

**Transcript for FDA's Media Briefing on the  
FDA's Evaluation of Consumer Medication Information  
December 16, 2008**

Coordinator: Welcome and thank you for standing by.

At this time, all participants are in a listen-only mode. During the question and answer session, all you have to do is press the star 1 on your touch tone phone. You'll be announced prior to your question.

Today's conference is being recorded. If you have any objections, you may disconnect at this time.

Now, I'd like to turn the call over to Sandy Walsh. You may begin.

Sandy Walsh: Hi, good afternoon. This is Sandy Walsh with the FDA's Office of Public Affairs. Thank you for joining us.

Today, we will be discussing a newly released FDA evaluation of consumer medication information. Our press release was just issued and information will be available today on our Website at [www.fda.gov](http://www.fda.gov).

Today, to provide brief remarks and to entertain your questions, I am joined by Dr. Paul Seligman, who is the Associate Director for Safety Policy and Communication, in the FDA's Center for Drug Evaluation and Research.

Dr. Seligman will provide an introduction and, following his remarks, we will open up the line for a question and answer period for reporters.

Dr. Seligman.

Paul Seligman: Thank you, Sandy, and good afternoon. Before I begin, I want to introduce (Jodi Duckhorn), who is here with me today from the FDA's Office of Surveillance and Epidemiology. (Jody) is the agency's lead of the study we will be discussing today.

The FDA places great emphasis on the need to provide consumers with science-based, understandable information they can use to maintain or improve their health. Patients and consumers alike play a vital role in assuring the medicines that they or their family members take are used properly and to their greatest advantage.

It is critical that patients have the information they need to be fully informed partners in making decisions about the safe and appropriate use of a medicine. Quality of the medication information distributed by pharmacies to patients when filling their prescriptions, whether the information is part of the FDA-approved labeling or information developed by the private sector, is of particular interest to the agency.

Today, we are announcing the results of an evaluation of one type of information about prescription medicines available to consumers, often called consumer medication information or CMI. These are the written - the written leaflets that are provided by retail pharmacies with each new prescription.

This system of voluntarily providing information has been implemented over the past ten years as a result of a congressional law setting goals for the distribution of these leaflets.

The FDA-sponsored study reveals that consumers are not consistently getting the information they need to promote the safe and effective use of prescription medicines.

While, there have been significant improvements since the FDA conducted its last study in year 2001, the current system in which the private sector provides consumers with important information about their prescriptions, has failed to meet the goal established by Congress of having 95% of all new prescriptions accompanied by useful, written information for patients.

This latest study, conducted by the University of Florida College of Pharmacy, under the aegis of the National Association of the Boards of Pharmacy, found that, while most consumers, 94%, do receive some form of consumer medication information with their new prescription, only about 75% of information provided to consumers meet the minimum criteria for usefulness as judged by an independent panel of experts.

As I mentioned, there have been improvements in the quality and content of this information since we last studied this issue in 2001. That study in 2001 showed that, while nearly 90% of consumers received information, only 50% at that time met the minimum criteria for usefulness.

The law passed by Congress in 1996, aimed at ensuring that patients received useful written information with their prescriptions through private sector efforts. The law, Public Law 104-180, set a goal for the private sector that by year 2006, 95% of all new prescriptions dispensed would include useful written information for patients.

That law also charged the FDA with accepting the distribution and quality of this drug information.

What do we mean by useful information? The minimum criteria for usefulness, established by a panel of experts, say CMI should be up-to-date, scientifically accurate and presented in an understandable and legible format.

More specifically, CMI should include the drug name and its uses, how to monitor it for improvement in the condition being treated, contraindications and situations when the medicine should not be used, symptoms of serious or frequent adverse reactions and what to do, and certain general information, including encouraging patients to talk to healthcare professionals if they have questions about their medicines.

The new study found that there are still wide variations in the length, legibility, readability and comprehensibility of the material patients are given at the pharmacy. Overall, three out of four leaflets satisfied the study definition of useful.

However, fewer than one in ten of these information leaflets met the criteria set for legibility and comprehensibility. And leaflets for the same drugs ranged from as few as 33 words to as many as 2400 words in length, depending on the pharmacy where the information was distributed.

The current system has had more than a decade to get it right. It's time to try a different approach with a greater chance of success. Toward that end, the FDA will initiate a plan to involve all of the key stakeholders, including information providers, pharmacy operators, drug manufacturers, healthcare professionals and consumers, in a cooperative effort to create and implement an effective approach.

The agency will seek public comments on initiatives that can be used to meet the congressionally-mandated goals. The FDA has created a Website to receive public comment on the study and to solicit feedback on the ways to provide useful prescription information to consumers.

And we have already announced a meeting of FDA's Risk Communication Advisory Committee for February 26 and 27 to help tackle this issue.

We believe that patients deserve, actually require, consistent, high-quality, easy to read and understandable information about their medicines. Ensuring that patients receive useful information about their medicines, whether CMI or other forms of patient-directed information is an area where the FDA intends to focus greater attention consistent with our mission to protect and promote the health of all Americans.

With this introduction, I look forward to your questions.

Sandy.

Sandy Walsh: Thank you. I'll now ask our operator, (Jim), to open up the line for questions and answers from reporters.

Coordinator: To ask your question, press star 1 on your touch tone phone.

One moment for the first question.

Sandy Walsh: Okay, we'll take our first question, please.

Coordinator: First question comes from Justin Blum.

(Justin Blum): I just wanted to know did the FDA pay for the study and, if so, what was the cost?

Paul Seligman: Yes, the FDA paid for the study. (Jodi), what was the cost of the contract?

(Jodi Duckhorn): I believe it was \$350,000.

Sandy Walsh: Did you get that Justin?

Justin Blum: Yeah, thank you.

Sandy Walsh: Okay, next question please.

Coordinator: The next question...

Sandy Walsh: I'm sorry; we didn't get the next question.

Coordinator: Next, we have (John Wilkerson).

(John Wilkerson): Would FDA like to get rid of CMI and use only the package inserts and their guides that FDA regulates?

Paul Seligman: We're going to take a comprehensive look at what the best way to get information to the consumer.

One of the things we observed in the study was that 94% of all prescriptions that were filled in the study were accompanied by some form of information which indicates that the current system, in terms of being able to distribute information seems to work very well.

So, I think when we start holding not only our Risk Communication Advisory Committee, but engage the public in a much more direct and meaningful conversation about these - about consumer information, we're going to really look at all options on the table.

(John Wilkerson): Okay. And, I guess I'm a little confused. What's the advantage of using CMI in the first place if FDA already regulates these other forms of labeling?

Paul Seligman: The only form of patient information that the FDA currently regulates is the medication guide, which is provided - actually there are two forms that we regulate. One of them is a medication guide, which is provided in pharmacy and produced by the manufacturers of the product. For certain drugs where there's a serious risk, for which the patient needs to be made aware of that information or for certain products, hormonal products or oral contraceptives, where patient package inserts are required.

So, there are other forms, but those forms of communication, the medication guide and the patient package insert only cover a small number of the relatively large number of medicines that are available both by prescription and over the counter.

(John Wilkerson): Thank you.

Sandy Walsh: Okay. Operator can you please remind people how to ask a question? And also, we will take one question and a follow-up from any reporter who's interested.

Coordinator: Once again, to ask your question, all you have to do is press star 1 on your touch tone phone.

Coordinator: And the next question, we have...

((Crosstalk))

Coordinator: ...is from (Ricardo Alonso). Your line is open.

(Ricardo Alonso Zaldivar): Hello? Yes, (Ricardo Alonso Zaldivar) with the AP. Thank you for taking my question.

I just wanted to find out a little bit more about the study. Can you tell us how many drugs you looked at and tell us what, you know, give us some kind of sense of what these drugs were for?

Paul Seligman: Could someone repeat the question?

(Ricardo Alonso Zaldivar): Yes. Can you tell us - I'm trying to find out a little bit more about this study. Can you tell us how many drugs you looked at?

Paul Seligman: Yes, the new study, we studied two drugs, lisinopril and methformin. Lisinopril is a common medication, it's a beta blocker.

(Ricardo Alonso Zaldivar): That's blood pressure drug, right?

Paul Seligman: Yes, it can be used for blood pressure, that's correct, but that's its most common use. And the other is methformin, which is a drug used for the treatment of Type 2 diabetes.

(Ricardo Alonso Valdazar): Okay. So, you only looked at the two drugs, but there are probably hundreds, if not thousands of commonly used drugs. How can you be confident that the results of the study are valid?

Paul Seligman: Well, we back - back in 2001, when we did this study, we actually studied four drugs and found, again, one of them was a - in addition to a drug for Type 2 diabetes and for hypertension, I believe we studied a nitrate at that time as well as a statin.

Now, we found that there was enough consistency in terms of the - of both the quality and distribution of the information for those four drugs that we felt confident, statistically, that we would get a very good representation of the kind - kinds of material and the quality of the material just based on the use of these, you know, commonly prescribed medications.

(Ricardo Alonso Zaldivar): So what's the next step here for FDA? I know you're going to have a meeting to talk all this out in March of next year, but it seems like - is the agency going to set up a format, a standard format for this kind of information?

Paul Seligman: We're going to be - we're going to be - it's not only this communication advisory committee that we're going to be holding at the end of February, we're going to hear the variety of opportunities not only our public Website, but engagement with stakeholders and probably subsequent discussions to really come up with what we think is not only the - a good science-based, evidence-based approach to providing this information.

But also understand what's the right way to engage pharmacies, manufacturers, information vendors and others to come up with the kind of approach that will allow us to ensure that patients are getting the same high-quality information at any pharmacy throughout the United States, irrespective of where they go, whether they go to a independent pharmacy or a chain pharmacy and whether they live, you know, urban, suburban or rural.

Sandy Walsh: Okay, next question please.

Coordinator: One moment. And next we have (Martin Gidron). Your line is open.

(Martin Gidron): Hi. Yes, thank you very much. I'm just wondering if you could outline just briefly some of the specific steps that drug makers are going to be asked to take for this labeling requirement?

Paul Seligman: Well, I think it's premature at this point to say what steps they're going - what they're going to be asked to take. If you look just historically, back in the - before the law was passed in 1996, there was a lot of discussion and proposed regulations back in the late 80s and early 90s, that would have required drug manufacturers to produce this consumer information that would be reviewed and approved by the FDA. That approach was rejected in 1996, but - when Congress passed Public Law 108.

So, I think that, again, all options and approaches and parties are on the table and we will certainly revisit what we think - what role the manufacturers or sponsors of these products should play in effective consumer information.

(Martin Gidron): Thank you.

Sandy Walsh: The next question please.

Coordinator: And, once again, to ask your question, all you have to do is press star 1 on your touch tone phone. Star 1 for questions please.

Sandy Walsh: Since there are no further questions, I'm going to ask Dr. Seligman to give me closing remarks.

Paul Seligman: Okay, sure, Sandy.

Well, in closing, I just want to say that what this is really about is ensuring that consumers have the information they need about the medication they're taking and sure that they understand the essentials about things such as appropriate dose, contraindications, side effects, interactions with other medication as well as some foods. And that, as I indicated, that this essential information be delivered in a format that is clear and consistent, whether someone is picking up a new medication in Winslow, Arizona or Boston, Massachusetts.

Congress decided in 1996 that this was an important goal and it should have been achieved two years ago. In order to meet this goal, we need to take a different approach and the FDA will be taking a leadership role in that process in a way that ensures full participation of all the stakeholders.

So, with that...

Sandy Walsh: Thank you, Dr. Seligman.

As I mentioned, we have quite a bit of information, including the full report on our Website, if you click through on the press release there's a link to all the information. And, if you have any questions, please contact me; this is Sandy Walsh, at (301) 796-4669. Thank you.

Coordinator: That concludes today's conference. You may disconnect at this time.

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