOCK. We have started writing the rule-making, but we—

Senator WARREN. Has the rule-making process started?

Dr. WOODCOCK. It depends what you mean by the rule.

We have not proposed a rule. No, there is no proposed rule out there.

Senator WARREN. So when do you plan to do that?

Dr. WOODCOCK. As quickly as we can.

Senator WARREN. So you are telling me that this is going to be a real priority for the FDA and that you are going to get this rule through.

Maybe I should ask this another way. What is the fastest you have ever gotten a rule through?

Dr. WOODCOCK. A few interim final rules on safety issues, where Congress told us to do it, we got it in place maybe in six months.

Senator WARREN. So it can be done in six months if it involves safety.

Dr. WOODCOCK. And congressional direction. Most of those had congressional direction that we do it.

Senator WARREN. Did the congressional direction give you new authorities you did not otherwise have.

Dr. WOODCOCK. Sometimes, in some cases.

Senator WARREN. Okay, but not in all cases. So you have the authority to get the rules done.

Dr. WOODCOCK. Well, with most regulations, our authority is always in question, as you know. And so that is one of the issues that happens in rule-making—is questioning whether the agency has the authority.

We regulate manufacturers, all right. And so one of the issues is, can the pharmacies be required to give out this information?

Senator WARREN. Are you saying you have some doubt about whether or not giving patients information that is effective, about how they should take their medications, is within the scope of the authority of the FDA?

Dr. WOODCOCK. I would say that certain parties would express doubt about that and how—

Senator WARREN. Well, I understand that is what litigation is about.

Dr. WOODCOCK. That is right.

Senator WARREN. But I also understand that the rule-making process can go forward.

Dr. WOODCOCK. We regulate manufacturers. We do not regulate the practice of a pharmacy.

Senator WARREN. I understand that. I understand that, but this is a question about getting the information out—safety to the patients. That was right.

And you did this for over-the-counter drugs.

Dr. WOODCOCK. Well, we regulate those directly. The manufacturers put that on the label. So we did do that.

Senator WARREN. Good.

I just want to say on this one, Mr. Chairman and to all of you, and particularly to the FDA, that if the FDA cannot commit to get this done in a reasonable time, then it is time for Congress to act. We are talking about a fundamental safety issue here. And it seems to me that is the judgment call we are going to have to make here.

The FDA has had a long time to do this and a lot of people who have died in the meantime. It is time for us to do something.

The CHAIRMAN. Well, I would suggest something we can do now that it looks like we are going to get a budget and a top line. The next process is the appropriations process. So let's visit with the appropriators with regard to the formulation of their appropriation for the FDA on language that would start this regulatory effort.

Let's talk about that.

Senator WARREN. Good, let's do.

Thank you, Mr. Chairman.

The CHAIRMAN. Okay. We want to thank all of you. This has been most enlightening, and you have been an excellent panel. Thank you very much.

The meeting is adjourned.

[Whereupon, at 5:09 p.m., the Committee was adjourned.]



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**APPENDIX**

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**Prepared Witness Statements and Questions  
for the Record**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

**STATEMENT**  
**OF**  
**JANET WOODCOCK, M.D.**  
**DIRECTOR**  
**CENTER FOR DRUG EVALUATION AND RESEARCH**  
**FOOD AND DRUG ADMINISTRATION**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**BEFORE THE**  
**SPECIAL COMMITTEE ON AGING**  
**UNITED STATES SENATE**  
**"PROTECTING SENIORS FROM MEDICATION LABELING**  
**MISTAKES"**

**December 11, 2013**

**INTRODUCTION**

Madam Chairwoman and members of the Subcommittee, I am Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss safe use of prescription medications and the steps FDA is taking to help reduce medication errors through labeling. My testimony will describe what FDA is doing to improve the quality of information being provided to patients about their medication.

FDA is charged with protecting and enhancing the public health by ensuring the safety, efficacy and quality of medicines. Helping all Americans make better informed decisions concerning their health care is a top priority of the Agency.

FDA's goal is for consumers to be provided with current, easy-to-understand information in a standardized format with an approved drug product. This is an important step in educating all patients, particularly vulnerable populations like seniors, about their medications and how to use them safely.

The current system for ensuring that patients receive essential medication information needed to use a drug safely requires improvement. In keeping with recommendations from FDA's Risk Communication Advisory Committee and input from stakeholders, FDA sees merit in adopting the use of a single document, standardized with respect to content and format, which we refer to as the Patient Medication Information (PMI). As I will discuss, FDA has been

working on a new framework for the development and distribution of PMIs to patients in consultation with stakeholders, including patients, providers, and drug manufacturers, among others.

#### **Statutory and Regulatory Authority**

FDA regulates the manufacture, sale, and distribution of drugs in the United States under authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), which includes approval of prescription drug labeling that provides information about the use of a drug. The term “labeling” is generally defined by section 201(m) of the FD&C Act as “all labels and other written, printed, or graphic matter: (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” Prescription drug labeling, as defined in the Federal regulations, specifically, 21 CFR 201.56, must meet certain requirements, including:

- Contain a summary of essential scientific information for the safe and effective use of the drug
- Be informative and accurate
- Not be promotional in tone, false, or misleading
- Not make claims or suggest uses for drugs when there is not sufficient evidence of safety and substantial evidence of effectiveness
- Contain information based, whenever possible, on data derived from human experience

The labeling also must be updated when new information becomes available that causes it to become inaccurate, false, or misleading.

In short, drug labeling contains important information essential to safe use of the drug. I will provide a brief overview of the history of prescription drug labeling and FDA’s efforts in this area.

**Providing Effective Information to Consumers about Prescription Drugs**

FDA is developing a new framework to provide patients with quality, up-to-date prescription product information that will promote the safe use of prescribed medication. The goal of the new PMI is to provide patient-oriented information for each prescription product. Currently, when a prescription is dispensed, a patient may receive any, all, or none of the following: Patient Package Insert (PPI), Medication Guide (MG), or Consumer Medication Information (CMI). These types of prescription information are developed by different sources and may be duplicative, incomplete, or not appropriately written for patient comprehension. FDA sees merit in adopting a single, standardized PMI document to accompany dispensed prescriptions.

Use of a standardized format for prescription product patient information is prevalent internationally. In the European Union (EU), Canada, Japan, Australia, and New Zealand, manufacturers provide patient information for prescription products based on regional regulations,<sup>1</sup> and distribution of this information generally occurs when the medication is dispensed to the patient. Almost all of these countries take steps to make the information consumer friendly; some require consumer testing with patient groups to ensure the information is legible, clear, and easy to use, and others simply stipulate that the documents should be simple, non-technical, easy to read, legible, and clearly written at a predefined reading level. Depending on regional regulatory requirements, disclosure of risks ranges from complete disclosure of all major risks and side effects to disclosure of only common and severe side effects.

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<sup>1</sup> Raynor DK, Svarstad B, Knapp P, et al. *Consumer medication information in the United States, Europe, and Australia: a comparative evaluation. J Am Pharm Assoc. 2007;47(6):717-724*

**Patient Package Inserts (PPIs)**

PPIs are developed by the manufacturer, approved by FDA, and required to be dispensed with specific products or classes of products (*e.g.*, estrogen-containing products). Since 1968, FDA regulations have required that PPIs written specifically for patients be distributed when certain prescription drugs, or classes of prescription drugs, are dispensed. The first FDA regulation requiring a PPI was published in 1968, mandating that isoproterenol inhalation medication contain a short warning that excessive use could cause breathing difficulties. Other PPIs are submitted to FDA voluntarily by the manufacturer and approved by FDA, but their distribution is not mandated. In the 1970s, FDA began evaluating the general usefulness of patient labeling for prescription drugs, resulting in a series of regulatory steps to help ensure the availability of useful written consumer information.

In 1979, FDA proposed regulations that would have required written patient information for all prescription drugs<sup>2</sup> and, in 1980, finalized those regulations, establishing requirements and procedures for the preparation and distribution of manufacturer-prepared and FDA-approved patient labeling for a limited number of prescription drugs.<sup>3</sup> However, FDA revoked those regulations in 1982 based on assurances, in part, by health care professional associations, private-sector providers of written information for patients, and pharmaceutical manufacturers that the goals of the final rule could be met more effectively without regulation.<sup>4</sup>

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<sup>2</sup> 44 FR 40016, July 6, 1979.

<sup>3</sup> 45 FR 60754, September 12, 1980

<sup>4</sup> 47 FR 39147, September 7, 1982

**Medication Guides (MGs)**

MGs come with many prescription medicines and address issues specific to particular drugs and drug classes. They contain FDA-approved information that can help patients avoid serious adverse events by underscoring significant safety concerns that can be weighed against the benefits of the drug. MGs are developed by the manufacturers, reviewed by FDA, considered to be part of the product's approved labeling, and required to be distributed by pharmacies with each prescription.

FDA is committed to monitoring the progress of this voluntary private-sector effort. FDA surveys showed that, although the distribution of written prescription drug information increased, the usefulness of the information was highly variable. As a result, FDA proposed a regulation entitled "Prescription Drug Product Labeling: Medication Guide Requirements,"<sup>5</sup> which was designed to set specific distribution and quality goals, and time frames, for distributing written information. Goals of the proposed rule were: by 2000, 75 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions, increasing to 95 percent in 2006. The proposed rule would have required manufacturers to prepare and distribute MGs for a limited number of prescription drug products that posed a serious and significant public health concern.

As FDA was reviewing the comments received in response to the proposed rule, in August 1996, legislation was enacted<sup>6</sup> regarding patient labeling that adopted the goals and time frames of the 1995 proposed rule. The legislation established a voluntary private-sector

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<sup>5</sup> 60 FR 44182, August 24, 1995

<sup>6</sup>Section 601 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, for the fiscal year ending September 30, 1997, Public Law 104-180, August 6, 1996.

process through which a committee (Steering Committee) of interested stakeholders (national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, and patient drug information database companies, among others) would develop a long-range, comprehensive action plan to achieve the goals of FDA's proposed rule concerning patient labeling, and required the Secretary of HHS to evaluate the private sector's progress toward meeting the goals.

Though the law prohibited FDA from taking further regulatory action if private-sector initiatives met the goals of the plan within specified time frames, legislative history makes it clear that this law did not preclude FDA from using its existing authority to "require as part of the manufacturer's approved product labeling the dispensing of written information inserts to consumers...to meet certain patient safety requirements."<sup>7</sup>

In 1998, FDA published a Final Rule<sup>8</sup> that established a program under which MGs would be required for a small number of drugs considered to pose a serious and significant public health concern. The Final Rule did not deal with the private-sector voluntary program but only applied to the mandatory program covering products of "serious and significant concern."

In September 2007, the FD&C Act was amended to include MGs as one potential element of a Risk Evaluation and Mitigation Strategy (REMS). FDA may require a sponsor to develop a REMS, if it determines a REMS is necessary to ensure that the benefits of a drug outweigh the risks. The use of MGs as part of REMS, particularly as part of REMS that affect whole

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<sup>7</sup> S. Rept. 104-317, 104<sup>th</sup> Cong., 2d sess., p. 132-33, July 11, 1996.

<sup>8</sup> 63 FR 66378, December 1, 1998

classes of drugs, has provided further impetus to evaluate different approaches to providing the type of prescription drug information that is normally provided in an MG to consumers.

Recognizing that many consumers rely on technology, the National Institutes of Health's Web site, DailyMed, provides quality information about marketed drugs, including medical product labeling that is currently in use and distributed by manufacturers as package inserts. This site provides health information for providers and the public with a standard, comprehensive, up-to-date, look-up-and-download resource of medical product labeling, including MGs. In addition, FDA posts updated information on MGs on its website.

#### **Consumer Medication Information (CMIs)**

CMI is information developed by the private sector intended for distribution with every prescription dispensed at a pharmacy. CMI information is not FDA-reviewed or approved.

In 1998, FDA contracted with the National Association of Boards of Pharmacy (NABP) to perform a pilot study to test the usefulness of the consumer medication information being developed. The standard for determining whether a particular piece of written medication information was useful to consumers came from a 1996 report entitled "Action Plan for the Provision of Useful Prescription Medicine Information,"<sup>9</sup> drafted by the Steering Committee established by the 1996 legislation. This plan, known as the Keystone Action Plan, delineated

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<sup>9</sup> Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, unpublished report submitted to The Honorable Donna E. Shalala, HHS Secretary, December 1996, available at <http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/reportsbudgets/ucm163793.pdf>

the following criteria for evaluating whether a particular piece of written medication information is useful to consumers, stating that materials should be:

- Scientifically accurate
- Unbiased in content and tone
- Sufficiently specific and comprehensive
- Presented in an understandable and legible format that is readily comprehensible to consumers
- Timely and up to date
- Useful, in that it enables consumers to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm

The results of the pilot study found that much of the CMI that were assessed failed to provide sufficiently clear or specific information.<sup>10</sup> More than 90 percent of the CMI was judged to be unacceptable in terms of comprehensibility or readability. Virtually none of the information met acceptable levels of legibility. The study's conclusion noted that existing CMI "falls short of the information quality level required in the 1996 federal legislation."

In July 2002, FDA's Drug Safety and Risk Management Advisory Committee (Advisory Committee) met to review the study results and public comments.<sup>11</sup> The Advisory Committee recommended that FDA take a more active role in advising and encouraging the private sector to meet the next target goal set for 2006.

A final report issued in 2008 concluded that the CMI distribution method through pharmacies appears effective but that the content and format for this information had various shortcomings, including lack of critical information about the management of medications,

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<sup>10</sup> Bonnie L. Svarstad, Ph.D. and Jeanine K. Mount, Ph.D., "Evaluation of Written Prescription Information Provided in Community Pharmacies (December 21, 2001)

<http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm169753.htm>

<sup>11</sup> <http://www.fda.gov/ohrms/dockets/ac/cder02.htm#DrugSafetyRiskManagement>

significant redundancy of information resulting in long leaflets, poor formatting, and inadequate legibility and reading level.<sup>12</sup> The 2008 report also noted that it was unclear what quantity, presentation, and format of CMI will result in adequate patient comprehension and appropriate actions to improve patient safety.

### **Evolution of Patient Medication Information (PMIs)**

In June 2008, FDA received a Citizen Petition from a large group representing pharmacy practice, medical consumers, and medical communications companies, requesting FDA adopt a “one-document solution” or PMI to replace CMIs, PPIs, and MGs.<sup>13</sup> In February 2009, the Advisory Committee also recommended adopting a single standard document for communicating essential information about prescription drugs, as a replacement for CMIs, PPIs, and MGs.<sup>14</sup> In September 2009, FDA held a public workshop to discuss optimal content and format of written prescription drug information. Input was sought on four draft patient information prototypes, which were developed through review of scientific literature, current labeling practices, and guidance. In response to the feedback provided during these meetings, FDA developed three draft patient information prototypes. In May 2010, FDA announced the design of an evaluation strategy to test different ways of presenting information about prescription drugs to patients, asking for comments by July 2010.

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<sup>12</sup>Carole L. Kimberlin, Ph.D., Almut G. Winterstein, Ph.D., “Expert and Consumer Evaluation of Consumer Medication Information (November 4, 2008) <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM163783.pdf>

<sup>13</sup> National Consumers League, et al. – Citizen Petition Requesting FDA Action on a “One Document Solution: for all Pharmacy-Based Communications, June 30, 2008, <http://www.regulations.gov/#/documentDetail;D=FDA-2008-P-0380-0001>.

<sup>14</sup><http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/riskcommunicationadvisorycommittee/ucm152593.pdf>

During 2010 and 2011, FDA convened a series of expert meetings and public workshops, through a cooperative arrangement with the Engelberg Center for Health Care Reform at the Brookings Institution, to obtain broad stakeholder input on the design, content, format, and distribution of PMIs. There was agreement among the expert participants that providing patients with clear, concise, and consistent information about their medication is an important and feasible goal, and that achieving this goal requires broad-based collaboration among key stakeholders, including health care professionals, pharmacies, academia, and technology vendors. Areas for further exploration were highlighted, such as evaluation metrics, stakeholder cooperation for PMI distribution, and potential pilot studies. Since the last Brookings Institution meeting in February 2011, FDA has held approximately 18 meetings with a variety of stakeholders on various aspects of PMI, such as labeling content, patient comprehension, and distribution studies. FDA is continuing these discussions with Brookings and others so that the many benefits of useful and effective PMI may be realized.

**Safe Use Initiative**

FDA is also taking additional steps to foster safe use of drugs and help prevent medication errors through our “Safe Use Initiative” program, established in November 2009, to help reduce the likelihood of preventable harm from medication use. Today, tens of millions of people in the United States depend on prescription and over-the-counter (OTC) medications to sustain their health—as many as 3 billion prescriptions are written annually. Too many people, however, suffer unnecessary injuries, and some die, as a result of preventable medication errors. We believe that many of these medication-related risks are manageable, if parties committed to the safe use of medications work together. Through this initiative, FDA

seeks to partner and collaborate with relevant stakeholders to measurably reduce preventable harms from medications, thereby improving patient health.

FDA's Safe Use Initiative identifies, using a transparent and collaborative process, specific candidate cases (*e.g.*, drugs, drug classes, and/or therapeutic situations) that are associated with significant amounts of harm. Cases are analyzed for their potential for coordinated FDA/stakeholder actions to better manage related risks and reduce harm. If the analysis suggests a potential benefit from an intervention, FDA and its collaborators will develop appropriate activities and evaluation metrics.

In September 2010, CDER's Safe Use Initiative team convened a roundtable of more than 40 experts from academia, health care management, consumer advocacy, and government to address the safe use of pain medications in older adults. The goal of the roundtable was to seek and bring into voluntary collaboration key stakeholders from the health care community to develop and implement interventions aimed at quantifiably reducing preventable harm from the use of pain medications in older patients. This roundtable was an important first step in stimulating collaboration and an exchange of information about appropriate approaches in safe pain management for older adults.

FDA is currently engaged in three collaborative activities focused on patient labeling and geriatric inclusion issues. First, as a direct outgrowth of the roundtable, in collaboration with Dr. Joseph Pergolizzi, M.D., a Florida pain practitioner and adjunct assistant professor at Johns Hopkins University, FDA has developed a collaboration of greater than 30

professionals with expertise in geriatrics and non-steroidal anti-inflammatory drugs (NSAIDs). Their goal is to increase awareness in health care providers about age-related factors and adverse events in patients using NSAIDs. The collaboration will highlight the “Best Practices in Safe NSAID Use in Geriatric Patients,” and that information will be shared with pain specialists through a series of open-access electronic publications.

The Safe Use Initiative is also working on a project with the National Council for Prescription Drug Programs that includes representatives from McNeil Consumer Healthcare, a Division of McNeil-PPC, Inc., whose objective is to ensure that when there are two-ingredient prescription medications for pain, acetaminophen and a second active ingredient, both are clearly labeled on the prescription vial. Instead of the abbreviation “APAP” from the active ingredient acetyl-para-aminophenol for acetaminophen, it is recommended that acetaminophen be spelled out along with the name of the second ingredient on the vial label so that patients taking these two-ingredient products are aware of the existence of acetaminophen in their prescription drug, can compare active ingredients in the prescription and OTC drugs, and can avoid an acetaminophen overdose by taking two or more drugs that contain acetaminophen. Another objective of this project is to have the overdose and liver toxicity warnings consistently displayed on prescription vials in language that is patient-centered and simple to understand. We have found that these warnings are also being voluntarily and consistently affixed to vials for prescriptions containing acetaminophen.

Finally, we are collaborating with the Institute for Safe Medication Practices (ISMP), which developed several information sheets on “high alert” prescription medicines such as warfarin,

insulin analogs, methotrexate, and opioids. These information sheets provide a tool for the pharmacist to use to point out a few selected important points for counseling, and provide an information sheet for the patient to use as reference. ISMP piloted the information and found that both pharmacists and consumers appreciate the information. Through FDA, ISMP has connected to Pharmacy Quality Alliance to determine how to best display and use these information sheets in retail pharmacy settings. Pharmacy Quality Alliance is a non-profit, consensus-based, multi-stakeholder membership organization committed to improving health care quality and patient safety with a focus on the appropriate use of medications.

### **Generic Drugs**

FDA understands that generic drugs play an important role in granting access to safe, effective, and affordable products that will benefit the health of consumers, and especially seniors—who often are on fixed incomes. All drug manufacturers, whether brand or generic, have an ongoing obligation to patient safety and to ensure that their product labeling is accurate and up to date. Just last month, FDA issued a proposed rule that would allow generic drug manufacturers to independently update product labeling with certain newly acquired, safety-related information and promptly distribute the revised labeling before FDA’s review of the change, just as brand manufacturers are currently allowed to do. If finalized, this proposed rule would help ensure that health care professionals and consumers have quicker access to the latest safety information for the medications they use. This proposed regulatory change would benefit the public health by improving communication of important drug safety information to health care professionals and consumers.

**CONCLUSION**

FDA recognizes that the current system used to ensure patients receive the essential medication information needed to use a drug safely can be improved. We share the views of our stakeholders that to use prescription medications safely, patients need to receive clear, actionable information. Through our PMI initiative, FDA is striving to reduce the harm caused by inappropriate drug use and enhance the benefits of drugs by facilitating their proper use. We will keep the Congress informed of our progress as we conclude this comprehensive effort. I am happy to answer questions you may have.



Questions Addressed to Dr. Janet Woodcock From The Special Committee on Aging

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

The Honorable Bill Nelson  
Chairman  
Special Committee on Aging  
United States Senate  
Washington, D.C. 20510-6050

MAY 05 2014

Dear Mr. Chairman:

Thank you for the opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the December 11, 2013, hearing before the Special Committee on Aging entitled, "Protecting Seniors from Medication Labeling Mistakes." This letter provides responses for the record to questions posed by certain Members of the Committee.

If you have further questions, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Sally Howard".

Sally Howard  
Deputy Commissioner  
Policy, Planning and Legislation

cc: The Honorable Susan M. Collins  
Ranking Member

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We have restated each Member's questions below in bold, followed by our responses.

**The Honorable Bill Nelson**

- 1. FDA indicated at the hearing that they have been thwarted in implementing FDA approved, manufacturer printed and distributed, PMI since 1979. Please explain specifically each of these efforts, and factors that contributed to FDA's efforts having been thwarted.**

The lengthy history of this issue illustrates various points in time where FDA intended to regulate prescription drug information directed to patients. In 1979, FDA proposed regulations that would have required written prescription drug information to be provided for patients for all prescription drugs<sup>1</sup> and, in 1980, finalized those regulations, establishing requirements and procedures for the preparation and distribution of manufacturer-prepared and FDA-approved patient labeling for a limited number of prescription drugs.<sup>2</sup> However, FDA revoked those regulations in 1982 based on assurances, in part, by health care professional associations, private-sector providers of written information for patients, and pharmaceutical manufacturers that the goals of the final rule could be met more effectively without regulation.<sup>3</sup>

After the rule was revoked, FDA monitored the progress of this voluntary, private-sector effort. FDA conducted surveys that showed that, although the distribution of written prescription drug information increased, the usefulness of the information was highly variable. As a result, in 1995, FDA proposed a regulation entitled "Prescription Drug Product Labeling: Medication Guide Requirements,"<sup>4</sup> which was designed to set specific distribution and quality goals, and time frames, for distributing written patient information. Goals of the proposed rule were: by 2000, 75 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions, increasing to 95 percent by 2006. The proposed rule would have required manufacturers to prepare and distribute Medication Guides (MGs) for a limited number of prescription drug products that posed a serious and significant public health concern.

In August 1996, as FDA was reviewing the public comments received in response to the proposed rule, legislation was enacted<sup>5</sup> regarding patient labeling that adopted the goals and time frames of the 1995 proposed rule. The legislation established a voluntary private-sector process through which a committee (Steering Committee) of interested stakeholders (national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, and patient drug information database companies, among others) would develop a long-range, comprehensive action plan to achieve the goals of FDA's proposed rule concerning patient labeling, and required the Secretary of HHS to evaluate the private sector's progress toward meeting the goals.

<sup>1</sup> 44 *Federal Register (FR)* 40016, July 6, 1979

<sup>2</sup> 45 *FR* 60754, September 12, 1980

<sup>3</sup> 47 *FR* 39147, September 7, 1982

<sup>4</sup> 60 *FR* 44182, August 24, 1995

<sup>5</sup> Section 601 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, for the fiscal year ending September 30, 1997, Public Law 104-180, August 6, 1996

Though the law prohibited FDA from taking further regulatory action if private-sector initiatives met the goals of the plan within the specified time frames, legislative history makes it clear that this law did not preclude FDA from using its existing authority to “require as part of the manufacturer’s approved product labeling the dispensing of written information inserts to consumers...to meet certain patient safety requirements.”<sup>6</sup>

In 1998, FDA contracted with the National Association of Boards of Pharmacy (NABP) to perform a pilot study to test the usefulness of the written medication information developed by the private sector; i.e., consumer medication information (CMI). The standard for determining whether a particular piece of written medication information was useful to consumers came from a 1996 report entitled “Action Plan for the Provision of Useful Prescription Medicine Information,”<sup>7</sup> drafted by the Steering Committee, organized pursuant to the 1996 legislation. This plan, known as The Keystone Action Plan, delineated the following criteria for evaluating whether a particular piece of written medication information was useful to consumers, stating that materials be:

- Scientifically accurate
- Unbiased in content and tone
- Sufficiently specific and comprehensive
- Presented in an understandable and legible format that is readily comprehensible to consumers
- Timely and up to date
- Useful, in that it enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm

The results of the pilot study found that much of the CMI assessed failed to provide sufficiently clear or specific information.<sup>8</sup> More than 90 percent of the CMI was judged to be unacceptable in terms of comprehensibility or readability. Virtually none met acceptable levels of legibility. The study’s conclusion noted that the existing CMI “falls short of the information quality level required in the 1996 federal legislation.”

In July 2002, FDA’s Drug Safety and Risk Management Advisory Committee (Advisory Committee) met to review the study results and public comments.<sup>9</sup> The Advisory Committee recommended that FDA take a more active role in advising and encouraging the private sector to meet the next target goal set for 2006.

<sup>6</sup> S. Rept. 104-317, 104th Cong., 2d sess., p. 132-33, July 11, 1996

<sup>7</sup> Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, unpublished report submitted to The Honorable Donna E. Shalala, HHS Secretary, December 1996, available at

<http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/reportsbudgets/ucm163793.pdf>

<sup>8</sup> Bonnie L. Svarstad, Ph.D. and Jeanine K. Mount, Ph.D., “Evaluation of Written Prescription Information Provided in Community Pharmacies (December 21, 2001)

<http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm169753.htm>

<sup>9</sup> <http://www.fda.gov/ohrms/dockets/ac/cder02.htm#DrugSafetyRiskManagement>

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In July 2006, a Guidance document was issued to help the private sector meet the 2006 congressionally mandated goals in PL 104-180.<sup>10</sup> This Guidance reviewed the initial Action Plan for CMI and made specific recommendations for each Action Plan criterion.

A final report, published in 2008 concluded that the CMI distribution method through pharmacies appears effective but the content and format for this information had various shortcomings, including lack of critical information about the management of medications, significant redundancy of information resulting in long leaflets, poor formatting, and inadequate legibility and reading level.<sup>11</sup> The 2008 report also noted that it was unclear what quantity, presentation, and format of CMI will result in adequate patient comprehension and appropriate actions to improve patient safety.

FDA began working on the PMI initiative based on several factors, including the failure of the private sector to meet the 2000 and 2006 goals of the Keystone Action Plan, a Citizen Petition, and the recommendation of the Advisory Committee. In June 2008, FDA received a Citizen Petition from a large group representing pharmacy practice, medical consumers, and medical communications companies, requesting FDA adopt a “one-document solution” to replace CMIs, Patient Package Inserts (PPIs), and MGs.<sup>12</sup> In February 2009, the Advisory Committee also recommended adopting a single-standard document for communicating essential information about prescription drugs as a replacement for CMIs, PPIs, and MGs.<sup>13</sup>

Since that time, FDA has made steps forward with the initiative. In September 2010, FDA held a public workshop to discuss optimal content and format of written patient prescription drug information. Input was sought on four draft patient information prototypes, which were developed through review of scientific literature, current labeling practices, and guidance. In response to the feedback provided during these meetings, FDA developed three draft patient information prototypes. In May 2010, FDA announced the design of an evaluation strategy to test different ways of presenting information about prescription drugs to patients, asking for comments by July 2010.

In 2010 and 2011, FDA convened a series of expert meetings and public workshops through a cooperative arrangement with the Engelberg Center for Health Care Reform at the Brookings Institution (Brookings) to obtain broad stakeholder input on the design, content, format and distribution of patient medication information (PMI). There was agreement among the expert participants that providing patients with clear, concise, and consistent information about their medication is an important and feasible goal, and that achieving this goal requires broad-based collaboration among key stakeholders, including health care professionals, pharmacies,

<sup>10</sup> Guidance: Useful Consumer Medication Information (CMI). Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM117156.pdf>

<sup>11</sup> Carole L. Kimberlin, Ph.D., Almut G. Winterstein, Ph.D., “Expert and Consumer Evaluation of Consumer Medication Information (November 4, 2008) <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM163783.pdf>

<sup>12</sup> National Consumers League, et al. – Citizen Petition Requesting FDA Action on a “One Document Solution: for all Pharmacy-Based Communications, June 30, 2008, <http://www.regulations.gov/#!documentDetail;D=FDA-2008-P-0380-0001>

<sup>13</sup> <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/riskcommunicationadvisorycommittee/ucm152593.pdf>

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academia, and technology vendors. Areas for further exploration were highlighted, such as evaluation metrics, stakeholder cooperation for PMI distribution, and potential pilot studies. Since the last Brookings meeting in February 2011, FDA has held approximately 18 meetings with a variety of stakeholders on various aspects of PMI, such as labeling content, patient comprehension, and distribution studies. FDA is continuing these discussions with Brookings and others so that the many benefits of a useful and effective PMI may be realized.

- 2. During the hearing, FDA mentioned a number of studies related to development of a single-page PMI document. Please provide the committee with any peer reviewed studies conducted or commissioned by FDA related to this issue.**

FDA is taking a scientific approach to the development of PMI, which includes conducting research to obtain public input to inform our decision-making process. The results of two recently completed studies, an FDA study (75 FR 23775, May 4, 2010) and a study being performed under a cooperative agreement with Brookings, are being used to help inform FDA on the usefulness and parameters of various options for patient information documents. The information concerning the study performed by Catalina Health under the cooperative agreement with Brookings is available online at <http://www.pm360online.com/making-prescription-medication-information-user-friendly-the-time-has-come/>. The results of the FDA study have not yet been released; however, they will be made available in the near future.

- 3. There was some discussion at the hearing regarding electronic v. printed consumer information for patients at the pharmacy. Has the Agency taken a clear position on this issue? Please articulate agency actions to ensure printed information remains available to all consumers about their medications.**

FDA intends to make PMI available in both printed and electronic formats.

- 4. Under the agency's proposal, pharmaceutical manufacturers would be charged with writing the patient medication information.**
- a. How will the FDA ensure that information is accurate and consistent and not result in any confusion because of differences between one manufacturer's product and another before being delivered to a patient?**

FDA has not formally announced a proposal at this time. We are currently in the process of developing the framework for PMI, including procedures for developing and maintaining PMI. To ensure accuracy, FDA intends that PMI will be based on FDA-approved professional labeling, consumer testing, updates when certain changes are made to the approved labeling, and a quality surveillance mechanism that enhances compliance.

FDA is considering a mechanism similar to that used with professional labeling, in which generic labeling generally aligns with the labeling of the branded product. Concerning class PMI, FDA is not considering class labeling for PMI at this time. We intend for PMI to contain information based on the product prescribed to the patient. Although products within the same class have similarities, the information specific to each product differs. For this reason, FDA

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believes that it is important that PMI contain information specific to the particular prescription drug product it accompanies.

- b. Are you concerned that promotional information might creep in as opposed to unbiased patient education materials, particularly since no one will be reviewing each piece before it gets into patients' hands?**

We intend that PMI be based on information found in FDA-approved professional labeling, and like the professional labeling, not be promotional in nature.

- c. If manufacturers haven't kept the labels that we've heard are relied upon by doctors and pharmacists up to date and consistent, how will this impact what's written for consumers?**

Ongoing work to ensure accuracy in PMI includes designing a framework that would base PMI on FDA-approved professional labeling, ensuring PMI is updated when certain changes are made to the approved professional labeling, and developing a quality surveillance mechanism to enhance compliance.

- 5. Dr. McEvoy's written testimony includes a number of examples documenting inconsistencies in the professional labels – the foundation for patient information under the FDA's proposal. Will you review each of the labeling cases presented in Dr. McEvoy's testimony and provide a written response to the Committee about how this occurred and what the FDA is doing to fix any inaccuracies?**

Our response focuses on the labeling issues identified with simvastatin products (warning about the increased risk of myopathy in patients of Chinese descent) and with nitroglycerin products (concomitant use with phosphodiesterase-5 inhibitors such as Viagra).

Simvastatin Products – Warning about Increased Risk of Myopathy in Patients of Chinese Descent

Generic companies submit labeling changes to their ANDAs to align their labels with changes in the labels of the brand name drugs, and their submission status may be the cause of what appears to be labeling inconsistencies.

Based on information that we have available, the generic labeling for simvastatin that is currently being manufactured has the safety information regarding risk of myopathy in Chinese patients. Of the 13 simvastatin ANDAs approved, 11 have labeling that includes the aforementioned safety information, and two are pending.

Concomitant Use of Nitroglycerin Products with Phosphodiesterase-5 Inhibitors such as Viagra

As noted in the statement of Gerald K. McEvoy, sildenafil (Viagra) (and related drugs for erectile dysfunction) should not be taken with nitrate products. Co-administration of these drugs can cause severe lowering of blood pressure, which is potentially fatal.

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In our review of the labeling of nitrate products, we could not corroborate Dr. McEvoy's statement, that "...29 of the 30 nitrate products still did not include the same complete class-wide contraindication about Viagra and other ED products on their professional labels." We found that, although there are some differences among the products with regard to the exact wording and/or placement of this information, a consistent message about this important safety issue is present in the labeling of nitrate compounds. We note that in some labels, the concomitant use of sildenafil (and related medications) is presented as a contraindication; in others it is presented as a warning.

Under the Agency's ongoing program to review and update product labeling that is not in the newest format (Physician Labeling Rule),<sup>14</sup> we plan to work with sponsors of nitrate products to update the labeling to modern standards.

**6. One of the biggest problems shown in the studies you have conducted to date was the downstream alteration by pharmacies of the content and format of patient medication information. How will you ensure that does not happen under your new initiative?**

Ensuring that patients receive information pertaining to their medications is of great importance to FDA. Ongoing work to ensure distribution and restrain downstream alteration of PMI includes developing a quality surveillance mechanism that includes distribution requirements. Mechanisms being considered include using a structure similar to the distribution requirements for Medication Guides in 21 CFR 208.24. Further, we intend for all PMI to also be available online, allowing greater patient access and reducing the possibility of downstream alteration.

**The Honorable Kirsten Gillibrand**

**1. Several published studies and independent reviews have demonstrated that it can be years before professional labeling of all affected products includes relevant material and necessary information, including black box warnings. If every manufacturer writes their own patient medication information, how can you ensure that manufacturers of identical or similar products will be consistent and updated on a timely basis so that seniors won't be confused? Actually, how can consistency ever be maintained if the results don't pass through some review that harmonizes and resolves conflicting information?**

FDA is currently developing the framework for PMI, including procedures for developing and maintaining PMI. Our internal review and analysis concerning the procedural aspects of PMI will include consideration of all stakeholder input. Ongoing work to ensure accuracy in PMI includes designing a framework that would base PMI on FDA-approved professional labeling, ensuring PMI is updated when certain changes are made to the approved labeling, and developing a quality surveillance mechanism to enhance compliance.

<sup>14</sup> 71 *Federal Register* 3922 (January 24, 2006), The rule is commonly referred to as the 'Physician Labeling Rule' (PLR) because it addresses prescription drug labeling that is used by prescribers and other health care practitioners.

**2. Shouldn't the patient medication information for identical products – brand and generic – be identical? And shouldn't product labels within the same drug class be consistent and of similar content for effects that apply to all members of the class?**

FDA is considering a mechanism similar to that used with professional labeling, in which generic labeling generally aligns with the labeling of the branded product. Concerning class PMI, FDA is not considering class labeling for PMI at this time. We intend for PMI to contain information based on the product prescribed to the patient. Although products within the same class have similarities, the information specific to each product differs. For this reason, FDA believes that it is important that PMI contain information specific to the particular prescription drug product it accompanies.

**3. Have you reviewed the Cody Miller Initiative for Safer Prescriptions Act – legislation I introduced last Congress and reintroduced earlier this year? As you may know, the legislation calls for patient medication information to be scientifically accurate and that the content not be limited to the professional label. Under my proposal, scientifically accurate, peer-reviewed literature would also be considered. Given the considerable limitations of the professional labels, do you agree that scientifically accurate, peer-reviewed literature should be considered when drafting patient medication information?**

We agree that providing patients with current, easy-to-understand information about prescription drugs in a standardized format is an important goal. We do not have a formal position on the bill, but we would be happy to continue to work with Senator Gillibrand's staff on this legislation.

**4. You stated that 85 percent of FDA-approved prescription drug label are out of date. How many individual labels does that represent? I know that not all labels currently are on DailyMed, but just looking at that it seems that more than 18,000 labels at a minimum will need to be revised and checked for consistency across drug classes. That seems like a daunting task. How many years will it take for all those labels to be revised and harmonized and then reviewed and approved by FDA staff?**

In 2006, FDA published a final rule, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,"<sup>15</sup> which revised the content and format requirements for prescription drug labeling to make it easier to access, read, and use. This rule is commonly called the Physician Labeling Rule (PLR). PLR applies to products for which a new drug application (NDA), biologics license application (BLA), or efficacy supplement (ES) was: (1) approved between June 30, 2001 and June 30, 2006, (2) pending on June 30, 2006, or (3) submitted after June 30, 2006. Products approved prior to June 30, 2001, are not subject to the final rule.

In 2013, we performed a high-level review of all prescription drug labeling in FDA's database and found that approximately 15 percent of prescription drug labeling is in the PLR format (in compliance with the requirements under 21 CFR 201.56(d) and 201.57), leaving approximately 85 percent (13,000) in the "old format" (in compliance with the requirements under 21 CFR

<sup>15</sup> 71 *Federal Register* 3922 (January 24, 2006).

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201.56(e) and 201.80). Although approximately 85 percent of this labeling is in the old format, we do not believe that all of this labeling contains outdated information. Because the PLR format provides a better communication tool for health care professionals on the safe and effective use of drugs and makes prescription information more accessible for use with electronic prescribing tools and other electronic information resources, FDA is exploring ways to increase the number of prescription drugs with labeling that complies with the PLR content and format requirements.

To address this issue, FDA launched the Prescription Drug Labeling Improvement and Enhancement Initiative (PDL-IEI or initiative). The focus of the initiative is to increase the number of drugs with labeling that complies with the PLR content and format requirements. This initiative is a voluntary program in which FDA will request that applicants with "old format" prescription drug labeling convert their labeling to PLR format. FDA is encouraging applicants with NDAs and BLAs approved before June 30, 2001, and applicants with abbreviated new drug applications (ANDAs) for which the NDA for the reference listed drug has been withdrawn (for reasons other than safety and effectiveness), to voluntarily convert the labeling to the PLR format. To ease the resource burden on application holders and to facilitate conversion to the PLR format, FDA will provide PLR conversion resources and services through the use of a government contractor.

The contractor will prepare draft PLR format labeling for review by FDA and application holders before final approval. The contract provides for the conversion to PLR format of labeling for approximately 750 prescription drug products over a period of five years. In this initiative, FDA plans to identify and prioritize prescription drug labeling in the "old format" by public health impact (e.g., drugs or classes of drugs with significant safety concerns, or drugs or classes of drugs most frequently prescribed) for PLR conversion.

Because we believe that PLR format labeling represents a better communication tool for health care practitioners on the safe and effective use of prescription drug products, we are aiming to increase the number of products with labeling in PLR format through initiatives such as the PDL-IEI.

Statement of Consumer Reports,  
an independent, non-profit organization.  
By Doris Peter, PhD, Associate Director, Consumer Reports Health Ratings Center

Before the Senate Aging Committee hearing entitled:  
“Protecting Seniors from Medication Labeling Mistakes”  
December 11, 2013

Thank you for this opportunity to speak on the consumer perspective in making Patient Medication Information more effective. Patient Medication Information (or PMI) is the new consumer drug information communication device that FDA has proposed, which aims to replace all other forms of drug information targeted at consumers (e.g. Medication Guides, Patient Package Inserts, Consumer Medication Information).<sup>1</sup>

According to the IOM report, “Preventing Medication Errors”, approximately 1.5 million preventable adverse drug events (ADEs) occur each year. Of these, more than 500,000 occur in outpatient settings, costing \$1 billion each year.<sup>2</sup> In consumers who are age 65 and older, it is estimated that ADEs cause approximately 100,000 emergency hospitalizations each year.<sup>3</sup>

Health literacy is an important factor in reducing the amount of harm consumers experience with regard to ADEs. For example, studies have shown that consumers with lower literacy are at greater risk for errors in dosing and administration.<sup>4</sup> Older adults can have a number of challenges related to health literacy: more than 70 percent of consumers over age 60 have trouble using print materials; 80 percent have trouble using forms and charts and about 70 percent have trouble interpreting numbers and performing calculations.<sup>5</sup> In addition, seventy-five percent of consumers age 65 and older regularly take a prescription drug, and those consumers take, on average, almost six prescription drugs at one time.<sup>6</sup> PMI must also be a comprehensive information source, since, according to Consumer Reports’ research, about 30 percent of older consumers reported that they did not have a conversation with their physician or pharmacist about side effects when starting a new drug.<sup>7</sup> Therefore it is critical that PMI address these concerns and

<sup>1</sup> <http://www.fda.gov/drugs/newsevents/ucm219716.htm>; Accessed December 9, 2013.

<sup>2</sup> Institute of Medicine. Preventing Medication Errors. Aspden P, Wolcott J, Bootman L, Cronenwett LR (eds). Washington D.C., National Academy Press, 2006.

<sup>3</sup> Budnitz et al., 2011. Emergency hospitalizations for adverse drug events in older Americans. NEJM. 365:2002. <http://www.nejm.org/doi/full/10.1056/NEJMs1103053>

<sup>4</sup> Standardizing Medication Labels: Confusing Patients Less, Workshop Summary; <http://www.iom.edu/~media/files/activity%20files/publichealth/healthliteracy/commissioned%20papers/improving%20prescription%20drug%20container%20labeling%20in%20the%20united%20states.pdf>

<sup>5</sup> National Library of Medicine - Health Literacy. <http://nmlm.gov/outreach/consumer/hlthlit.html>. Accessed December 6, 2013.

<sup>6</sup> Consumer Reports Prescription Drug Tracking Poll #5; July 2013. Available upon request.

<sup>7</sup> Ibid.

that it is tested to ensure that the content (in addition to format) adequately addresses the needs of consumers, including older consumers and their caregivers.

Consumers Reports<sup>8</sup> is a non-profit organization, and through our Best Buy Drugs Project,<sup>9</sup> we create and disseminate unbiased information about the comparative effectiveness, safety and cost of prescription and over-the-counter medications. We have conducted our own consumer research through national annual surveys of consumers on their perspectives on the use of prescription and over-the-counter medications.<sup>10</sup> This research, taken together with our experience and the research and experience of others, has informed Consumers Reports' recommendations regarding the development and dissemination of PMI.

As an overarching theme, **PMI content and format must be evidence-based, patient-centered, and transparent. This is an opportunity for FDA to make an enormous impact on the ability of consumers to participate in their healthcare and transfer some of the power of knowledge to the consumer.** Consumers are at a disadvantage (compared to the FDA, the drug industry and prescribers/pharmacists) in terms of their knowledge and access to information that can help them better manage their care. We urge FDA to provide consumers with the information (both in terms of content and format) that has been shown, in controlled clinical trials with consumers, to promote better decision making. **Currently, important information that can improve the outcomes of patients (in terms of both benefit of treatment, and safety) is being intentionally withheld from consumers.**

**Consumer Reports urges FDA to adopt our recommendations below:**

- **Consumers need (and can understand) quantitative information about the benefits and risks of a drug.** There is an evidence-based approach to presenting this information to consumers -- the Drug Facts Box -- developed by Drs. Lisa Schwartz and Steven Woloshin. The Drug Facts Box is a one-page table that summarizes the benefits and harms for each use of a drug (an example is provided on the last page of this document).<sup>11</sup> This approach has been carefully studied, including through national, randomized trials. These studies have shown that most consumers understand the information presented in the Drug Facts Box and

<sup>8</sup> Consumer Reports is a nonprofit membership organization chartered in 1936 to provide consumers with information, education, and counsel about goods, services, health and personal finance. Consumers Union's publications have a combined paid circulation of approximately 8.3 million. These publications regularly carry articles on Consumers Reports' own product testing; on health, product safety, and marketplace economics; and on legislative, judicial, and regulatory actions that affect consumer welfare. Consumers Reports' income is solely derived from the sale of Consumer Reports®, its other publications and services, fees, noncommercial contributions and grants. Consumers Union's publications and services carry no outside advertising and receive no commercial support.

<sup>9</sup> [www.ConsumerReportsHealth.org/BestBuyDrugs](http://www.ConsumerReportsHealth.org/BestBuyDrugs); information provided free to the public; funded in part by the Attorney General Consumer & Prescriber Education Grant Program.

<sup>10</sup> Consumer Reports Prescription Drug Tracking Poll #5; July 2013. Available upon request.

<sup>11</sup> Schwartz, LM and S Woloshin. 2013. PNAS. 110 (Suppl 3); [http://www.pnas.org/content/110/Supplement\\_3/14069.full](http://www.pnas.org/content/110/Supplement_3/14069.full). Accessed December 8, 2013.

that it improves decision-making.<sup>12,13</sup> In fact, FDA's own Risk Communication Advisory Committee<sup>14</sup> and Congress (in the Affordable Care Act)<sup>15</sup> supported FDA's consideration of the Drug Facts Boxes. FDA, however, has not decided to implement the boxes as part of the PMI process. Importantly, FDA's own work in this area has identified that "fear of potential side effects is the single greatest deterrent from filling and taking prescription drugs."<sup>16</sup> The FDA report goes on to cite that, if consumers do fill the prescription, the long list of potential adverse effects keeps some from taking the drug. Then, on the other extreme, for some consumers the long lists result in ignoring the potential adverse effects, or missing important ones that are buried in the long lists. In addition, results from FDA focus groups underscore the point that consumers feel that they need to be involved in the process of weighing a drug's benefits and harms.<sup>17</sup> Providing consumers with quantitative information about the potential benefits and harms (rather than a long list of adverse events that are out of context) will aid consumers in their decision to take a prescription medication, or to not take it, but for reasons based on fact rather than on fear.

- **PMI needs to include dosing information; consumers want (and need) dosing information.** The current FDA proposal for PMI does not include the approved dosing information. However, patients characterize dosing information as "very important" and rank it second only to approved uses among the drug information items they need.<sup>18</sup> In another study, dosing errors were found to be the most common medication error associated with death<sup>19</sup> and in a study of adverse drug events in patients 65 years and older, almost two-thirds of hospitalizations were caused by unintentional overdoses.<sup>20</sup> In a database collected by Consumer Reports of consumer-reported harm related to drugs, 40 percent of reports were related to dosing errors and more than 12 percent were due to problems with packaging, labeling, or complicated or incomprehensible instructions.<sup>21</sup> In other

<sup>12</sup> Schwartz SL and Woloshin, S., 2011. Communicating uncertainties about prescription drugs to the public: A national randomized trial. *Arch Intern Med* 171(16):1463–1468.

<http://www.ncbi.nlm.nih.gov/pubmed/21911629>

<sup>13</sup> Schwartz et al., 2009. Using a drug facts box to communicate drug benefits and harms: Two randomized trials. *Ann Intern Med* 150 (8):516–527. <http://www.ncbi.nlm.nih.gov/pubmed/19221371>

<sup>14</sup> <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM152593.pdf>. Accessed December 8, 2013.

<sup>15</sup> Patient Protection and Affordable Care Act. Pub. L. No. 111-148, Section 3507 (Mar. 23, 2010).

<sup>16</sup> Prescription Drug Risk and Benefits, Focus Group Reports (FDA); <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM312395.pdf>. Accessed December 6, 2013.

<sup>17</sup> Consumer Perceptions of Prescription Drug Communications, Focus Group Reports (FDA); <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM312767.pdf>. Accessed December 9, 2013.

<sup>18</sup> A survey of package insert use by patients, 2005. [http://paint-consult.com/de/publikation/pdf/PAINT-Consult\\_package\\_inserts\\_use\\_patients.pdf](http://paint-consult.com/de/publikation/pdf/PAINT-Consult_package_inserts_use_patients.pdf). Accessed December 6, 2013.

<sup>19</sup> Phillips et al., 2001. Retrospective analysis of mortalities associated with medication errors. *Am J Health System Pharm*; 58(19):1835. <http://www.ncbi.nlm.nih.gov/pubmed/11596700>

<sup>20</sup> Budnitz et al., 2011. Emergency Hospitalizations in for Adverse Drug Events in Older Americans. *NEJM*. 365: 2002. <http://www.nejm.org/doi/full/10.1056/NEJMsa1103053>

<sup>21</sup> Internal Consumer Reports database; summary information available upon request.

countries, the usual dosages can be found as part of the patient leaflets,<sup>22,23</sup> but not the consumer medical information (CMI) published here in the United States.<sup>24</sup> In addition to providing key information that consumers need to stay safe, providing dosing information can help alert consumers to other prescribing errors and potential unsupported off-label use of drugs (by noting any inconsistencies in the dosing indicated in the PMI compared with the label on the prescription drug container).

- **PMI should not be based on the professional package insert for each drug; package inserts are inconsistent and not timely.** The FDA position is to base PMI on the professional package insert. However, it is widely known that package inserts can contain errors, are often not up-to-date, and that they can be inconsistent across drugs in the same class, and lack consistency across brand and generic versions of the same drug.<sup>25,26</sup> Therefore, PMI that is based on inconsistent package inserts will generate PMI that is inconsistent across classes and between brand and generic drugs. There is also evidence that it can take years or even decades for important safety information to be published in the package insert.<sup>27</sup> Therefore consumers will not have the most accurate and up-to-date information if PMI is based on the package insert.
- **Manufacturers should not author PMI** -- Virtually every major pharmaceutical company has either been fined or is under investigation by the Department of Justice. Companies have either pled guilty or paid a fine to resolve allegations of: illegal promotion of drugs, failing to report safety problems, and financial fraud.<sup>28</sup> The pharmaceutical industry currently ranks 7<sup>th</sup> out of 11 industries in terms of consumer trust, according to a 2012 study.<sup>29</sup> Furthermore, FDA's own work in this area has shown that consumers mistrust the pharmaceutical industry based on consumers' feeling that the industry is more concerned with profit than with safety.<sup>30</sup> Therefore, to ensure the generation of objective, unbiased PMI, and to ensure consumer confidence and trust in the content, the creation of PMI should be delegated to an independent, unbiased third party other than that of the drug manufacturers.

<sup>22</sup> Patient leaflet for Celebrex in Australia: <http://www.mydr.com.au/medicines/cmis/celebrex-capsules>; Accessed December 9, 2013

<sup>23</sup> Patient leaflet for Celebrex in the United Kingdom: <http://www.medicines.org.uk/emc/pdfviewer.aspx?isAttachment=true&documentid=4079>

<sup>24</sup> Consumer Medication Information for Celebrex (United States); <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a699022.html>. Accessed December 9, 2013

<sup>25</sup> Panagiotou et al., 2011. Different black box warning labeling for same-class drugs. *J Gen Intern Med.* 26(6):603. <http://www.ncbi.nlm.nih.gov/pubmed/21286838>

<sup>26</sup> Duke et al, 2013. Consistency in the safety labeling of bioequivalent drugs. *Pharmacoepidemiol Drug Saf.* 22(3):294. <http://www.ncbi.nlm.nih.gov/pubmed/23042584>

<sup>27</sup> <http://www.propublica.org/article/tylenol-mcneil-fda-use-only-as-directed>

<sup>28</sup> <http://projects.propublica.org/graphics/bigpharma>. Accessed December 6, 2013.

<sup>29</sup> <http://trust.edelman.com/trust-and-health/>. Accessed December 6, 2013

<sup>30</sup> Prescription Drug Risk and Benefits, Focus Group Reports (FDA); <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM312395.pdf>. Accessed December 6, 2013.

# Lunesta

(compared to sugar pill) to reduce current symptoms for adults with insomnia

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## What this drug is for:

To make it easier to fall or to stay asleep

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## Who might consider taking it:

Adults age 18 and older with insomnia for at least 1 month

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## Recommended monitoring:

No blood tests, watch out for abnormal behavior

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## Other things to consider:

Reduce caffeine intake (especially at night), increase exercise, establish a regular bedtime, avoid daytime naps

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## How long has the drug been in use?

Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold up over time. In general, if there are unforeseen, serious drug side effects, they emerge after the drug is on the market (when a large enough number of people have used the drug).

## Lunesta Study Findings

788 healthy adults with insomnia for at least 1 month – sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep – were given LUNESTA or a sugar pill nightly for 6 months. Here's what happened:

What difference did LUNESTA make?	People given a sugar pill	People given LUNESTA (3 mg each night)
<b>Did Lunesta help?</b>		
LUNESTA users fell asleep faster (15 minutes faster due to drug)	<b>45 minutes to fall asleep</b>	<b>30 minutes to fall asleep</b>
LUNESTA users slept longer (37 minutes longer due to drug)	<b>5 hours 45 minutes</b>	<b>6 hours 22 minutes</b>
<b>Did Lunesta have side effects?</b>		
<b>Life threatening side effects:</b>		
No difference between LUNESTA and a sugar pill	<b>None observed</b>	<b>None observed</b>
<b>Symptom side effects:</b>		
More had unpleasant taste in their mouth (additional 20% due to drug)	<b>6%</b>	<b>26%</b>
More had dizziness (additional 7% due to drug)	<b>3%</b>	<b>10%</b>
More had drowsiness (additional 6% due to drug)	<b>3%</b>	<b>9%</b>
More had dry mouth (additional 5% due to drug)	<b>2%</b>	<b>7%</b>
More had nausea (additional 5% due to drug)	<b>6%</b>	<b>11%</b>

**Statement to the Senate Special Committee on Aging from Richard J. Scholz, RPh., Esq.**

**Chairman Nelson, Ranking Minority Member Collins, Members of the Committee, and distinguished panelists:**

I am Richard J. Scholz, RPh., Esq., Managing Member of Jacobs Scholz & Associates, LLC, Amelia Island, Florida. It is a pleasure to be here today to discuss the opportunities and challenges of protecting seniors from medication mistakes and adverse drug events via a focus on communicating medication labeling more effectively to patients. The lens through which I view this complex issue is very personal: thirty-six years of experience as a community pharmacist, chain pharmacy executive, founder of a national pharmacy benefit management corporation, pharmaceutical industry advisory board member, litigation of wrongful death from adverse drug events, and chief legal officer of a multidisciplinary group medical practice. I currently serve on the Board of Directors of the Pharmaceutical Printed Literature Association (PPLA) as a delegate of G&K Vujuk International, Elmhurst, Illinois. Aside from my professional experiences, much of the context of my comments today arise from observing the medication management challenges of my eighty-three year old mother, along with many similarly situated Floridians and American senior citizens.

Protecting American citizens from adverse drug events via improved printed communication about prescription medicines to consumers is not a new policy discussion. The first FDA reviewed, pharmaceutical manufacturer printed and distributed, pharmacy dispensed consumer-oriented written information was required on isoproterenol inhalation products in

1968.<sup>1</sup> In 1979, when I was a community pharmacist practicing in a predominately senior citizen neighborhood of Cleveland, Ohio, the FDA proposed a rule that would have required manufacturers to produce and distribute (after FDA review) written information known as patient package inserts (PPI) for pharmacists to provide to patients.<sup>2</sup> In 1982, the FDA withdrew the proposed PPI regulation with the promise of a private-sector solution to improve communication about prescription medicines to consumers.<sup>3</sup> In 1996, Public Law 104-180 required adoption of an action plan to assess the effectiveness of current private-sector approaches used to provide oral and written prescription information to consumers. FDA committed to monitor the progress of this private-sector effort. Unfortunately, periodic FDA surveys showed that, although distribution of written prescription drug information increased, the usefulness of the information was highly variable. As a result, in 1995, FDA proposed a regulation entitled *Prescription Drug Product Labeling: Medication Guide Requirements*, designed to set specific distribution and quality goals and time frames for distributing written information. The regulation had the following goals:

- By the year 2000, 75 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions.
- By 2006, 95 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions.<sup>4</sup>

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<sup>1</sup> Action Plan For The Provision of Useful Prescription Medicine Information, HHS, December 1996, p. 9.

<sup>2</sup> Action Plan For The Provision of Useful Prescription Medicine Information, HHS, December 1996, p.9.

<sup>3</sup> Action Plan For The Provision of Useful Prescription Medicine Information, HHS, December 1996, p.9.

<sup>4</sup> Guidance Useful Written Consumer Medication Information (CMI), HHS, July 2006 Procedural, p.2.

Several independent studies evaluated the progress toward achieving the goals for distribution and quality of useful written information to consumers, and in each case the data demonstrated pharmacy printed CMI has fallen woefully short of meeting goals for useful written patient information. In a study published in 2003, University of Wisconsin School of Pharmacy researchers found that consumers received written information with greater than seventy-five percent of prescriptions, but the length and quality of the information varied greatly. "A majority of the leaflets did not include adequate information about contraindications, precautions and how to avoid them."<sup>5</sup> Five years later, University of Florida, College of Pharmacy researchers found that the dispensation of written patient information had increased to over ninety percent of prescriptions at retail pharmacies, with some improvement in overall quality as compared to the 2003 study. The University of Florida study determined only sixty percent of the written patient medication leaflets dispensed to patients in the study adhered to the threshold for acceptable quality, and identified shortcomings in the provision of critical information about the management of medication, significant redundancy of information, poor formatting, and inadequate legibility and reading level.<sup>6</sup> Each study addressed the critical components of CMI, as defined by FDA, but did not address the quality, presentation, and format of CMI that will result in adequate patient comprehension and ultimately, appropriate actions to improve patient safety.

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<sup>5</sup> Svarstad, BL, Bultman, DC, Mount, JK, Tabak, ER. Evaluation of Written Prescription Information in Community Pharmacies: A Study in Eight States *J Am Pharm Assoc.* 2003;43:383-93.

<sup>6</sup> Kimberlin, CL, Winterstein, AG, Expert and Consumer Evaluation of Consumer Medication Information-2008; Final Report to the U.S. Department of Health and Human Services and the Food and Drug Administration, November 4, 2008

Consumer health and the cost of U.S. health care are hugely affected by adverse drug events and misuse of prescription medication:

- In 1995, FDA estimated that hospitalizations associated with outpatient adverse (drug) reactions cost \$4.4 billion per year;<sup>7</sup>
- In its 2006 report on medication errors, the Institute of Medicine estimates that 1.5 million errors occur annually in the United States. A large proportion of these occur in the outpatient setting, generating costs of more than \$3.5 billion. Poor labeling was identified as a critical source of those errors;<sup>8</sup>
- Poor adherence to medication regimens accounts for substantial worsening of disease, death, and increased health care costs in the United States;<sup>9 10 11 12 13</sup>
- Of all medication-related hospital admissions in the U.S., 33-69% are due to poor medication adherence, with a resultant cost of approximately \$100 billion a year;<sup>14 15</sup>

<sup>7</sup> 71 FR 3922 at 3974; January 24, 2006

<sup>8</sup> *Health Affairs* 26, no.3 (2007):731-740; 10.1377/hlthaff.26.3.731

<sup>9</sup> McDonnell PJ, Jacobs MR, Hospital admissions resulting from preventable adverse drug reactions. *Ann Pharmacother* 2002; 36:1331-6.

<sup>10</sup> Schiff GD, FUNG S, Speroff T, McNutt RA, Decompensated heart failure: symptoms, patterns of onset, and contributing factors. *AmJMed* 2003;114:625-30.

<sup>11</sup> Senst BI, Ahusim LE, Genest RP, et al. Practical approach to determining costs and frequency of adverse drug events in a health care network. *Am J Health Syst Pharm* 2001; 58:1126-32.

<sup>12</sup> Misdrahi D, Llorca PM, Lancon C, Bayle FJ, Compliance in schizophrenia: predictive factors, therapeutical considerations and research implications. *Encephale* 2002;28:226-72.

<sup>13</sup> Rodgers PT, Ruffin DM. Medication nonadherence: Part II-a pilot study in patients with congestive heart failure. *Manag Care Interface* 1998;11(9):67-9, 75.

<sup>14</sup> Levy G, Zamacona MK, Jusko WJ, Developing compliance instructions for drug labeling. *Clin Pharmacol Ther* 2000;68:586-91.

<sup>15</sup> Berg JS, Dischler J, Wagner DJ, Raia JJ, Palmer-Shevin N. Medication compliance: a healthcare problem. *Ann Pharmacother* 1993;27 Suppl 9:S1-S24.

- Adherence with medication therapy is generally low- approximately 50% to 65% on average, for common chronic conditions such as hypertension and diabetes,<sup>16 17</sup>
- 4.5 million ambulatory visits related to adverse drug events occur each year.<sup>18</sup>

It is what patients know and understand that makes a difference in patient behavior and their health status.<sup>19</sup> Written prescription information is an essential part of patient counseling because it can reinforce instructions or warnings, improve patient understanding and recall of instructions, increase patient satisfaction, and provide supplemental information during brief pharmacy visits.<sup>5</sup> U.S. prescription drug consumers, especially senior citizens, are challenged by the fragmented delivery system of communication regarding their prescription drugs and are uniquely susceptible to conflicting information and misinformation. They receive prescription drug information from their physician(s), pharmacist(s), pharmaceutical manufactures via direct to consumer advertising, insurance companies via drug formulary communication, and family and friends, but are ill equipped to comprehend and process this divergent information. In an article published in Health Affairs, the authors document the prescription drug information communication challenges faced by consumers:

“Surveys indicate that most patients prefer to receive information regarding their prescriptions from their physicians, as learned intermediaries.

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<sup>16</sup> Nichol MB, Venturini F, Sung JCY. A critical evaluation of the methodology of the literature on medication compliance. *Ann Pharmacother*, 1999;33:531-540

<sup>17</sup> Schlenk Ea, Burke LE, Rand C., Behavioral strategies to improve medication-taking compliance. In: Burke LE, Ockene IS, eds. *Compliance in Healthcare and Research*, Armonk, NY; Futura Publishing Co: 2001:57-70.

<sup>18</sup> Sarkar, U, Lopez, A, Maselli, J, Gonzales, R, Adverse Drug Events in U.S. Adult Ambulatory Medical Care: *Health Serv Res*. 2011 October; 46(5): 1517-1533. doi:10.1111/j.1475-6773.2011.01269.x

<sup>19</sup> Office of Disease Prevention and Health Promotions in the U.S. Department of Health and Human Services. *Health People 2000 National Goals*.

However, there is considerable evidence that such discussions occur infrequently and are often quite limited. A recent study evaluated audiotaped office visits and found major shortfalls in the quality of information communicated to patients about their prescribed medicines; physicians explained adverse effects and duration of therapy in only about a third of the discussions and provided patients with instruction for use in only 55 percent of the discussions. Communications with pharmacists is also inadequate. As a result, many patients rely on written information, either on labels or in package inserts.

About half of all Americans have difficulty reading and using health information; poor literacy is a critical barrier to adequate care. These problems are especially important concerning medication information. In a recent multisite study of primary care patients, nearly half were unable to understand one or more of the label instructions of five common prescription drugs. Another study evaluated low-literacy patients' ability to interpret warning stickers (usually colorful stickers often indiscriminately placed on the backs of prescription bottles) and found profound deficits in their understanding. Elderly patients have particular difficulty reading, and understanding drug labeling. In a survey of older hospitalized patients prior to discharge, only 40 percent reported no problems in reading their drug labels, and even fewer reported that they had a clear understanding of the instructions. Another survey of geriatric patients found that they frequently did not understand how to time their dosing in relation to meals.<sup>8</sup>

As a nation, we have failed to empower our citizens with critical information to participate in the management of their prescription drug regimens, resulting in therapeutic failures and excessive costs. For more than a decade, patient advocates and others have expressed concerns about the quality and consistency of patient drug information.<sup>20</sup> It is a challenge that was recognized in 1979, delegated to a fragmented private-sector to search for a solution, yet remains unsolved thirty-three years later.

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<sup>20</sup> GAO-13-592 Electronic Drug labeling July 8, 2013 p.7.

Senior citizens and all Americans would greatly benefit from Congress amending the Food Drug and Cosmetic Act to enable the FDA to regulate the authorship, content, format, color scheme, printing, and dissemination requirements for patient medication information to ensure consistency of communication of drug identification, indications for use, clinical benefits, directions for use, proper dosage instructions, warnings, contraindications, side effects, and measures patients may take to minimize side effects and enhance the success of their therapy. The legislation must include a mandate for: 1) FDA approved content, 2) a universal PMI format that has been scientifically studied using real patient cognitive studies to clearly demonstrate its quality and effectiveness, 3) be manufacturer printed and distributed, and 4) mandatory pharmacy dispensing, with each prescription dispensed in an outpatient setting.

It is what patients know and understand that makes a difference in patient behavior, and thus, their health status. Please empower our citizens with the tools and knowledge to participate in the complex U.S. healthcare delivery system and optimize the return on investment of our health care resources. The safety and well-being of America's patients, especially our elderly Americans, is too important to do otherwise.

On behalf of the thousands of patients I have been fortunate to serve as a pharmacist, the patients I have represented as a health care attorney, and the millions of Americans whose empowerment depends on knowledge only available through concise, consistent, written, FDA approved and manufacturer delivered communication, I thank you for this opportunity.

I welcome any questions or further inquiry.

**RICHARD J. SCHOLZ, RPh., Esq.****Managing Member, Jacobs Scholz & Associates, LLC.**

Mr. Scholz graduated from The Ohio State University College of Pharmacy in 1977, became a Licensed Pharmacist in the state of Ohio, and embarked on a career in community pharmacy. During his years of practice in the community pharmacy setting, he was responsible for implementing a regional drug chain pharmacy computerized record system, founded and managed an institutional pharmacy services division to serve the long term care industry, and created an FDA approved repackaging operation. In 1987, Mr. Scholz founded Complete Pharmacy Network, a pharmacy benefit management company that pioneered the implementation of real time computerized pharmacy management and cost controls to clients throughout the United States. During his tenure as CEO of Complete Pharmacy Network, he led a management team that successfully built a nationwide pharmacy provider network, created technology based drug therapy management strategies, and developed client marketing and retention programs. In the summer of 2005, Mr. Scholz graduated cum laude from Florida Coastal School of Law in Jacksonville, Florida and became a member of the Florida Bar in 2006. Mr. Scholz joined the law firm of Jacobs and Associates, PA in 2005 to build a legal practice focused on business law, health care, and government relations. In 2008, Scholz became a founding member in the firm of Jacobs Scholz & Associates, LLC. Scholz was appointed as a delegate to the Pharmaceutical Printed Literature Association (PPLA) by Vijuk Equipment Inc. (now, G&K Vijuk International) in 2010 to further the communication of the importance of printed literature to educate health care professionals and consumers and optimize pharmacy outcomes.

Senate Special Committee on Aging

Hearing on

Protecting Seniors from Medication Labeling Mistakes

December 11, 2013

Statement for the Record

Submitted by the



American Society of  
Health-System Pharmacists®

Testimony by

Gerald K. McEvoy, Pharm. D.

Editor in Chief

AHFS Drug Information and Consumer Medication Information

**American Society of Health-System Pharmacists**

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## Testimony Overview

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Good afternoon Chairman Nelson, Ranking Member Collins, and distinguished members of the Special Aging Committee.

I also want to thank Senator Gillibrand for her leadership on this issue.

My name is Gerald McEvoy, and I serve as Assistant Vice President of Drug Information for the American Society of Health-System Pharmacists and as Editor in Chief for our federally recognized professional drug information compendium and consumer medication information database.

ASHP is the national professional society representing over 42,000 pharmacists and technicians who practice in hospitals and health systems.

ASHP has a nearly 40-year history of providing patients with meaningful information about medications and provides the only trusted and objective compendium-based database of CMI published by a not-for-profit professional and scientific society in the US. Our patient medication information is provided electronically free of charge to consumers through the National Library of Medicine and our own [safemedication.com](http://safemedication.com) website.

I am here today to provide ASHP's perspective on the issue of patient medication information. For more than a decade, I have been involved with efforts to simplify, and make more meaningful, patient medication information. It is critical that patients receive the necessary information along with their prescription that explains directions for taking the medication, potential side effects, critical warnings and precautions, and the potential for drug to drug interactions. Given the number of medications a typical senior citizen takes, this information is especially critical to the health and well-being of our nations' seniors.

In response to a 2008 Citizen Petition and other events, FDA proposed achieving this goal by putting manufacturers in charge of authoring the patient information for each of their products, and based solely on their own FDA-approved professional label. Although we agree with the goal of streamlining and enhancing the usefulness of patient medication information, we strongly disagree with FDA's plan. The FDA approach fails to ensure patients will receive timely, accurate, consistent, and impartial information.

Under their proposal, FDA would replace the existing system with manufacturer authored information. More than 800 manufacturers would be charged with authoring patient medication information without any central editorial oversight. FDA estimates that under their proposal approximately 22,000-25,000 individual documents initially would need to be created.

First, we are concerned that FDA's proposal to allow manufacturers to develop their own PMI will result in inconsistent information across tens-of-thousands of drug products, creating confusion for patients and their caregivers. There is no mechanism to ensure PMI for identical products would be identical or that similar information would be included in every relevant medication within a drug class.

For example, Zocor's professional label first included a warning about the increased risk of myopathy in patients of Chinese descent in early 2010, yet almost 4 years later the labeling for some generic products still does not include this critical risk information. If a patient is switched from an innovator product to a generic or from one generic to another, what safeguards would be in place to ensure the information is consistent, regardless of whose product the patient is taking?

Second, we have concerns with the timeliness in which this information would be updated for all related products. FDA's proposal to tie medication information to the product label is troubling due to the lag times we currently see with respect to changes in professional labeling. Information that is critical to safe, effective medication use must be made available to the patient as soon as it's known.

For example, when Viagra was approved in 1998, the professional label included an appropriate warning that it should not be taken with a nitrate product – a potentially fatal interaction. And yet, almost 15 years later we found that 29 of the 30 nitrate products still did not include the same complete class-wide contraindication about Viagra and other ED products on their professional labels.

Additional examples of inconsistencies and inadequacies of professional labeling as the sole source of information for manufacturer-authored patient medication information are provided below.

Third, the FDA maintains they lack the resources to review and approve each manufacturer's patient medication information for every product it makes. FDA claims approval is unnecessary because manufacturers will base their patient information off of the FDA-approved professional label. Yet, as I described, this claim clearly is not valid.

Given these concerns, ASHP continues to urge the FDA to consider alternative models. ASHP believes that PMI developed by a single entity is the best pathway to ensure that timely, accurate prescription medication information gets into the hands of patients to ensure safe, effective medication use.

We strongly support Senator Gillibrand's Cody Miller Initiative for Safer Prescriptions Act, which would permit the Secretary of HHS to pursue this alternative pathway.

## Introduction

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FDA has proposed replacing the current system of independent drug information publisher-authored consumer medication information (CMI) with one of self-regulated, manufacturer-authored patient medication information (PMI). Under this proposal, more than 800 disparate manufacturers would independently develop and publish PMI employing a self-regulated model that includes no central editorial oversight. The content and format of each manufacturer-authored PMI document would not be subject to review by FDA to ensure compliance with agency-developed PMI standards or consistency with PMI for the same or similar medications prior to distribution to patients and their caregivers. In addition, FDA has proposed that printed PMI content be subject to an arbitrarily selected one-page limit regardless of medication risk or complexity. And finally, FDA has proposed that the content of the manufacturer-authored PMI will be limited to information in the respective manufacturer's own professional labeling, regardless of how inaccurate, out-of-date, or inconsistent that labeling may be.

Reasons for FDA embarking on this path include:

- Findings from 2001 and 2008 FDA-commissioned assessments of the current system of CMI to meet usefulness standards established by the Department of Health and Human Services (DHHS) 1996 *Action Plan for the Provision of Useful Prescription Medication Information* (the Action Plan, Keystone Guidelines) and subsequent 2006 FDA interpretive guidance
- 2008 Citizen Petition Requesting FDA Action on a “One Document Solution” for all Pharmacy-based Communications
- 2009 Recommendations of FDA’s Risk Communication Advisory Committee (RCAC) that the agency adopt a single standard document for communicating essential information about prescription drugs, which would replace CMI, patient package inserts (PPIs), and Medication Guides (MedGuides)
- 2009 FDA public workshop on providing effective information to consumers about prescription drug risks and benefits
- Failure of Medication Guides and the impetus that their inclusion as a potential element of risk communication and mitigation strategies (REMS) provided for evaluating alternative approaches to communicating risk and benefit information about prescription medications to consumers
- Perceived benefit to consumers of providing more concise CMI

By its own admission, FDA has no evidence concerning the optimal length of PMI.<sup>1</sup> And while a recent pilot study survey found that patients reported one-page CMI as useful,<sup>2</sup> FDA never established through adequate research the essential level of information required by patients for safe and effective use of their medications prior to this study, and the agency’s current research agenda is not designed to establish this. Thus, FDA is headed down a path that risks providing patients with inadequate information concerning the safety and optimal use of their medications. As practical matter, once one page is filled with information that is deemed important to patients, what do you do when equally important new information about the drug emerges?

Yet, more troubling than the length requirement is FDA’s proposal to put drug manufacturers in charge of authoring their own patient information. FDA has never shown that the current system of CMI authorship by manufacturer-independent private publishers is not working. Instead, it only has been able to show that substantial downstream alteration of both the content and format of CMI by pharmacies or their information system vendors resulted in the provision at the point of dispensing of substandard CMI. And yet, rather than attempting to correct the real problem of downstream CMI alteration, FDA has neglected to consider fully a well-established editorial process that has exceeded the standards the Agency set for useful consumer medication information. In fact, had patients received the CMI intended for distribution by the authoring drug information publishers, it would have exceeded greatly the Agency’s goals. Instead, FDA is focused on addressing concerns with authorship quality that simply do not exist.)

<sup>1</sup> Discussion guide. Expert workshop on Designing Pilot Programs to Distribute Patient Medication Information. Engelberg Center for Healthcare Reform at Brookings. February 2011.

(<http://www.brookings.edu/~media/events/2011/2/23%20pmi%20pilots/discussion%20guide.pdf>)

<sup>2</sup> Catalina Health releases results of patient information quality improvement initiative. Press release. April 9, 2013. (<http://www.catalinamarketing.com/news-events/press-releases/details.php?id=335>)

Another key premise of FDA's proposed model also is not valid. The Agency has argued that because it will limit the content of manufacturer-authored PMI to each company's FDA- approved professional label for their products, there is no need for the Agency to review and approve PMI. However, FDA's failure to ensure the accuracy, consistency, and timeliness of professional labeling it approves will result in a transfer of the same inadequacies that plague professional labeling. These problems will be described in more detail later in this testimony.

Inappropriate use of medications by patients is known to have extensive and sometimes severe human and economic consequences. Empowering the patient with knowledge to optimize medication therapy is a goal of all medication education and counseling efforts. Without this knowledge, the patient cannot form an effective partnership with healthcare professionals to manage their medication therapy. ASHP and other drug information publishers such as First DataBank (FDB Health) and Wolters Kluwer, independent consumer advocacy groups such as Consumers Union (CU), and government agencies such as the National Library of Medicine (NLM) have a history of providing accurate, high-quality prescription medication information to consumers.

Making well-informed healthcare decisions, including decisions about medications, can be difficult for consumers. A variety of factors may influence consumer decisions about medications, including information they receive from trusted healthcare providers (e.g., physicians, pharmacists) and from their health benefit managers; direct-to-consumer advertising; advice from family, friends, and internet contacts (e.g., chat rooms, blogs); advisories from the government (e.g., FDA); and information obtained independently (e.g., from medication information resources such as those that are Web-accessible). Contributing to this difficulty is the sheer magnitude of information and uncertainties about its quality and trustworthiness—factors that can greatly influence difficulties in understanding safe and effective medication use, including off-label uses, and the level of evidence concerning their benefits and risks.

For several decades, the principal source of objective, unbiased CMI in the US has been drug information publishers, whose independence from the influence of pharmaceutical manufacturers and consistently applied editorial standards have resulted in objective, timely information for patients about their drugs. These publishers have a record of developing CMI that meets the usefulness standards of the Department of Health and Human Services Action Plan for the Provision of Useful Prescription Medication Information (the Action Plan, Keystone Guidelines) and subsequent 2006 FDA interpretive Guidance. This information most typically is obtained by patients at the point of dispensing from pharmacies, whose downstream policies ultimately control what the patient actually receives. Unfortunately, because of this downstream control by pharmacies or their information system vendors, the intended content and format of what the patient receives often is substandard, with changes such as poorly readable typography and wholesale deletion of entire sections of safety information depriving patients of the high-quality information intended by drug information publishers.

### Dispelling the Myths about Drug Information Publisher Authored Consumer Medication Information (CMI)

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The FDA frequently cites two studies that raise concern about the consumer medication information that currently is provided to patients. However, as set out below, both of these studies failed to look at the information that was actually prepared by the private publishers. Any concerns about usefulness are most likely attributable to alterations of the information that are made downstream such as

wholesale safety content deletion before the information is provided to the patient. That is the issue the FDA should be focusing on fixing.

ASHP has submitted to the Agency's docket two detailed analyses of FDA's contracted assessments of CMI—the 2001 study published by Svarstad (principal investigator) and the 2008 study published by Kimberlin and Winterstein (principal investigators).<sup>3,4</sup>

ASHP has consistently pointed out methodological problems with the study designs, particularly the inclusion of a substantial proportion of specific criteria for determining usefulness that were not supportable from FDA-approved labeling and/or the Action Plan. For example, only about 50–65% of the criteria used in the 2001 Svarstad study could be directly attributed to professional labeling and were explicitly required by the Action Plan as part of ASHP's analysis; that means that up to half of the criteria used to assess the consumer medication information of private publishers fell outside FDA's standards. At a June 17, 2004 meeting that was convened by FDA with the assistance of the National Council on Patient Information and Education (NCPIE), both Dr. Svarstad and FDA acknowledged such methodological problems and agreed that a Guidance should be developed to ensure a fairer, more objective evaluation that was consistent with the language and intent of the original Action Plan. While the Guidance was finally published in 2006, the 2008 study design repeated the flaws of the original study, most notably failure to evaluate the source CMI from the publishers themselves and the inclusion of assessment criteria that fell outside the standards established by the Action Plan and Guidance. Thus, with the 2008 study, ASHP's analysis found that only about 70% of subcriteria could be supported by the 2006 Guidance and manufacturer's professional labeling.

Even with these subcriteria problems, Kimberlin and Winterstein found that the versions of CMI authored by FDB and Wolters Kluwer (the principal publishers of CMI accessed at the point of dispensing in community pharmacies) that were least altered downstream by pharmacies or their information system vendors actually greatly exceeded the usefulness threshold by over 20 percentage points. The magnitude of this downstream alteration of FDB's CMI for the same metformin leaflet was described to range from 760 words for a leaflet obtained from one chain pharmacy versus 2457 words for the same leaflet obtained from another chain pharmacy; the latter leaflet exceeded the usefulness threshold by 28 percentage points. In the shorter leaflet, the warnings section had been eliminated as well as sections on brand names, precautions, drug interactions, overdose, missed dose, and storage. Similar findings of downstream alteration of Wolters Kluwers' CMI by pharmacies or their information system vendors also were reported. When the subcriteria falling outside FDA's standards for useful CMI as defined by the Action Plan and 2006 Guidance were excluded from the 2008 analysis, the CMI performed even better.

The inaccurate selection of subcriteria, methodological flaws, and inappropriate timing and communication of standards for the development of useful CMI all contributed to an inaccurate assessment of medication information available to consumers in 2008. In addition, the 2008 Final Report did not establish the root cause of subcriteria adherence issues, since the study did not perform a separate evaluation of the original content provided by the source publisher versus the content

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<sup>3</sup> Docket No. FDA-2005D-0169 as part of ASHP comments on the Draft Guidance on Useful Written Consumer Medication Information (CMI). Gary C. Stein for ASHP. July 25, 2005.

<sup>4</sup> Docket No. FDA-2008-S-0627 as part of ASHP comments on Expert and Consumer Evaluation of Consumer Medication Information—2008. Justine Coffey for ASHP. May 29, 2009.

distributed downstream at the point of dispensing. Therefore, conclusions that can be drawn from the 2008 Final Report are incomplete and often presented in a misleading way, since FDA did not address important study design flaws and associated concerns raised by ASHP relating to the earlier 2001 evaluation. Even without this separate evaluation of the original content, there was a strong indication in the 2008 evaluation that problems noted in the Final Report reside at the point of distribution, rather than with the content provided by the CMI source publishers. Thus, FDA has started to create a new model of self-regulated, manufacturer-authored PMI without clear justification.

### Inadequacies of FDA-approved Labeling as Sole-source Documents for Creating PMI

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As discussed, under the FDA proposal, manufacturers would author their own patient medication information and the content would be based on the FDA-approved professional label.

The Government Accountability Office (GAO), health policy and epidemiology researchers, medical informatics researchers (including natural language processing [NLP] of DailyMed labeling files), and others have identified important inadequacies in FDA-approved professional labeling, including outdated, inaccurate, and inconsistent information as well as missing critically important safety information. Yet despite important evidence of the inadequacies of FDA-approved professional labeling, the Agency continues to recommend that it be the sole source of information to be used by manufacturers in a self-regulated environment to create PMI.

FDA recently acknowledged substantial deficiencies in its approved labeling when it issued a request for proposal for the private sector to convert a substantial backlog of outdated labeling into the format the Agency implemented in 2006.<sup>5</sup> However, even if FDA somehow could update and correct all existing professional labeling, a daunting task, it still couldn't ensure consistency for patient medication information from one product to another when over 800 manufacturers would be independently authoring PMI with no central editorial oversight. Even by its own estimates, only 15% of professional labeling is in the current form for both content and format, commonly referred to as the physician labeling rule (PLR) format, despite implementation of PLR almost a decade ago.<sup>6</sup> Only 10% of generic drugs are in the current PLR format, which is particularly troubling since 80% of prescriptions are currently filled with generic drugs.

Notably, Dr. John Jenkins, Director of FDA's Office of New Drugs for CDER in 2008, acknowledged the problems the Agency had in maintaining fully accurate and up-to-date labeling. He noted that many labels are out-of-date and in many cases contain incorrect information.<sup>7</sup>

<sup>5</sup> FDA Request for Proposal (RFP) No. FDA-SOL-13-1113769 entitled "Prescription Drug Labeling Improvement and Enhancement Initiative." Issued July 10, 2013.

([https://www.fbo.gov/index?s=opportunity&mode=form&id=f34a5dae448324a0df299ae69ea12f6a&tab=core&\\_cview=1](https://www.fbo.gov/index?s=opportunity&mode=form&id=f34a5dae448324a0df299ae69ea12f6a&tab=core&_cview=1))

<sup>6</sup> Food and Drug Administration. Center for Drug Evaluation and Research; prescription drug labeling improvement and enhancement initiative; request for comments and information. 21 CFR Parts 201, 314, and 601. [Docket No. FDA-2013-N-0059] Fed Regist. 2013; 78:8446-8.

<sup>7</sup> US House of Representatives Committee on Oversight and Government Reform. Majority Staff Report. "FDA Career Staff Objected to Agency Preemption Policies." October 2008.

“[It is] a false assumption that the FDA approved labeling is fully accurate and up-to-date....we know that many current approved drug labels are out of date and in many cases contain incorrect information.” Dr. Jenkins 2008

There also will be substantial editorial control challenges in global content revision and updating with the tens-of-thousands of proposed PMI documents and extreme difficulty in maintaining content consistency and currency from product to product with the same drug, among medications in the same drug class, and throughout the database. For example, changes associated with all affected drugs/products (e.g., for drug interactions, drug class effects) most likely would be updated over a period of many months, or even years, given the number of manufacturers affected by the changes in content information.

For example, when Viagra was approved in 1998, a specific warning was included on the professional label regarding a potential fatal drug interaction if Viagra is taken with a nitrate product. Yet, many of the nitrate labels still do not provide adequate warning about the contraindication against use with Viagra, Cialis, and other phosphodiesterase inhibitors. In fact, an ASHP review of the professional labels in 2011 found that 29 of the 30 nitroglycerin products failed to properly warn about the contraindication. And only one piece of FDA-approved nitroglycerin patient labeling posted in the Agency's electronic labeling repository even mentioned this risk. Many wonder how that is possible, but the FDA has no process in place to automatically update labels across a class of drugs as appropriate at the same time. That is a major advantage of using a single, independent author.

A 2012 GAO report found that FDA failed to ensure that antibiotic labels are updated on a timely basis. More than 3.5 years after FDA contacted manufacturers, the Agency had not yet confirmed whether critical information on the effectiveness of antibiotics was up-to-date in 70% (146 out of 210) of labels.

Likewise, a study on black box warning (BBW) information (Panagioutou), the strongest medication-related safety warnings, found the time lag for appearance of drug class BBWs within individual medications labels in the class ranged from 2 months to 14 years (median 5.5 years). In a more extensive analysis, almost 600 labels in DailyMed (the official repository for FDA-approved labels) that should have had BBWs were missing them. In another study (Duke et al), natural language processing of labels from DailyMed found that safety information for the same drug available from multiple manufacturers often differed. For safety information that applies class-wide to medications within a given drug class, a single centrally controlled authoring model could ensure that the labels for all members of the drug class and their generic equivalents would get updated simultaneously.

As another example, Zocor professional labeling first included a warning about the increased risk of myopathy in patients of Chinese decent in early 2010, yet almost 4 years later the labeling for some generic products still does not include this critical risk information. If a patient is switched from an innovator product to a generic or from one generic to another (a common practice with senior prescriptions), what safeguards would be in place to ensure that the information a patient receives is consistent regardless of whose product the patient is taking?

Problems with interacting drug pairs are common examples of professional labeling inconsistencies. As noted in the Viagra–nitrate example above, the interaction and associated warning often appears only in the professional label of one of the interacting drugs. As a result, patients may not be aware of the interaction depending on the sequence in which they get their prescriptions filled for the 2 drugs under

FDA's PMI model. By comparison, a single centrally controlled authoring model could ensure that the labels for both drugs and their generic equivalents would get updated at the same time.

Because of the important inadequacies of FDA-approved professional labeling and the Agency's model that depends solely on the manufacturer's label as the source for PMI content development, ASHP strongly opposes the current proposal for self-regulated, manufacturer-authorship and instead supports a central authorship model.

Even if the Agency were to permit use of the reference listed drug's (RLD) patient medication information, the substantial lag times and inconsistencies already observed for adoption by generic manufacturers of changes from the RLD professional labeling and the anticipated exacerbation of delays and inconsistencies that will result when generic manufacturers are permitted to independently revise their own safety information would remain with FDA's model. Further, differences that exist for drug interaction warnings between drug labels and safety information differences that exist for medications within a drug class also would remain with FDA's approach. As a result, patients will be confused and possibly deprived of potentially life-saving information if FDA's rather than ASHP's model were followed.

### Recommended Alternative Path for PMI Development and Maintenance

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ASHP fully supports FDA's goal of adopting a single document that is standardized and simplified with respect to content and format and that provides clear, accessible, and actionable information. Further, ASHP recommends that FDA's one-page limit be replaced by the optimal model defined through adequate patient-centered research to establish the best level and presentation of information as a first step to ensure that PMI will optimally promote safe and effective use of medications by patients and oversight by their caregivers.

At the core of ASHP's recommendation is full consideration by FDA of an alternative model of a single centrally controlled authoring model. ASHP believes that there is compelling evidence that such a model, if structured and administered properly, could avoid all of the issues associated with FDA's manufacturer-authored model, particularly those resulting from nearly 1000 authors operating without central editorial control and relying solely on problematic professional labeling as the source material.

Thus, we propose an alternative model for providing patients with the essential information needed for safe and effective use of their prescription medications. Elements of this PMI development model include:

- Single-source authorship by an independent scientifically based organization with experience in evaluating patient medication information and expertise suitable to develop PMI that is accurate, consistent, and timely, and updated as needed
- Compliance with FDA-established and enforced, evidence- and consensus-based standards for optimal PMI content and format
- Creation and maintenance of a central repository of XML-structured PMI at the National Library of Medicine that is readily accessible in the public domain and available for integration and distribution by information system vendors into pharmacy and other workflow environments and for alternative patient-centered access and applications

- Proposed new language in the National Association of Boards of Pharmacy's (NABP's) model state pharmacy act and rules reinforcing requirements for distribution to patients of unaltered PMI that meets FDA's content and format standards and exploration of other means such as endorsement and/or adoption by standards development organizations of FDA's PMI content and format standards to minimize downstream data alterations

Combined, the components of this alternative model for PMI can ensure that patients consistently receive the essential information about their prescription medications that is:

- Patient-centered
- Accurate
- Balanced
- Comprehensible
- Consistent
- Credible, trusted
- Up-to-date
- Evidence- and standards-based
- Accessible

As proposed by Senator Gillibrand in the Cody Miller Initiative for Safer Prescriptions Act, such an alternative model can be achieved by requiring the Secretary of HHS to promulgate regulations regarding the authorship, content, format, and dissemination of PMI aimed at ensuring that patients receive consistent and high-quality information about prescriptions medications and are aware of the potential risks and benefits in a consistent, accurate, and timely fashion.

Under this proposal, PMI would be scientifically accurate and based on professional labeling approved by the Secretary and authoritative, peer-reviewed literature and would be subject to new FDA standards for timely updates as new drugs and information becomes available. The regulations would ensure that common information is applied consistently and simultaneously across similar drug products and classes of medications to avoid patient confusion and harm and would require that a process, including consumer testing, be developed to assess periodically the quality and effectiveness of PMI to ensure that it promotes patient understanding and safe and effective medication use.

The scientifically based authoring organization should have experience in evaluating PMI and demonstrated expertise in:

- reviewing drug data
- researching appropriate clinical sources to identify the information needed to promote patient understanding and the safe and effective use of medications
- authoring in form and content that is high-quality, credible, accurate, balanced, consistent, up-to-date, and evidence- and standards-based and that is designed to ensure accessibility and comprehension by the general public

FDA would develop performance and quality metrics to ensure that the authoring organization monitors the marketplace to ensure PMI is promptly available for new drugs, has procedures in place to address relevant new information in a timely fashion, and is subject to FDA evidence-based standards for PMI content and format.

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**Additional Statements for the Record**

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Statement  
of  
The National Association of Chain Drug Stores

for:

United States Senate  
Special Committee on Aging

Hearing on:

“Protecting Seniors from Medication  
Labeling Mistakes”

December 11, 2013  
2:15 p.m.

562 Dirksen Senate Office Building

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The National Association of Chain Drug Stores (NACDS) thanks Chairman Nelson, Ranking Member Collins, and Members of the Special Committee on Aging for consideration of our statement for the hearing entitled "Protecting Seniors from Medication Labeling Mistakes." Ensuring that patients have accurate and useful information about their prescriptions is critically important to promoting the safe and correct use of medications. NACDS supports policies that facilitate this aim, and encourages lawmakers to implement policies that better inform patients about their medications.

NACDS represents traditional drug stores along with supermarkets and mass merchants with pharmacies. Its 125 chain-member companies include regional chains with a minimum of four stores to national companies numbering their stores in the thousands. NACDS members also include more than 800 suppliers of pharmacy and front-end products, and nearly 40 international members representing 13 countries. Chains operate more than 40,000 pharmacies, and employ a total of more than 3.8 million employees, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and have annual sales of over \$1 trillion. For more information about NACDS, please visit [www.NACDS.org](http://www.NACDS.org).

**Patients Would Benefit from Receiving Improved and Streamlined Patient Medication Information with their Prescriptions**

Currently, when patients receive their prescriptions, they are provided with numerous written materials including medication guides, patient package inserts and other consumer medication information. Particularly for seniors who are more likely to take multiple prescriptions, receiving numerous, confusing and lengthy documents can lead to oversight of critical information, which can further lead to severe health consequences. Patients need a useful document, designed and written for them in a manner that recognizes their information needs, that provides both concise and critical information.

A single, concise and well-designed patient medication information document -- a "one-document solution" -- would better serve patients' information needs. The one-document

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solution could be used by pharmacists as a tool in their counseling sessions with patients to highlight and clearly delineate any critical information about a prescription, including drug interactions and possible side effects that may occur with a particular medication. This document would also serve as an important resource for patients to take away from their counseling session, reinforcing the key information that they learned from their pharmacist about their medication.

#### **FDA's Role in Facilitating Implementation of the One-Document Solution**

A few years ago, the United States Food and Drug Administration (FDA) held public hearings to gather information to assist the agency with the adoption of a single patient medication information document in lieu of the various other written materials that patients receive with their prescriptions. However, the agency has not yet moved forward with guidance to implement the one-document solution. We urge lawmakers to encourage FDA to continue to work towards implementing the one-document solution with all reasonable haste -- doing so should be one of the agency's highest priorities.

#### **Specific Requests for Implementing a One-Document Solution to Patient Medication Information**

*Voluntary Distribution by Pharmacies.* FDA should issue a draft interim and then, if warranted by comments received, a final guidance permitting the distribution in pharmacies of a patient-friendly document that FDA would approve. The guidance would describe how FDA would exercise its enforcement discretion and permit distribution of this document in lieu of all other documents that pharmacies are currently required to provide to patients.

NACDS does not request the creation of yet another required document for pharmacies to distribute to patients. Instead, the guidance would describe how a pharmacy electing to distribute this FDA-approved single patient document would be relieved of providing the jumble of existing documents.

*Flexible Availability.* Consumers should be allowed various options for receiving this FDA-approved medication information, whether that information is provided or made available at the prescriber's office, pharmacy, by email, or via website. Consumers should not have to wait until they go to the pharmacy to learn about their medication, especially the risks and benefits. Similarly, consumers should be able to access this information electronically from home if they lose or misplace the information.

*Flexible Standards and Guidelines.* FDA should focus on developing flexible standards and guidelines for how the information should be presented. These guidelines should consider the various formats in which the information may be provided, as well as the technological capabilities of those responsible for providing the information. The platform, methodology, and technology used to move that information to the patient should be allowed to evolve. For the short term, printed material would be the preferred method of distribution and must be accommodated. In the longer term, there is great likelihood that other methods of communicating that information, including multiple media solutions, will be available.

In sum, we believe that the one-document solution to patient medication information should be based on a common, FDA-approved template that has been validated by social science, written by the manufacturer and reviewed and approved by FDA. This information would be available electronically, should be used by physicians and pharmacists as a communications tool, and also made available to the public.

#### Conclusion

NACDS thanks the Committee for consideration of our comments. We look forward to continuing to work with policy makers and stakeholders on important issues related to the safe and effective use of medications.

## **Protecting Seniors from Medication Labeling Mistakes: The Role of Cognitive Accessibility**

Ruth S. Day<sup>1</sup>  
Duke University

### **Context of Testimony**

I am a faculty member at Duke University, Director of the Medical Cognition Laboratory, and Senior Fellow at the Duke Center for the Study of Aging. I was a charter member of the FDA Drug Safety and Risk Management Advisory committee and continue to serve as a voting member at selected Advisory Committee meetings on medications used across a wide range of health conditions. I have participated in many meetings on patient-directed medication information (advisory committee meetings, workshops, public hearings, work groups) and given research presentations at many of them.

My expertise is in cognitive science (perception, attention, comprehension, memory, language, problem solving, decision making), with a focus on medical cognition (how patients and healthcare providers understand, remember, and use medication information). I have conducted empirical research on comprehension of drug information for 20 years, both in the laboratory and in everyday settings. This work documents how well – or poorly – people understand medication information, what types of information they have difficulty understanding, why they have such difficulty, and how to improve comprehension to enable them to take medications in a safe and effective way.

This testimony focuses on “cognitive accessibility” -- the ease with which patients can find, understand, remember, and use medication information (Day, 2006). Cognitive in-accessibility occurs whenever people have trouble with any of these processes. When patient medication information violates well-established principles of normal cognition, it renders the information less accessible.

### **Older Adults**

For a given medication to be safe and effective, patients must understand key information – such as what condition(s) it treats, possible risks, and directions for use. Without good comprehension of such information, they are less likely to use the medication in a safe and effective way. This is especially challenging for older adults, who often take many medications; they may also have challenges in reading, understanding, and remembering information.

### **Appropriate Information**

There are many types of labeling problems in patient-directed materials such as the multiple-page Consumer Medication Information (CMI) currently provided with prescription medications and the one-page Patient Medication Information (PMI) currently under discussion. (*For convenience, the term “leaflet” is used below to refer to both CMI and PMI.*) What information

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is included is part of the problem – is there too much information, too little information, or incorrect information? Even when appropriate information is provided, it may still be difficult for people to understand and use it. There are many reasons for this difficulty beyond sheer legibility – for example, there may be a heavy information load or complex and technical language. The overall layout or design of the information can also be critical – to what extent does it enable patients to see major topics quickly, read sections in more depth, find needed information later, and remember enough to know to whether to consult the leaflet again or contact a health professional?

### **Amount of Information**

It is often argued that too much information about medications can overwhelm patients – either they will not understand or remember much or will just not read it. How much information is too much? Although it is tempting to answer this question in terms of number of pages, this is only a measure of *information load*. A more important measure is *cognitive load* – how much mental effort is needed to read and understand a document. Patients may understand and remember the information in a longer document better than in a shorter one – IF the information is provided in a more cognitively accessible way. Then important information does not need to be excluded, simply to produce a shorter document.

### **Cognition vs. Metacognition**

Many investigators evaluate the usefulness of medication information by asking patients how well they like a given leaflet and how well they understand the information it contains. These studies examine metacognition, not actual cognition. *Cognition* involves processes such as perception, attention, comprehension, memory, problem solving, and decision making. *Metacognition* is knowledge about our own cognitive processes – what we think we know and how well we think we know it. Our research in the Medical Cognition Laboratory shows that there is a gap between metacognition and actual cognition – people think they know and understand more about medications than they actually do. Although metacognition studies can be useful, it is critical to test actual cognition – what people actually know and understand about a medication, what kinds of errors they make, and how their errors reflect the leaflet. This approach enables us to develop evidence-based strategies for improving cognition and promoting more safe and effective use of medications.

### **Readability vs. Overall Design**

Both patients and stakeholders often say that medication leaflets should be more “readable.” Some ways to get better readability scores are to use shorter sentences and more familiar words. This strategy certainly is valuable, but does not go far enough. Without additional design features such as the overall layout of information, leaflet pages all look more or less the same, without features to distinguish various types of information. Recently, FDA developed some new formats that go beyond standard text formats and invited public comment. This is a welcome shift in focus. However cognitive analysis of the current “prototypes” reveals that they violate some important cognitive principles, so more work is needed to refine these formats or find more suitable ones.

### **Current Research Example**

We recently completed a nation-wide study with over 1,400 patients currently taking a specific prescription medication. Patients varied widely in age (19-97), gender, education, occupation, ethnicity, and geographic region (38 states). All read a one-page medication leaflet (PMI)

containing information for the same medication. On a random basis, they saw different versions of the leaflet that varied in the overall layout of the information and other features. The “Current Version” was a prototype currently under public discussion and the “Enhanced Versions” were developed in the Medical Cognition Lab at Duke University, based on well-established cognitive principles and our past research. After reading one of the versions, patients participated in a series of cognitive tasks to test their comprehension and memory.

Although data analysis is still under way, some preliminary results are clear and relevant to this hearing. Patients liked the PMI formats overall, but preferred the Enhanced designs. Those who saw the Enhanced designs performed better on many types of content and across many cognitive tasks. This advantage of the Enhanced formats was often substantial – people who saw these formats performed 100% better on some measures.

Research in the field of cognitive aging generally finds that younger adults perform better than older adults in many cognitive tasks. And everyday wisdom says that as people get older they suffer cognitive deficits, especially in memory. Nevertheless in this study, older adults performed just as well as younger adults on certain key information (such as knowledge of serious risks). Judicious use of Enhanced designs may help narrow the gap between younger and older adults.

### **Conclusions & Recommendations**

Many drug information stakeholders have worked hard to improve the quality of medication information provided to patients – FDA, healthcare providers, industry, and researchers. It is a long journey spanning several decades. Many patients and stakeholders are impatient with the slow pace and eager to adopt new policies such as a standard format for medication leaflets. However critical work is needed concerning cognitive accessibility:

- 1) New formats for patient medication information are needed but must be examined to determine the extent to which they support and/or violate well-established principles of cognition.
- 2) Potentially viable formats must be tested in cognitive experiments to examine their effects on patient attention, comprehension, memory, and other cognitive processes.
- 3) Viable formats must be tested against each other in cognitive experiments to select the one(s) that maximize patient cognition.
- 4) For older adults, it is important to ensure good reading conditions (such as adequate font-size) and include information relevant to them (e.g., differences in susceptibility to certain side effects); however special formats may not be needed – IF they provide the information in cognitive accessible ways.

With this approach, we can foster more safe and effective use of medications for patients of all ages.

### **Reference**

Day, R.S. (2006) Comprehension of prescription drug information: Overview of a research program. *Proceedings of the American Association for Artificial Intelligence, Argumentation for Consumer Healthcare.*

**Statement From Kate Miller, Constituent of Senator Gillibrand**

Hello, my name is Kate Miller. I would like to make a victim impact statement in regards to a very important legislation, "The Cody Miller Initiative for Safer Prescriptions".

On August 4, 2007, our only child Cody took his life by hanging himself in an upstairs closet. This terrible tragedy could have been prevented had we been informed consumers of the prescription drug, Singulair.

This drug was prescribed to our child for allergies. I asked the doctor the right questions. He said it was perfectly safe and would be a better choice for our son. So I read all the material and did not see any terrible things listed. I filled the prescription and started dispensing the drug to my child. I will never stop regretting that decision.

The doctor, the pharmacist, myself and my husband, were all unaware that depression had been added to the labeling four months before it was prescribed to our son. The new updates were not communicated to the prescribing physicians and were not in our Consumer Medicines Information (CMI) or the Patient Package Insert (PPI).

The people who did know about the updates were the FDA and the drug manufacturer, Merck.

I can tell you as the mother of my child, I would never have given him a drug with side effects of that nature for a seasonal allergy. At the very least, I should have had all the information about possible risks in order to make an informed decision. I would have known that my child was having an adverse reaction to the drug. I and many other consumers were denied that right.

After the early communication announcement, the FDA allowed the drug company and their employees to be in the driver's seat on the information highway. They used our dead and injured children like they were speed bumps in the road to re-marketing this drug. They veered around the truth and watered down the side effects language.

I refer to this as 'damage control'. Patients were told there were no real dangers of these side effects, doctors were being kept in the dark. This important issue was being downplayed, always going back to the clinical trials, where to my knowledge, depression was seen and should have been considered more thoughtfully in the initial labeling of this drug.

There has to be a way of speeding up the notification process and getting important information into the hands of the prescribers and consumers. Patients are being treated for side effects that are diagnosed as primary illnesses. This is a pattern we as an advocacy outreach group have reported about Singulair. Prescribing physicians are not being informed that these are updated side effects that have been linked to a pattern of reports. Families have been through hell and children are dying because of critical side effect information not reaching key people in their treatment.

Our pediatrician and every pediatrician in that practice, had zero information in regards to any reported neuropsychiatric side effects being reported. These side effects have been reported to the FDA for many years and it took this long to make it to the label. We believe the lag in communication time was a direct contributor to our tragic situation.

I work in a business where I encounter many elderly people. As we all know they are usually on a great deal of medications. That being said, I believe it would greatly benefit the elderly to have this legislation in place as a consumer safety net. Many prescriptions are refilled over and over again without the newly added side effects being brought to the consumers attention.

The elderly consumer may experience side effects and not know or realize they are in fact having adverse reactions to their medications. This often leads to more tests and more medications.

If medication sheets were regulated by the FDA, people would be continually updated on emerging side effects of medications they are consuming. This is a fundamental right as a consumer, to be updated in a timely manner, with accurate information about their prescriptions.

In the year 2006 the consumer medication sheet should have reached 95 percent accuracy as Congress had proposed. I believe with FDA regulation it has the potential to reach 100 percent accuracy. It is time to take big pharma out of the driver's seat and put safety back at the wheel.

I can attest to the fact, that had the safety information made it onto our sheet, I would be enjoying my family and watching our son enjoy his senior year of college. I would not be imploring this panel to do something that will greatly improve our health care system.

Please take this moment to think about your own loved ones and ask "At What Cost Must Change Come"?

Thank You.

