Transcript of FDA Media Briefing on the FDA's Proposed Rule Amending the Tentative Final Monograph for Over-the-Counter Consumer Antiseptics
Moderator: Andrea Fischer
December 16, 2013
10:30 am ET

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode until the question and answer portion of today's call. At that time to ask a question, please press star 1.

This conference is being recorded. If you have any objections, you may disconnect your line at this time.

I would now like to turn the call over to your host. We have Ms. Andrea Fischer. Ma'am, you may begin.

Andrea Fischer: Good morning and thank you for participating in today's call. My name is Andrea Fischer from the FDA's Office of Media Affairs. This briefing is for credentialed media, announcing an FDA proposed rule amending the tentative final monograph for over-the-counter consumer antiseptics known as antibacterial hand and body washes.

By now, the agency's news release for this announcement has been shared with our media list and posted on the FDA Home Page. Today, I'm joined by

Dr. Sandy Kweder, Deputy Director in the Office of New Drugs, in the FDA Center for Drug Evaluation and Research or CDER.

Dr. Kweder will make some brief opening remarks. Following those remarks, we will move to the question and answer portion of the call. Reporters will be in a listen only mode until we open up the call for questions.

When asking a question, please state your name and affiliation. Also, please limit yourself to one question and one follow up, so we can get to as many questions as possible.

I will now turn the call over to Dr. Kweder.

Sandra Kweder: Thank you, Andrea. Good morning everyone and thank you for joining us. Millions of Americans and probably including some of you use antibacterial hand soaps and body washes. They're used every day at home at work and at schools and in other public settings, where the risk of bacterial infections is relatively low.

Because of consumers' high exposure to these products and the ingredients in them, we at the FDA believe that there should be a clearly demonstrated benefit from using antibacterial soaps to balance out any particular or potential risk.

While use of antibacterial soaps and body washes has become part of many consumers' routines, we at the FDA have not been provided with data to demonstrate that these products are any more effective at preventing people from getting sick than washing with plain soap and water.

To put it simply, we need to collect additional information from the companies that make these products, so that consumers can be confident about their effectiveness and about their safety.

So, today, the FDA has issued a proposed rule that, if finalized, would require manufacturers of antibacterial hand soaps and body washes to provide additional data on the effectiveness of these products.

In order for antibacterial soaps and body washes to be considered generally recognized as effective, manufacturers would be required to conduct clinical trials demonstrating that their products are more effective than plain soap and water in preventing illness and the spread of certain infections when they're used by consumers.

Under the rule, manufacturers also would be required to provide additional safety data for these products before they could be considered generally recognized as safe for use. You heard me, and FDA uses the term generally recognized as effective and generally recognized as safe, to refer to any substance that among qualified experts has been adequately shown to be effective and safe under the conditions of its intended use. And, those are definitions that come from the Regulations of Laws that govern some of these products.

If manufacturers do not demonstrate that they are safe and effective, these products would need to be reformulated or relabeled to remain on the market. Reformulating would mean that companies would have to remove the antibacterial active ingredient and relabeling would mean removal of the antibacterial claim from the products label.

At this time though, these antibacterial products do not have to be removed from the market. The FDA wants to hear from the public about our proposal, this proposed rule. We're encouraging consumers, health professionals, industry and others to comment on the proposed rule and particularly the data that it discusses.

The comment period will be open for 180 days. We recognize that today's announcement will likely raise questions among consumers and we want to be very clear.

Washing with plain soap and running water, is one of the most important steps people can take to avoid getting sick and preventing the spread of germs to others. The FDA continues to collect additional information on antibacterial hand soaps and body washes, to determine how that factors into the equation.

Some data, suggests that long-term exposure to certain active ingredients used in antibacterial products, for example Triclosan, which is a common ingredient in liquid antibacterial soaps and Triclocarban, which tends to be used in antibacterial bar soaps, could post health risks.

For example, in recent years, emerging research from animal studies suggests that daily exposure to some antibacterial ingredients could result in hormonal effects, including effects on estrogen, testosterone and thyroid hormone. Laboratory studies also suggest that antibacterial ingredients may contribute to changes in antibiotics susceptibility of bacteria.

How these effects specifically link to human safety, if at all, has not been established. However, we think this warrants further evaluation. And, we're seeking additional information and considering how those laboratory studies have relevance to humans.

Today's announcement also comes as a result of concerns expressed by outside health care organizations and consumer groups, and expert advisory committees, which have raised concerns about the safety and effectiveness of these antibacterial consumer products.

Almost all soaps labeled as antibacterial or antimicrobial contain at least one of the antibacterial ingredients addressed in the proposed rule. The most common active ingredients in antibacterial liquid and bar soaps, as I mentioned are Triclosan and Triclocarban.

Some soaps that are labeled as deodorant may also contain these ingredients. Consumers can look at the packaging of these products in a section called drug facts, to determine if the product contains any of these ingredients, such as Triclosan or Triclocarban or any of the others.

Today's announcement is part of a larger ongoing review of antibacterial active ingredients by the agency to ensure that these ingredients are proven to be safe and effective. However, it is important to note that this proposed rule does not effect hand sanitizer products that don't require use with water or hand sanitizing wipes that you don't have to use with water.

Those are products that are often alcohol based and come in a gel form. It also does not affect the antibacterial products used in health care settings, such as hospitals or in food preparation facilities. Those we will address separately.

The FDA wants to remind consumers to continue to be diligent about washing your hands. If soap and water are not available and alcohol based hand sanitizers that contains at least 60 percent alcohol should be used. Again, that's if soap and water aren't available.

Consumers, who want more information, can visit our web site, fda.gov. And, another great source for tips and information about benefits of appropriate hand washing is the Centers for Disease Control web site and their web site is CDC.gov/handwashing. And with that, I'm going to turn the call back over to Andrea. Thank you very much for listening.

Andrea Fischer: Thank you, Dr. Kweder. At this time, we will begin the question and answer portion of the briefing. In addition to Dr. Kweder, we are also joined by Colleen Rogers, lead microbiologist in the Division of Nonprescription Regulation Development in the FDA Center for Drug Evaluation and Research to assist with the Q&A portion of the call.

When asking question, please remember to state your name and affiliation. Also, please limit yourself to one question and one follow-up so we can get to as many questions as possible.

Operator, we'll take the first question.

Coordinator: Thank you very much. This question is from Maggie Fox of NBC News. Your line is open.

Maggie Fox: Hi, thanks. Can you tell us a little bit more about the studies that raised your particular level of concern? And, can you also address the fact that you can't buy liquid soaps that don't have Triclosan in them. Thanks.

Sandra Kweder: Okay. Well first let me go to the second one. You absolutely can buy liquid soaps that don't have Triclosan in them, absolutely. I looked this weekend to be sure. And, there are some companies that actually used to include Triclosan

in their soaps and they've recently removed them for reasons that I'm not sure of, but I know that they have.

The data that we're talking about are mostly - they're animal studies, they're studies in rats and hamsters. That's pretty typical for the first types of studies that look at these kinds of risks. Collecting this kind of information in people is very difficult, because you're looking at exposures over long periods of time.

There are also studies in laboratories in cell-based systems that look at potential hormonal effects of some of these ingredients. And, we're hoping that there are other data that are out in the hands of manufacturers or in academic institutions that can help us understand what these risks may be and if at all possible, is there a way to look at them in humans. But, that's really a challenge.

Maggie Fox: Thanks.

Andrea Fischer: Operator, we'll take the next question.

Coordinator: And, this question is from Sabrina Tavernise from New York Times. Your line is open, ma'am.

Sabrina Tavernise: I wanted to ask a question, it's just the same question the NBC reporter had. What's the longer-term health effects? Can you talk a little bit about the hormonal effects that you mentioned and I missed you were talking quickly. I kind of missed, you said, I think estrogen or maybe it was progesterone and testosterone.

Sandra Kweder: Sure, I'll say a little bit. Some of this information is spelled out in the proposed rule. I'm not going to go into a lot of detail. But, in some rat studies, we've seen decreases in thyroid hormone levels. And, in some cell-based systems, we've seen changes in cells' abilities to response to estrogen and testosterone.

Now, again, we recognize that these are laboratory tests. And, the challenge is trying to understand what those actually mean for effects on humans. We do have some ongoing work in another part of the government, looking at whether these agents, with certain types of exposures through the skin might cause cancers.

Those are common ways that we look at long-term effects based on animal studies when they are difficult to specifically test in humans. Now, the challenge - so these are - of course these are potential risks. But, our prospective is that we want to understand all of the potential risks, not just in terms of the risk. But, in this case, we're also asking that if a consumer - if there are unknowns and there's even a slight potential for a risk, we think consumers ought to know and we ought to know what the benefits of these products are.

And, that's a really critical part of this proposed rule, is to say, we want companies to actually test these products, so that consumers who purchase them have a sense of whether there really is any benefit, at all, over plain soap and water.

I suspect that there are a lot of consumers. I know many, who assume that by using an antibacterial soap product, they are protecting themselves from illness. They are protecting their families. They are protecting their classroom,

if they're a teacher. But, we don't have any evidence that that is really the case, over simple soap and water, whether it's liquid soap or bar soap.

Andrea Fischer: Operator, we'll take the next question.

Coordinator: And, this question is from Robert Lewis of Medscape Medical News. Your line is open sir.

Robert Lewis: Thanks for taking my call. Could you discuss the timetable for when products could be removed from the market or the deadline for that, if they hadn't proved efficacy and safety? I see in the press release that the public comment period is 180 days. There's a concurrent one-year period for companies to submit new data and information.

That would be, what, after the rule is made final or - can you explain that?

Sandra Kweder: Sure, I can explain. Yes, yes, the public comment period that our target deadline for that is June 2014. And then, up until December 2014, we will allow submission of actual data and studies from companies or anyone else who have information to be brought to bear on this issue.

Our goal - we expect we will get many, many, many comments and we hope we'll get a lot of data, as well. Our goal is to finalize the rule one way or another. Either to find these products generally recognized as safe and effective or not, around September 2016.

And, if at that time - pardon me?

Robert Lewis: To finalize?

Sandra Kweder: To finalize the rule, the regulation, yes.

Robert Lewis: To finalize the rule, okay.

Sandra Kweder: Right.

Robert Lewis: So that's 2016?

Sandra Kweder: September 2016, yes. And, at that time, we may find that some of these ingredients are generally recognized as safe and effective and others we may find not so or that there's just no additional information on them.

Robert Lewis: By that time, then the companies would have to have already proved safety and efficacy. Or, will they get additional time to prove that.

Sandra Kweder: They would have to have established it, yes.

Robert Lewis: By then?

Andrea Fischer: All right, thanks Robert. We'll have to move on to the next question.

Sandra Kweder: Yes, you've got it.

Coordinator: And, this question is from Matt Perrone of AP. Your line is open, Matt.

Matthew Perrone: Hi guys. I know the FDA has previously ruled that Triclosan in toothpaste, at least one brand of toothpaste, is safe and effective. And, has some sort of benefit over other brands of toothpaste. Is that decision under review now, in light of all of the safety and efficacy questions you're raising now?

Sandra Kweder: Actually, no it is not. And, there's a reason. The reason is that the Triclosan in toothpaste, it does fall under a little bit of a different regulatory framework. It's a new drug application. And, that has a specific use. Triclosan in toothpaste has been shown to be effective in preventing gingivitis that's caused by bacteria in the mouth.

Gingivitis can really wreak havoc with people's teeth. And, they have done studies to show that use of Triclosan in that setting is safe and effective. And, the benefit outweighs any potential risk. It's not for everyone. But, it's for people who need that gingivitis prevention.

Matthew Perrone: Well, I guess I'll sort of put these two follow ups together. You mentioned that there's part of the government study whether Triclosan coming in contact with the skin can cause cancer. Can you talk a little bit about what part of the government is doing that? And, in light of that, I mean, wouldn't consuming toothpaste with Triclosan be a safety concern.

Sandra Kweder: The National Toxicology Program is doing the testing, working with us. And the questions about toothpaste, is in very tiny amounts what our concern here is, is that it's for a specific use. Here we're talking about widespread use in a multitude of products where most of the time the consumer does not even know they're being exposed to these ingredients.

And, we consider that a different setting of use.

Andrea Fischer: All right, thanks. Operator, we'll take the next question.

Coordinator: And, that question is from David Pittman of MedPage Today. Your line is open, sir.

David Pittman: Thanks for taking my call. My question has to do with the timeframe. You say you hope to finalize this September 2016. Is that enough time for manufacturers to compile and conduct these studies and compile the information they need to submit to you or do you have a reason to believe that there is ongoing studies about this?

Sandra Kweder: We actually don't know how much information companies already have available. We think that some companies may have some data. They have not been previously required to submit to us. And, we do believe that some of these studies may already be in the works.

We have been having discussions, public discussions, about this and these types of studies since 2009. So, we held an advisory committee meeting and other public hearings. So, the industry has long been aware of our concerns.

And, if companies come to us with data or at a point where they almost have the data completed, we have the option to extend the comment period.

David Pittman: But, the bottom line is that you think that this will allow companies enough time to meet your standards, given that this has already been known this is on your radar?

Sandra Kweder: We certainly hope so.

Andrea Fischer: All right, thank you. Operator, we'll take the next question.

Coordinator: And, that comes from Alexander Gaffney, the Regulatory Focus. Your line is open, sir.

Alexander Gaffney: Thanks. Sandy, I had a question about the ingredient or any of these ingredients and their relationships to the products' labeling. Now, will this apply to all products with Triclosan as an ingredient or just those that are advancing specific claims within the labeling, such as being antibacterial, for example?

Sandra Kweder: So, you're talking about, so if it's in there and they don't say it's antibacterial, it's just in there. Does it apply to them? No, it only applies to the ones that make a claim of antibacterial.

Alexander Gaffney: Okay, thank you.

Andrea Fischer: All right operator, we'll take the next question.

Coordinator: And, that is from Brady Dennis of the Washington Post. Your line is open.

Brady Dennis: Oh hi. You touched on this earlier, but I just wanted to go back really quickly. And, I wonder if from the FDA's perspective, if you could talk a little bit about your ultimate goal here or your hopes, when it comes to the manufacturers, whether the goal is to potentially get these ingredients out of the products or to simply have them re-labeled. Does it become a truth in labeling question more than the active ingredient question?

Sandra Kweder: Our goal is like our goal for most products, if a company is making a claim that something is antibacterial and in this case, promoting the concept that consumers who use these products can prevent the spread of germs, then there ought to be appropriate data behind that and I think consumers expect us to be monitoring this.

So, for instance, if you see some of these products and advertisements for these products, you'll see pictures of people sneezing and coughing and looking pretty ill, when in fact, we don't have any information to suggest that those ingredients actually prevent people from looking like that in those pictures on the products.

And, in fact, the pictures on the products often look like people who have viral illnesses. And, even an antibacterial will not prevent the common cold or viral illnesses, which are the most common causes of community infections in this country.

So, we think that companies ought to have data before they make those claims or promote those concepts.

Andrea Fischer: Thank you. Operator, we'll take the next question.

Coordinator: And that's from Deborah Kotz of Boston Globe. Your line is open.

Deborah Kotz: Thanks for taking my call. I was just wondering if you can reiterate a little bit more on the antibacterial resistance that you're worried about. Have there been any epidemiological studies to suggest that the growing use of these products is leading to more antibacterial resistance and if so, is there any way to account for how much of the rise in these diseases is occurring from these products.

Sandra Kweder: Yes, well a lot of - if anyone who follows the whole world guidance and challenges of assessing and understanding antimicrobial resistance knows how challenging it is. Our laboratory data that show that bacteria exposed to these products do change their resistance pattern.

What we don't understand is how that specifically related to these products is operative in the real world or say in the home of a family that uses these products regularly. And, those are some of the questions that we're very interested in, in having data on. And, we're hopeful that there are researchers out there who have actually looked at some of these questions.

Andrea Fischer: Thank you. Operator, we'll take the next question.

Coordinator: And, that comes from Steve Baragona, of Voice of America. Your line is open, sir.

Steve Baragona: Hi, thanks. Yes, you've partially addressed the question there. I'm wondering, I know you just finalized your guidance on antibiotics in use in livestock. I wonder if you're going to put this in perspective of the FDA's broader look at antimicrobials.

Sandra Kweder: I think that the recent statement and guidance that you just referred to, like this, is all part of the general equation of what are the benefits of using antibacterial products and how do these stack up against any potential risks.

Whether you're talking about in livestock setting with animal feed and treating of herds or you're talking about in the setting of consumers in the kitchen. So, they aren't the same, but they're part of a larger framework of assuring that there is a well-established benefit and risk assessment that can be conducted before these products could just be put out there widely for general use.

Steve Baragona: Great, thanks.

Andrea Fischer: Operator, we'll take the next question.

Coordinator: And, that's from Family of ABC. Your line is open.

Family of ABC: Thank you for taking my call. I just had a question. So, you mentioned that this is nothing new. According to an American Journalist section control article, the FDA nonprescription drug committee has been reviewing this since 2005, called to action for experts to come up with a model or a way to test this. And, at that time, they said they would use a surrogate infection model, using Shigella, as a test subject.

And, I was wondering has something come from that or what's the natural progression of things that have happened since 2005 or if there's anything new that sparked this announcement today.

Sandra Kweder: I'm going to actually ask Dr. Colleen Rogers if she can answer that question.

Colleen Rogers: Yes, I would say that this is not anything new. We have been looking at this since 2005. We, as you're mentioned, we did have a public advisory meeting at that time. And, we did have a public meeting also to discuss an alternate testing model for hand washing. And, that's all part of our evaluation. There's nothing new in the current proposal that we haven't been discussing publically.

Sandra Kweder: Does that answer your question?

Family of ABC: I guess what I'm saying is, so since the call has been since 2005, and there was a proposed publication that says this is how we're going to test it, has there any studies that have come out using the model.

Sandra Kweder: Oh, has anyone used the model question.

Family of ABC: Yes, or do you know of anyone who is currently using it and if you're expecting data soon or anything like that.

Colleen Rogers: You're asking if anyone has used the alternative model. We're not aware of anyone using it. We're not sure. Someone may decide to submit data at this time, but we're not aware of it right now.

Sandra Kweder: Right. Prior to this no one - companies particularly may have used that model to test their product. But, they simply weren't required to submit it to us. But, this call for them, this is a specific request for them to do so. And, I wanted to just assure you that just because companies do this testing, doesn't mean that they submit the results to us, unless we specifically require it or ask for it.

Andrea Fischer: I just want to remind everyone that the additional voice that you're heard is Colleen Rogers, a lead microbiologist in the Division of Nonprescription Regulation Development in the FDA Center for Drug Evaluation and Research.

And operator, we have time for two more questions. We'll take CNN and USA Today as the last two.

Coordinator: Thank you. Sandra Young, your line is open, from CNN.

Please check to see if your phone is muted.

Sandra Young: Hi, thanks for taking my question. Can you talk a little bit more about the hand sanitizers? You said this proposed rule doesn't affect hand sanitizer products and wipes that you don't have to use with water. Is it, that they have no Triclosan in them or why is there a difference?

Sandra Kweder: Well, thank you for that question. We consider hand sanitizers different. They are made up different. Most hand sanitizers that are on the market today, the gels that you use, most of them use 60 percent ethanol or alcohol.

And, we have previously found those to be generally recognized as safe and effective, for use when water is not available. We still recommend, as does the CDC, that hand washing with soap and water, is absolutely the best thing you can do to protect yourself from infections and transmitting infections.

But, when you can't, those products, particularly the ones that are alcohol based, are effective.

Andrea Fischer: Okay operator, we'll take the last question.

Coordinator: And, that is from Elizabeth Weise, of U.S.A. Today. Your line is open, ma'am.

Elizabeth Weise: Thanks for taking my call and sorry I was getting on a little late. Did you discuss numbers for about what percentage of the soaps sold in the U.S. contain these antibacterials?

Sandra Kweder: Well, we do know that there are about 2,000 individual products, soap type products that do contain these individual ingredients. Our understanding is that about, 90, I think it's something like - and of those, 93% of them use Triclosan, in the liquid form.

Someone, before you came on, I guess, someone did ask the question they said you can't find - I can't find a product, a soap that doesn't say it's antibacterial or a body wash. And, absolutely there are those products. But, the antibacterial products we know are increasingly prevalent on the shelf.

Elizabeth Weise: Thank you very much.

Andrea Fischer: All right, thank you everyone for participating this morning. This concludes today's media briefing. A replay will be available in about an hour and will be up for 30 days. Thank you.

END